Assessing the influence of FDM to the postoperative healing processes in distal fracture of the radius

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ABSTRACT

Introduction: Distal radius fractures are among the most common types of fractures. Irrespective of the choice of therapy (whether conservative or surgical), these fractures may entail negative consequences in the form of limited range of motion and diminished muscle strength. Such sequelae cause limited hand performance, which, considering the important function of the hand, may negatively affect the quality of life and impair patient's independence in performing everyday activities Despite a considerable progress in medicine and physical therapy over the last several years, distal radial fracture outcomes seem to be unsatisfactory. Conventional mobilization methods do not increase the number of very good and good outcomes. Nevertheless, the effects of a therapist's efforts concentrated on specific tissues of the musculoskeletal system, such as fasciae, seem to be an effective treatment method rapidly restoring the normal range of motion and muscle strength and consequently – full hand function.

Aims: To present the Fascial Distortion Model (FDM) as a potentially effective treatment of musculoskeletal dysfunctions after distal radius fractures.

Methods: A total of 65 patients (12 men, 53 women, 22 to 81 years of age) suffering a distal radial fracture were randomized into a study group (n=33) and control group (n = 32). Due to nine drop outs, the effective sample size of the study group is n=24.

Apart from the standard recommendations and exercise instructions, the study group underwent three sessions with the use of FDM techniques. These therapeutic sessions were conducted once a month. The therapy was adjusted to individual limitations and patient feedback related to pain. The utilized therapeutic techniques included triggerbands, herniated triggerpoints, continuum distortion, folding distortion, cylinder distortions, and tectonic fixation. An efficiacy analysis of the FDM techniques was done by pre- and posttherapeutic measurements of grip strength, the range of motion (extension, flexion, adduction and abduction) at the radiocarpal joint, of the ability to perform daily tasks (DASH 100 scale) and the level of pain (100 mm VAS).

Results: Single FDM therapy sessions conducted in the evaluation group resulted in immediate and significant improvement in all measured parameters ($p < 0.05$). In comparison with the control group, patients treated with the use of the FDM techniques achieved a higher improvement especially in range-of-motion within three months after removal of the Kirschner wires. No negative effects of therapy, such as a decrease in strength or limited range of motion, were observed in any patient.

Conclusion: The results indicate very high efficacy of the FDM as a therapeutic technique rapidly improving the range of motion and the muscle strength in the affected joint.

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Abstract

Introduction and aim of the study

Distal radius fractures of the radius are among the most common types of fractures. In young people, these are usually direct-mechanism fractures or high-energy injuries. In the elderly, distal radial fractures are caused by a low-energy trauma such as a fall from the standing height [57, 61]. Irrespective of the choice of therapy (whether conservative or surgical), these fractures may entail negative consequences in the form of limited range of motion and diminished muscle strength. Such sequelae cause limited hand performance, which, considering the important function of the hand, may negatively affect the quality of life and impair patient's independence in performing everyday activities [12, 24, 26].

Despite a considerable progress in medicine and physical therapy over the last several years, distal radial fracture outcomes seem to be unsatisfactory. A number of patients, especially the elderly, still complain of limited function and performance in the injured hand. Conventional mobilization methods do not increase the number of very good and good outcomes [9, 30, 48]. Meanwhile, the number of publications on the use of novel therapies, and particularly the osteopathic methods, remains low. Nevertheless, the effects of a therapist's efforts concentrated on specific tissues of the musculoskeletal system, such as fasciae, seem to be an effective treatment method rapidly restoring the normal range of motion and muscle strength and consequently – full hand function [49, 75].

The aims of this study are:

- To present the problem of distal radial fractures as function-limiting injuries of the hand,
- To present the Fascial Distortion Model (FDM) as a potentially effective treatment of musculoskeletal dysfunctions,
- To present the results of our studies on the efficacy of FDM techniques in the treatment of radial fracture patients,
- To review the available literature concerning previous studies.

1. Background

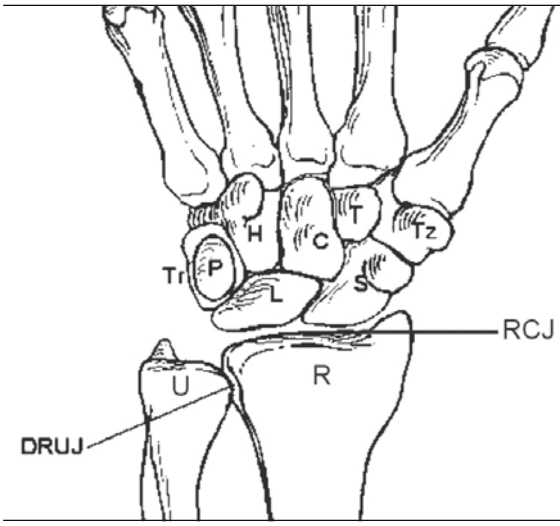
1.1. Anatomy of the distal radius area

1.1.1. Bones and joints

The articulations at the distal end of the radius include the radiocarpal joint and the distal radioulnar joint (DRUJ).

The DRUJ comprises the circumference of the head of the radius and the radial notch of the ulna serving as its socket. The articular capsule is loose yet strong.

The radiocarpal joint connects the radius with the proximal carpal bones, comprising the following bones: the scaphoid, lunate, triquetral, and pisiform (however, the pisiform bone is not part of the articular facet). The articular facet of the distal end of the radius constitutes 75% of the joint's socket and the remaining part of the socket is made up by the articular disc filling the space between the head of the ulna and the carpal bones. The articular socket is slightly inclined toward the ulna and tilted anteriorly, which results in an increased range of adduction and flexion. The head of the joint, comprising three carpal bones (the scaphoid, lunate, and triquetral), is ellipsoid in shape (Fig. 1) [5, 22].



S – scaphoid
L – lunate
P – pisiform
Tr – triquetral
H – hamate
C – capitate
T – trapezoid
Tz – trapezium
U – ulna
R – radius
RCJ – radiocarpal joint
DRUJ – distal radioulnar joint

Fig. 1. The bones forming the radiocarpal and the distal radioulnar joint.

The proximal carpal bones are connected via arthrodial joints of limited mobility held firmly together by ligaments, which facilitates synchronized movements of all three bones constituting the radiocarpal joint with respect to the radius. The articular capsule is loose. The radiocarpal ligaments, which strengthen the articular capsule and control the movements in the joint include:

- the radial collateral ligament – extends from the styloid process of the radius to the scaphoid bone, controls the adduction (ulnar abduction) of the hand and transfers the rotational movements of the forearm onto the hand,
- the ulnar collateral ligament – extends from the styloid process of the ulna to the triquetral bone and to the pisiform bone; it controls the abduction (radial abduction) of the hand and, together with the radial collateral ligament, transfers pronation and supination of the forearm onto the hand,
- the palmar radiocarpal ligament – extends from the styloid process and the palmar margin of the radius to all four bones of the proximal carpal row; it controls the extension and supination of the hand,
- the dorsal radiocarpal ligament – has its origin on the dorsal margin of the distal radius and its insertion on the dorsal surface of the proximal carpal bones, controls the palmar flexion and pronation, but is weaker than the one mentioned above,
- the palmar arcuate ligament of the wrist – combines fibers of the palmar radiocarpal ligament and ulnar collateral ligament; it controls the extension in the joint,
- the dorsal arcuate ligament of the wrist – connects only the scaphoid and triquetral bones; it controls the flexion and abduction (Fig. 2) [5, 22].

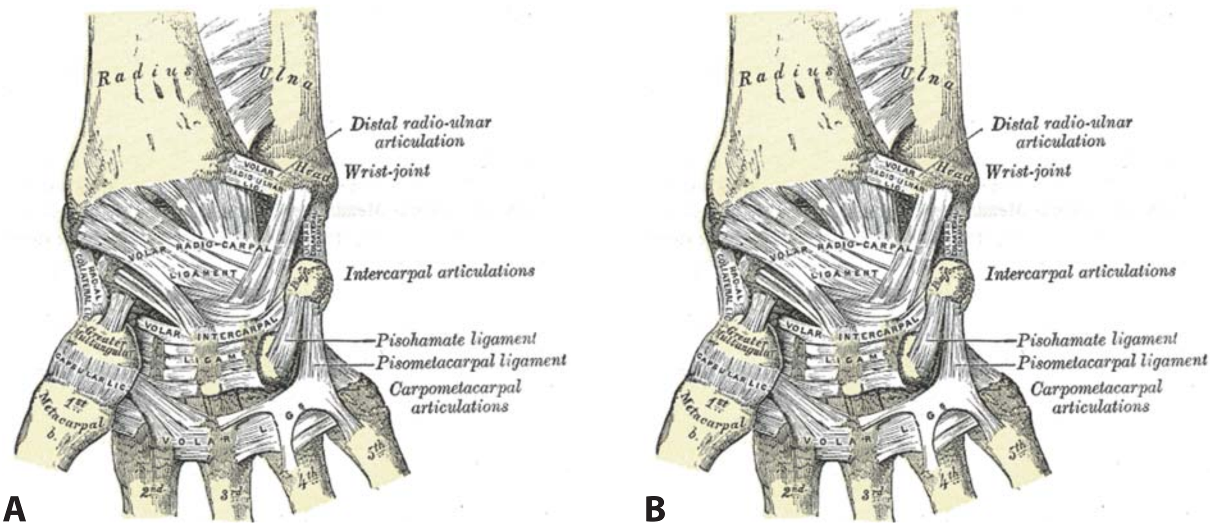


Fig. 2. Ligaments of the radiocarpal joint; palmar view (A) and dorsal view (B).

1.1.2. Muscles

The muscles mobilizing the joints at the distal end of the radius belong to a group of forearm muscles. They can be divided into three groups:

- the anterior (palmar) group – comprising eight muscles: the pronators teres and quadratus, the flexors carpi radialis and ulnaris, the flexors digitorum superficialis and profundus, the flexor pollicis longus, and the palmaris longus muscle; this group is responsible for the flexion of the radiocarpal joint and pronation of the forearm,
- the posterior (dorsal) group – comprising seven muscles responsible for the extension of the radiocarpal joint: the extensors digitorum, indicis, digiti minimi, pollicis longus and extensor brevis, as well as the extensor carpi ulnaris and the abductor pollicis longus,
- the lateral (radial) group – comprising four muscles: the brachioradialis (not involved in wrist movements), the extensors carpi radialis longus and brevis, and the supinator muscle. This group of muscles is responsible for the extension in the radiocarpal joint and supination in the radioulnar proximal and distal joints (Fig. 3) [5, 22].

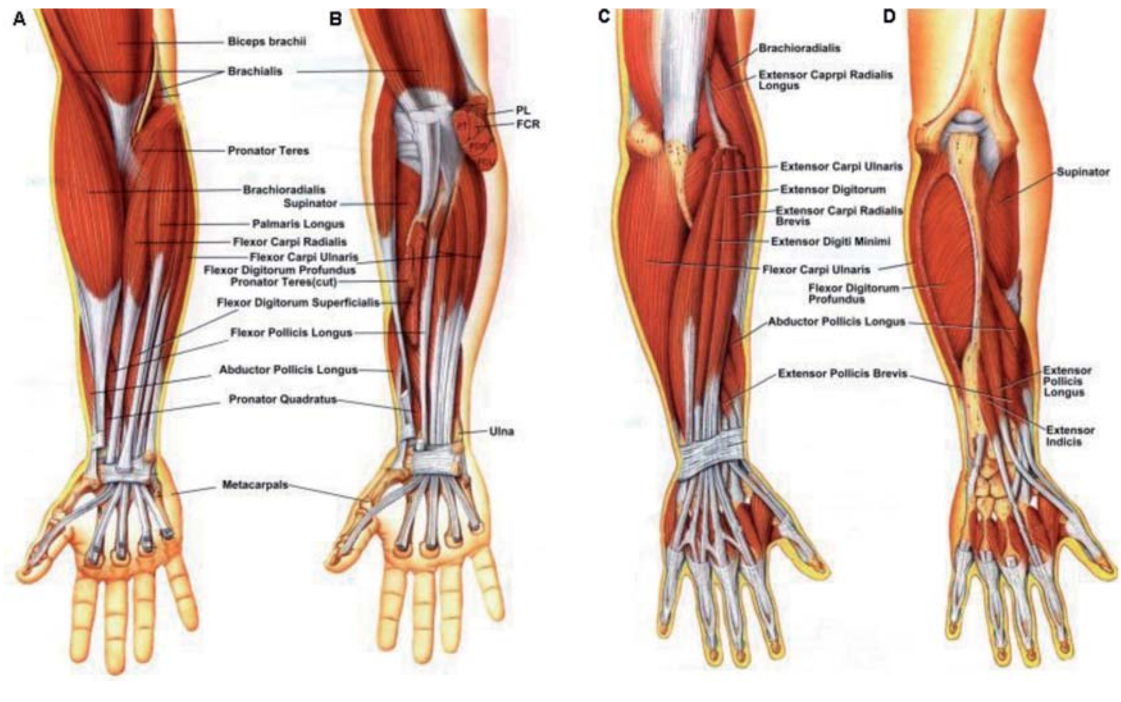


Fig. 3. Muscles of the forearm; anterior views (A and B) and posterior views (C and D).

1.1.3. Fasciae

The antebrachial fascia, which is a continuation of the brachial fascia, surrounds all the muscles of the forearm. From the anatomical point of view, it can be divided into the proximal part, the cubital fascia, surrounding the structures of the elbow joint and enclosing the cubital fossa, and the distal part continuing into the fascia of the hand at the wrist level.

Joined with the posterior margin of the ulna along its entire length, the antebrachial fascia forms intermuscular septa separating individual groups of antebrachial muscles. Moreover, the fascia forms multiple divisions separating individual muscles. Fibres of the antebrachial fascia run circularly and are particularly thick and strong where the fascia continues into the fascia of the hand.

The fascia of the hand is divided into four laminae. Two of them – the palmar deep fascia and the dorsal interosseous fascia – are the deep layers. More superficially, on the dorsal side, the superficial dorsal fascia of the hand can be found, beneath which lie the tendons of the extensors digitorum longus. On the palmar side, there is the superficial palmar fascia of the hand. In its middle part, it thickens markedly and forms the palmar aponeurosis, whose palmar fibers intertwine with the palmar longus muscle tendon, and the dorsal (deep) fibers interlace with the extensor retinaculum [5, 22, 27, 68].

1.2. Selected biomechanical aspects

1.2.1. The radiocarpal joint

The radiocarpal joint is ellipsoid, with the distal part of the radius and the articular disc forming the socket, and the proximal carpal bones forming the head. This is an articulation with two degrees of freedom. The possible movements occur in a sagittal plane around a transverse axis (flexion and extension) and in a frontal plane around a sagittal axis (adduction and abduction). These movements can be combined into circumduction around the long axis of the arm [6, 29, 32, 34].

All of the above movements involve both the radiocarpal and the midcarpal joints (the latter connecting the bones of the proximal and distal carpal rows) as well as the arthrodial joints between all the carpal bones. These articulations are conjoined, thus their combined mobility is being considered.

The range of movements in a frontal plane is extensive, as it is 85° for active flexion and active extension each. The passive range of these movements is even greater at 95° and 100°, respectively (Fig. 4, 5) [29]. During flexion, the radiocarpal joint is responsible for 50° of mobility, and the midcarpal joint for 30°. During the extension, the greater role can be attributed to the mobility in the midcarpal joint (45°), whereas the radiocarpal joint is responsible for only approximately 35° of the range of extension [6].

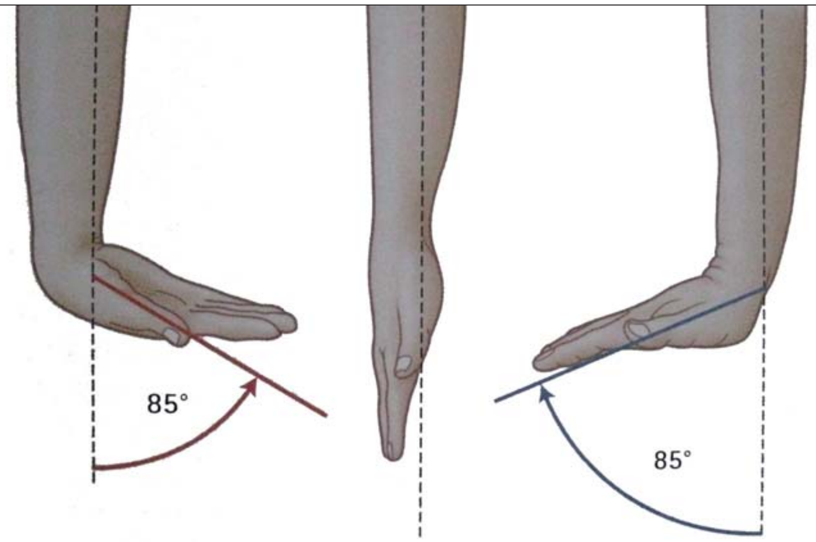


Fig. 4. The range of active flexion and extension in the wrist.

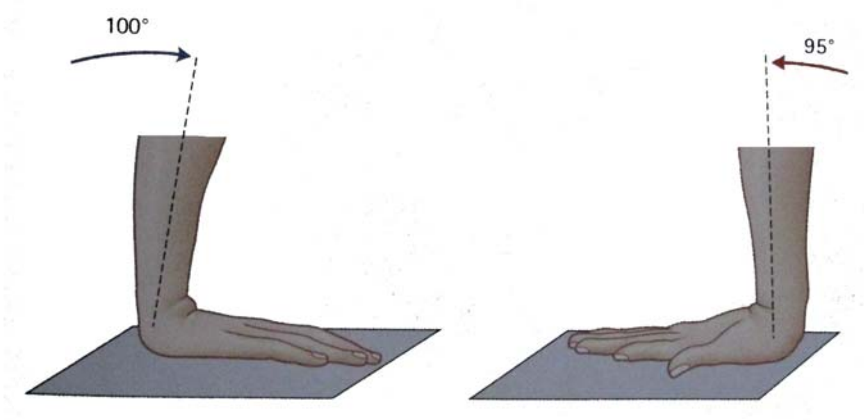


Fig. 5. The range of passive flexion and extension in the wrist.

Range of motion in a frontal plane is smaller at 15° of the active abduction (radial abduction) and 40–45° of the active adduction (ulnar abduction) (Fig. 6) [6, 29, 32, 34].

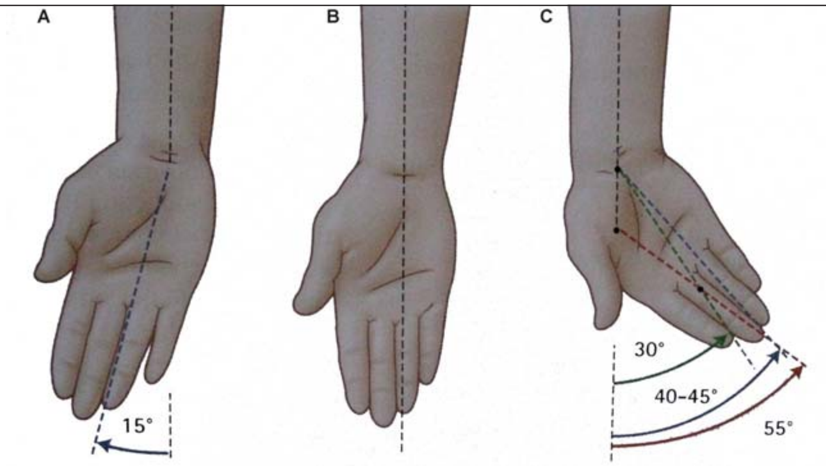


Fig. 6. The range of abduction (A) and adduction (C) of the wrist starting from the intermediate position (B).

1.2.2. The distal radioulnar joint

This articulation is a pivot joint with one degree of freedom. The movements of pronation and supination of the forearm occur in a horizontal plane around the long axis of the forearm. This articulation is functionally coupled with the proximal radioulnar joint, formed by the circumference of the head of the radius and the radial notch of the ulna. This coupling means that movement in both of these joints is necessary in order to achieve rotation of the forearm. Movement in these joints is controlled by the pronator and supinator muscle flexion and, in extreme positions, by the articular capsules. The interosseous membrane stabilizes the movements in those joints controlling the mobility of the ulna and the radius, relative to each other in the long axis of the forearm. The range of supination in the forearm is 90° and pronation – 85° (Fig. 7) [6, 29, 32, 34]].

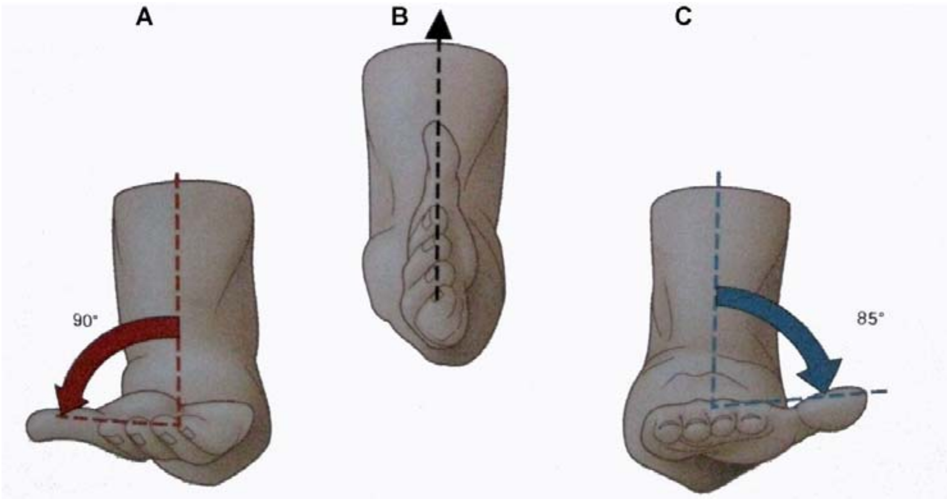


Fig. 7. The range of supination (A) and pronation (C) of the forearm from the intermediate position (B).

1.3. Distal radial fractures

Distal radial fractures are among the most common injuries reported in emergency departments and A&Es. Moreover, these are among the most common fractures in the elderly, although they are not uncommon in the young adult population or children and adolescents where they occur as a result of high-energy injuries [10, 20, 26].

1.3.1. Mechanisms of injury and fracture classifications

A distal radial fracture is most commonly a result of indirect force, i.e. fall on the hand. Direct fractures caused by an impact of a heavy object are rare. Depending on the mechanism of injury, fractures can be divided into fractures in extension mechanism (when the hand was extended during the fall) and, less common fractures in flexion mechanism (when the hand was flexed).

Usually, conventional names are used for the different types of distal radial fractures:

- Colles' fracture – a distal metaphyseal fracture of the radius, where the fracture slit may reach the articular surface; with angulation and radial shortening,
- Smith's fracture – also known as a reverse Colles' fracture, characterized by volar displacement of distal fracture fragments, it may be extra-articular or may involve the radiocarpal joint,
- Barton's fracture – involves the dorsal or palmar margin of the radial articular surface and is complicated by wrist subluxation,
- Chauffeur's fracture – an intra-articular fracture of the radial styloid process,
- Die-Punch fracture – involves a depression fracture of the lunate fossa or a depression of a central facet fragment.

There are also other classification systems intended to facilitate communication among the medical personnel and help the clinician to select the most effective treatment. Among the oldest, there is the Frykman's classification which divides fractures into intra-articular and extra-articular, and then according to the damage to the styloid process of the ulna; this classification comprises eight types of fractures (Fig. 8) [18].

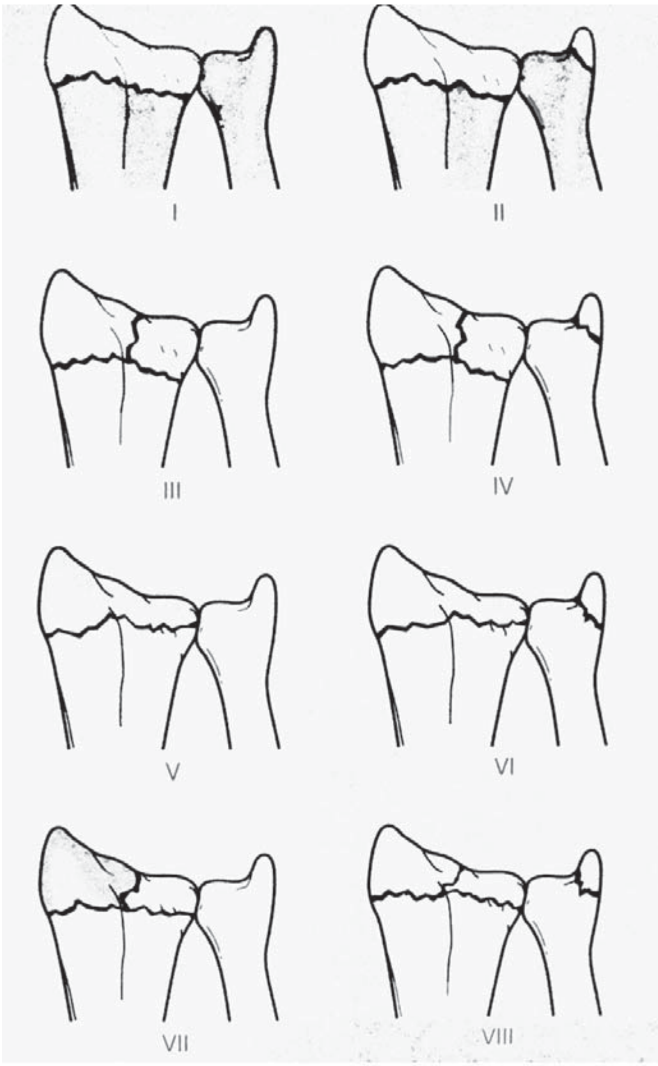


Fig. 8. The Frykman's classification of distal radial fractures.

The fracture classification most commonly found in literature is the AO classification, due to its simplicity on one hand and precise division of fractures into types and subtypes on the other. The AO classification divides fractures into three main categories:

A – extra-articular fractures,

B – partly intra-articular fractures,

C – fully intra-articular fractures.

Fracture subtypes can be classified based on the extent of injury to the joint and metaphyseal fragmentation (Fig. 9). This classification is of practical benefit, considering that assigning a given fracture to the right type has bearing on the selection of treatment approach.

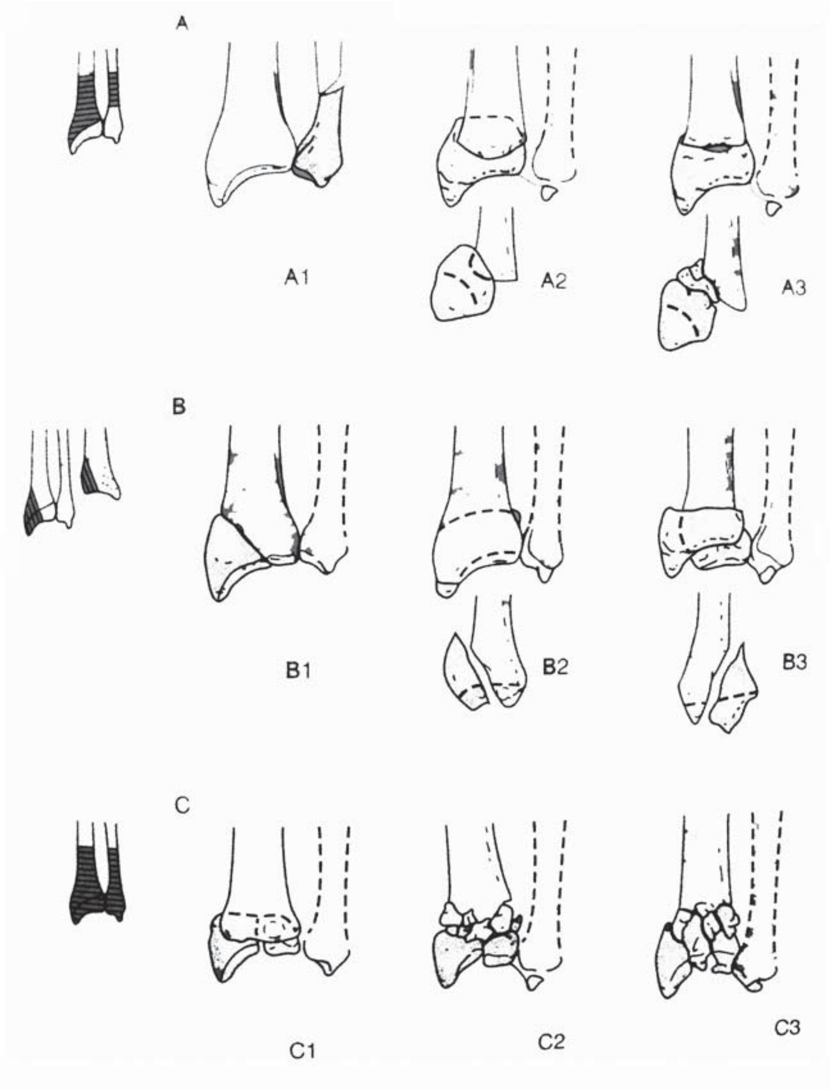


Fig. 9. The AO classification of distal radial fractures [Muller].

Similar principles are used in the so-called universal classification of fractures into four main types, as well as in the Medoff's classification based on radiographic findings and the selected treatment method. These classification systems, however, are less commonly applied.

Relatively frequently encountered is the Fernandez classification, which divides fractures according to the mechanism of injury and co-existing damage as well as the recommended treatment into:

Type I – bending fracture of the metaphysis,

Type II – shearing fracture of the joint surface,

Type III – compression fracture of the joint surface,

Type IV – avulsion fracture, radiocarpal fracture with dislocation,

Type V – complex fractures of types I-IV, high-energy fracture [Brown, Sanders].

Distal radial fractures can be divided into indirect (more common) and direct (less common) mechanism injuries. Based on the kind of trauma, there may be high-energy or low energy fractures. High-energy fractures occur usually in young people as a result of falls from a height, a forceful impact or a traffic accident. Low-energy fractures are caused by falls from the standing height and are typical for the elderly suffering from osteoporosis. As mentioned above, distal radius fractures may result from a fall on an extended hand (Colles' fracture), which is the most common fracture type or on a flexed hand (Smith's fracture) [15, 26, 79].

The following may be associated with distal metaphyseal fractures of the radius:

- fracture of the ulnar styloid process,
- fracture of the scaphoid bone and other carpal bones (particularly in children),
- periscaphoid dislocations,
- injury to the triangular fibrocartilage complex,
- ligament injuries (especially of the interosseous ligaments),
- injury to tendons, nerves, and other soft tissues surrounding the fracture.

Fracture-associated soft tissue injuries occur in about 70% fractures, which in the case of misdiagnosis may lead to carpal instability [15, 20, 26, 35].

1.3.2. Fracture epidemiology

Distal metaphyseal fractures of the radius constitute 12–15% of all fractures. A vast majority of distal radial fractures are osteoporotic. These are seven times more frequent in women over 60 than in men of the same age. Incidence of these fractures ranges from 0.5% to 2% annually, and the number of people suffering from this injury grows rapidly in the age group of 60 to 69. Risk factors for fractures in this population include mainly low bone mineral density (BMD) and a fracture in the family. This is often the first sign of osteoporosis, particularly in regions where early osteoporosis diagnostic tests are neglected. Poor mechanical strength of bones is another factor predisposing to fragment displacement during treatment, late instability, and deformities [21, 41, 57, 61, 62].

1.3.3. Diagnostics

Early assessment of the injury involves visual inspection and physical examination. The wrist is often deformed, immobilized in one position, and any attempt at movement causes severe pain. Before any further diagnostics or treatment is undertaken, the distal limb has to be assessed for pulse and superficial sensibility.

Radiographic imaging is the evaluation of choice in suspected distal radial fracture. Routine radiographic images are postero-anterior and lateral views showing the fracture line (Fig. 10).

Additionally, a lateral view may be obtained with the wrist positioned in a neutral position and elevated by 10º off the image plate. This projection more accurately shows the radiocarpal joint surface.

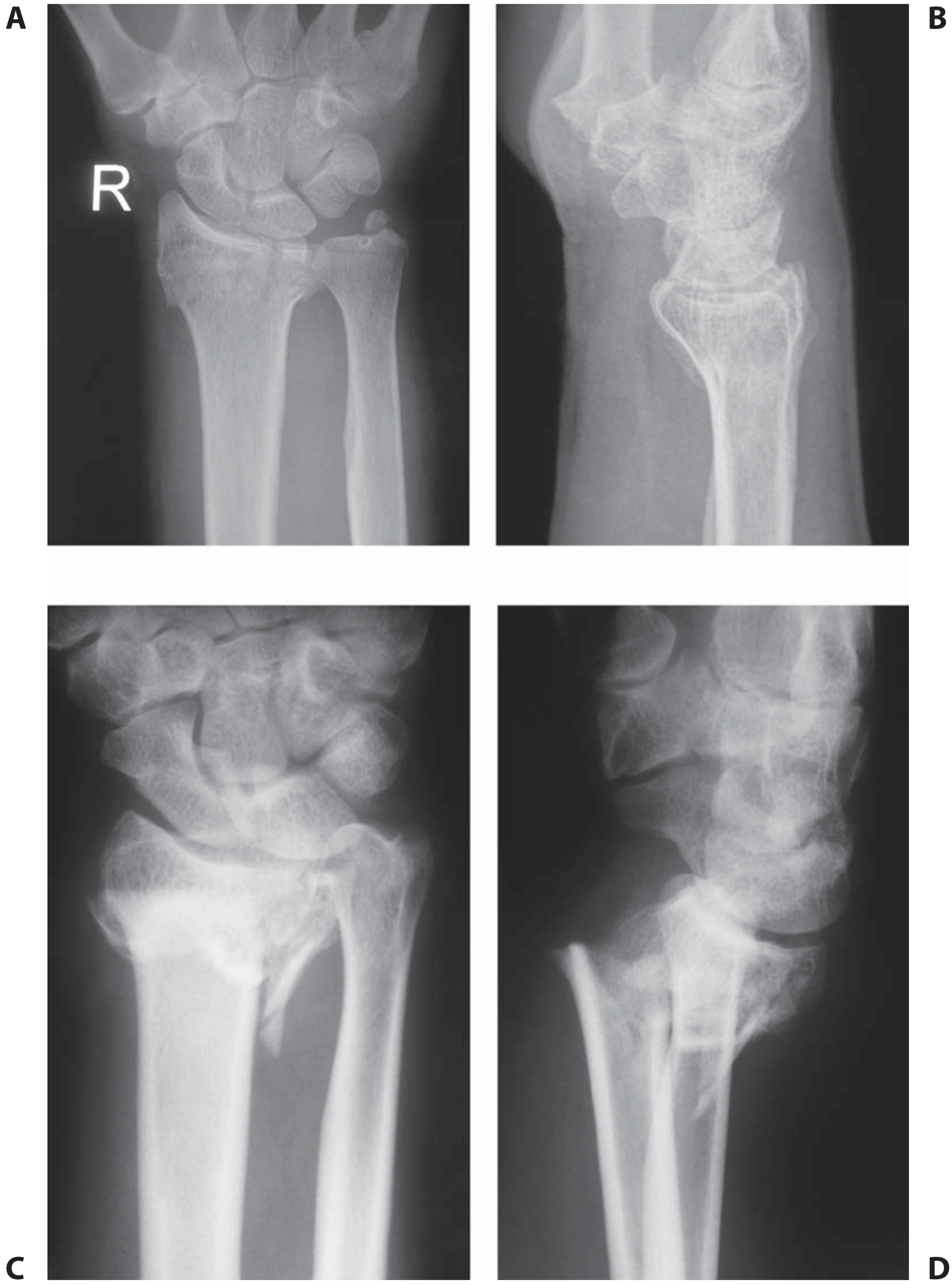


Fig. 10. A radiographic image of a radial fracture in antero-posterior (A) and lateral (B) views; C, D – distal radius fracture – type C3.

Computed tomography (CT) and magnetic resonance imaging (MRI) are among the additional examinations used in differential diagnosis assessing the associated injuries, such as ligament and tendon tears, as well as in assessing the joint surface fit in trans-articular fractures (Fig. 11) [26, 71].

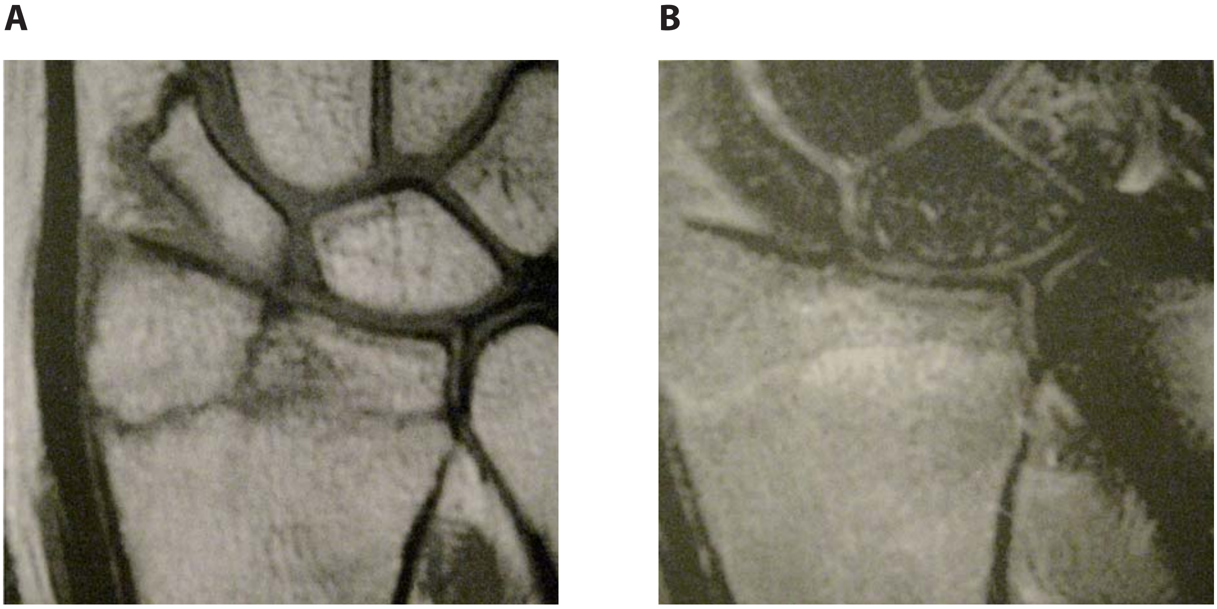


Fig. 11. An MRI scan of an intra-articular fracture of the radius: the fracture line in the T1-weighted sequence (A) and a hyperintense area of bone marrow edema in the FST2-FSE sequence (B).

1.3.4. Treatment of distal radial fractures

The treatment goals in fractures of the distal radius are reconstructing the anatomical angles of the radiocarpal joint surface, as well as maintaining the proper radial height and the stability of the distal radioulnar joint. The congruence of articular surfaces of the scaphoid and lunate fossas is of major importance, as it allows forces to be properly distributed across the wrist and ensures the execution of smooth movements in the radiocarpal joint. Important from the point of view of restoring the hand function is reconstruing the normal biomechanical parameters of the wrist, in particular:

- the radial inclination angle, normally between 22–23°, with an acceptable range of 13-10°,
- the palmar tilt of the distal radius (norm 11–12°, range 0–28°),
- the radial height in comparison with the ulna (norm 11–12 mm, acceptable range 8–18 mm) (Fig. 12).

The expected long-term treatment effects are the return of full range of flexion, extension, radial abduction and ulnar abduction of the wrist, as well as forearm rotation [12, 24, 26].

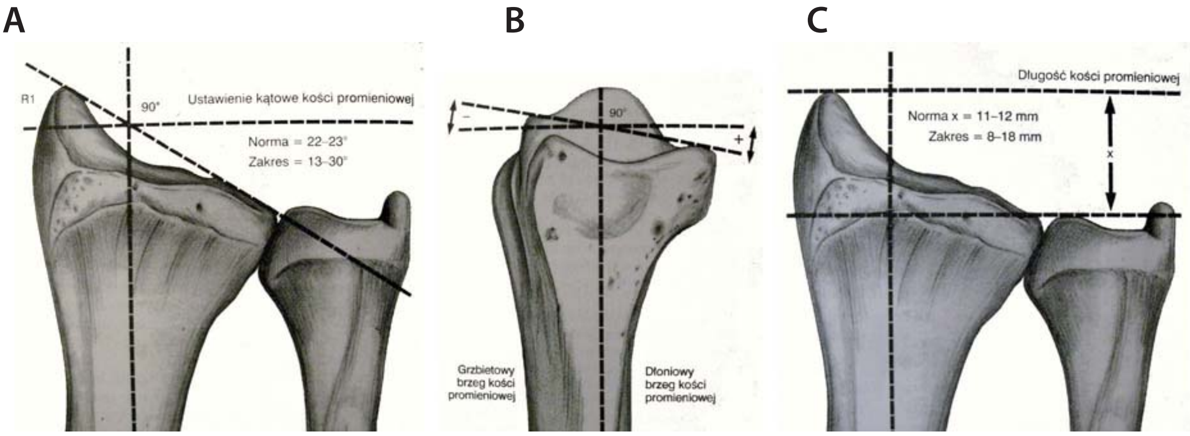


Fig. 12. Normal positioning of the distal end of the radius: radial inclination angle (A), radial tilt (B), and radial height (C).

1.3.4.1. Conservative management

Conservative management indications include:

- extra-articular fractures with or without displacement,
- intra-articular extension fractures without displacement,
- compression fractures with slight fragment displacement.

Moreover, conservative management is used in patients with contraindications to general anesthesia.

In fractures with displacement, reduction of fragments is required prior to fragment immobilization. This is most commonly done using closed methods under local anesthesia. During the reduction procedure, the fragments are pulled apart with the help of another person or using finger traction. Non-displaced and reduced fragments are stabilized with the use of an individually moulded sugar-tong splint. This splint remains in place for 2–3 weeks with a weekly inspection for the axial positioning of fragments. After splint removal, the forearm is placed in a cast for 3–5 weeks. After 6 weeks of immobilization, the cast is removed and passive wrist movements are introduced. Further rehabilitation is similar to that following surgical treatment and its purpose is to restore full joint mobility, muscle strength, and the ability to perform daily activities.

If any fracture displacement occurs within 2 weeks after the fracture reduction and immobilization, surgical stabilization should be considered [16, 24, 26, 40].

1.3.4.2. Surgical treatment

Surgical treatment indications are:

- intra-articular fractures with displacement,
- unstable fractures,
- fractures with significant initial fragmentation,
- fractures with a significant shortening of the radius, particularly compression fractures,
- fractures impossible to reduce using the closed methods.

The methods of choice in surgical treatment of distal radial fractures include: percutaneous Kirschner-wire stabilization, external fixation, external fixation with K-wireing or internal fixation, and internal fixation with the use of plates and pins. Fracture stabilization is preceded by closed, open or arthroscopic-assisted reduction [26, 40, 73].

Percutaneous wire stabilization is conducted after closed reduction of the fracture. Kirschner wires are introduced via small incisions in the skin through the styloid process of the radius and into the cortical layer of the proximal fragment of the ulna (Fig. 13). In the Kapandji method, the wires are utilized as levers for the entire fracture and help reduce the fracture as well as maintain the required shape of joint surfaces. After the wires are introduced, the wrist is immobilized in a splint or plaster cast for 4–5 weeks. This method is not recommended for treating fractures in the elderly; however, in younger patients, it leads to significantly better outcomes than conservative management [4, 24, 26, 65, 73].

A **B**

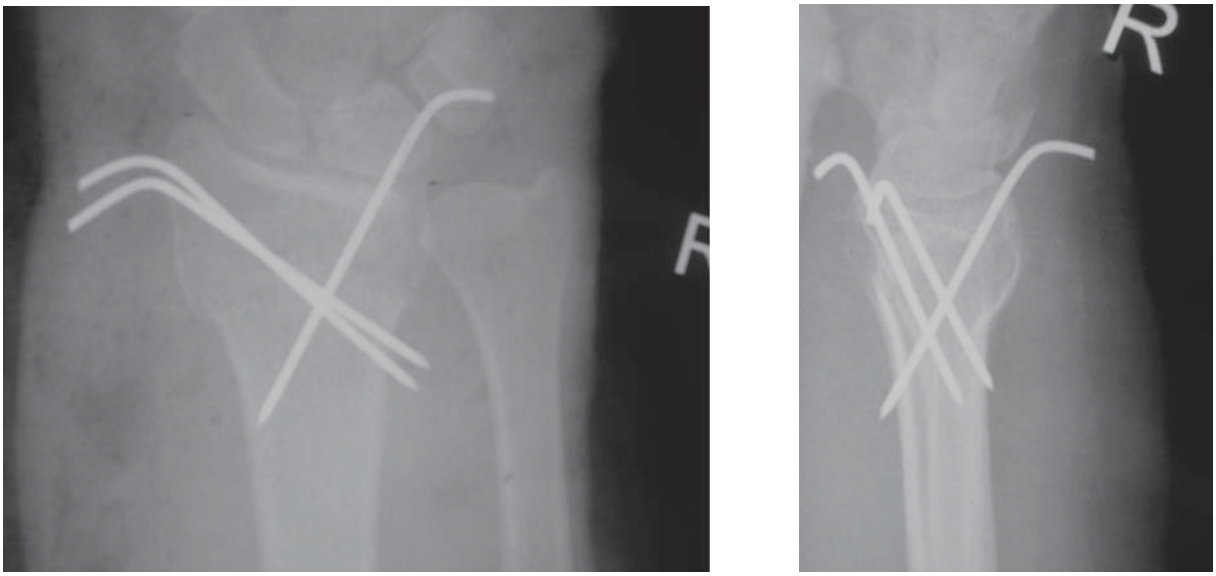


Fig. 13. Post-surgery radiographic images of a fracture treated with Kirschner wires – antero-posterior (A) and lateral (B) views.

Good long-term effects are also achieved with external fracture stabilization. This is performed with the use of an external fixation device, comprising pins introduced into the bone and external bars (Fig. 14). External stabilization is sometimes supported with the Kirschner-wire fixation or internal stabilization, a bone graft or arthroscopic-assisted fragment reduction. The use of external stabilization with the support of Kirschner wires is an effective means of fragment immobilization and it decreases the risk of repeated surgery. However, it may increase the incidence of infection [14, 21, 25, 26].

A **B**

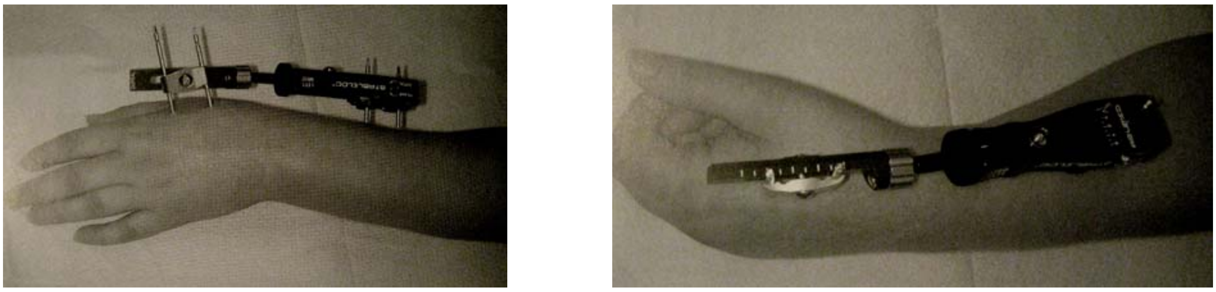


Fig. 14. The use of external fixation in radial fracture management.

Arthroscopic reduction of fragments is particularly useful in injuries with extensive fragmentation of the epiphysis and appears to be a more effective method of assessing the articular surface of the reduced fragments than fluoroscopy. Moreover, it facilitates the diagnosis of any co-existing damage to ligaments and the triangular cartilage [24, 26].

In the case of fractures impossible to reduce, open reduction and internal fixation are used. Internal fixation is also used in multiple-fragment and compression fractures, with a co-existing ulnar fracture, and in people with osteoporosis. In multiple-fragment fractures, stabilization can be achieved with the use of screws and Kirschner wires. With fewer fragments, a dorsal distraction plate or fixed-angle plates can be used dorsally or volarly. Distraction plates are utilised in high-energy fractures with considerable fragmentation of the distal radial epiphysis. Stabilization with the use of a dorsal plate is indicated in Barton's fracture (shear type) and in fractures with displacement of the dorsal margin of the articular surface. This technique, however, is less and less common, as it may result in irritation or damage to the extensor digitorum tendons. Stabilization with the use of palmar plate helps to restore the length of the radius and achieve appropriate ulnar inclination (Fig. 15). Some authors report clinically asymptomatic joint instability following this treatment. It is worth noticing that the use of internal stabilization contributes to a quicker restoration of full range of motion, whereas its long-term effects seem to be similar to those achieved with the use of external stabilization. Mechanical stabilization with a plate is equally effective to that with external fixators, although clinical studies show inconsistent results of comparative evaluation of these types of stabilization among different authors [8, 14, 17, 25, 26, 36, 52, 53, 55, 64, 72].

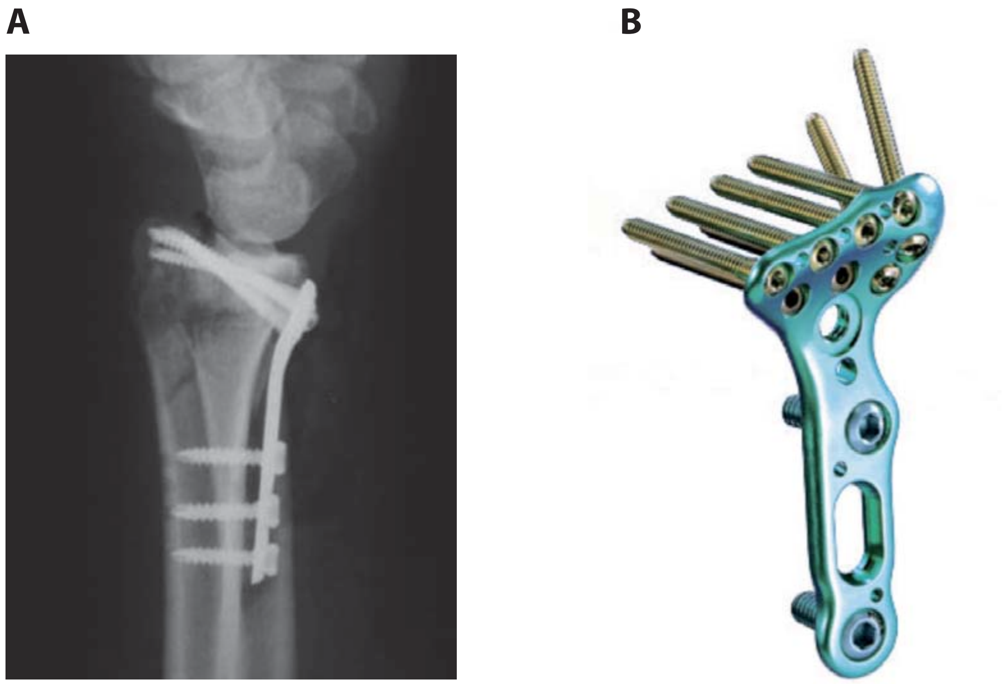


Fig. 15. A post-operative radiographic image of a fracture stabilized with a fixed-angle palmar plate (A) and an image of a palmar plate (B).

In the case of significant bone loss, which is most often due to fragment impaction, grafts of bone or bone replacement materials are implemented. Bone grafts are also utilized with the placement of stabilizing plates in order to replace any larger bone defects [26, 64].

The outcomes achieved one year after the injury seem to be similar irrespective of the treatment method, provided that it has been properly matched to the type of fracture and the patient's condition [14, 50].

1.3.4.3. Complications

Management of distal radial fractures is associated with a high rate of complications that eventually contribute to a significant number of unsatisfactory outcomes. Complications of both conservative and surgical management include:

- displacement resulting in incorrect bone union,
- delayed, or lack of, bone union,
- permanent nerve damage due to injury, surgical procedures or long-term pressure,
- inflammation of the joint and periarticular tissues (also as a result of infection), which may cause bone nonunion,
- tendon rupture,
- inadequate mobility or instability of the radiocarpal or distal radioulnar joint,

- Sudeck's atrophy (reflex sympathetic dystrophy syndrome),
- Volkmann's ischemic contracture,
- rarely: pressure sores caused by incorrectly applied plaster cast, carpal tunnel syndrome.

Incorrect union is one of the easily manageable sequelae causing most problems with restoring the hand function. Bone axis correction is achieved by intra-articular or extra articular osteotomy. An osteotomy procedure does not guarantee full joint function recovery, however, in most cases the results are satisfactory [26, 38, 43, 63, 78].

In the case of lack of union or delayed bone union, attempts are undertaken at conservative treatment with the use of physical therapy procedures (magnetotherapy with high-induction fields) as well as surgical treatment (resection of the fractured bone ends, re-fixation, cortico spongeous graft) or compression-distraction osteosynthesis (the Ilizarov technique), particularly with a co existing radial shortening and axis warping. If the treatment is ineffective, carpal arthrodesis can be performed, which improves the hand function with relatively few complications [39, 56, 60, 66].

Treatment of other complications is consistent with the generally accepted management procedures and will not be addressed in this article due to the detailed character of the subject.

1.3.4.4. Physical therapy

The objectives of physical therapy following the removal of an immobilization device or the union of surgically fixed fragments are:

- restoring the full range of motion at the radiocarpal and distal radioulnar joints,
- achieving the full muscle strength, particularly grip strength,
- full recovery of the affected hand in terms of daily functioning.

The rehabilitation period can be divided into three phases:

- the early phase, lasting from fracture immobilization to approximately week 6,
- the intermediate phase, lasting from week 6 to week 8 post injury,
- the late phase, beginning approximately in week 8 post injury and lasting until the full hand function is restored (approximately week 12).

Early phase (weeks 0–6)

The main purpose of this phase is to decrease the rigidity and edema of the hand. Effective means include hand elevation above the heart level, frequent movements of fingers, the use of hand and wrist compression supports (or appropriate adhesive tapes). Active and passive finger range-of-motion exercises are also recommended (Fig. 16). The patients should use the hand as much as they can in performing light daily tasks, especially in the case of stable or successfully surgically stabilized fractures. If there are no contraindications for forearm rotation, forearm supination exercises should begin already in the early phase of rehabilitation, as this is one movement that can quickly become limited. Other wrist movements can be also performed, provided there are no contraindications and wrist stability is maintained (e.g. with palmar plate fixation or non-bridging external fixation). Post operative management requires the gently massaging of the scar to prevent its hypertrophy. Additionally, active exercises of the elbow and shoulder joints are recommended in order to prevent limitation of the range of motion in these joints. Magnetotherapy, local cryotherapy and, in the case of conservative management, electrotherapy are used to minimize pain, as well as to accelerate bone union and normal remodeling of the existing union.

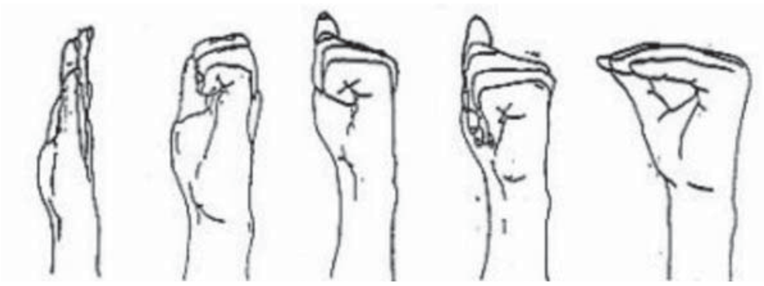


Fig. 16. Finger exercises for flexor tendon mobilization.

Intermediate phase (week 6–8)

After approximately 6 weeks, Kirschner-wire or external stabilization is removed. Also with other treatment methods, the patients should be encouraged to gradually give up external immobilization after 6 weeks. This phase focuses on increasing the limited range of motion of the wrist (flexion and extension, abduction and adduction) and forearm (supination and pronation). To this end, active-assistive and passive exercises are used, as well as supination splints or other dynamic splints, if required. Any physical therapy initiated to that point should be continued in this phase.

Late phase (weeks 8–12)

After about 8 weeks following the injury, complete bone union is achieved, allowing the patient to begin the strengthening exercises of the hand using soft balls of various types and rubber hand trainers, as well as small weights, dumbbells or specially constructed devices for strength training in various movements. Additionally, wrist, metacarpal, finger, and forearm range-of-motion exercises are continued (Fig. 17). An important element of the late phase of rehabilitation is restoring the normal hand function. This is achieved through exercises with the use of various common objects – mugs, balls, cylinders, knobs, door handles, dials and other elements used daily by the patient. If necessary, electrotherapy (to fight pain as well as in the form of electric muscle stimulation) and local cryotherapy are used to prevent development of post-exercise edema and pain.

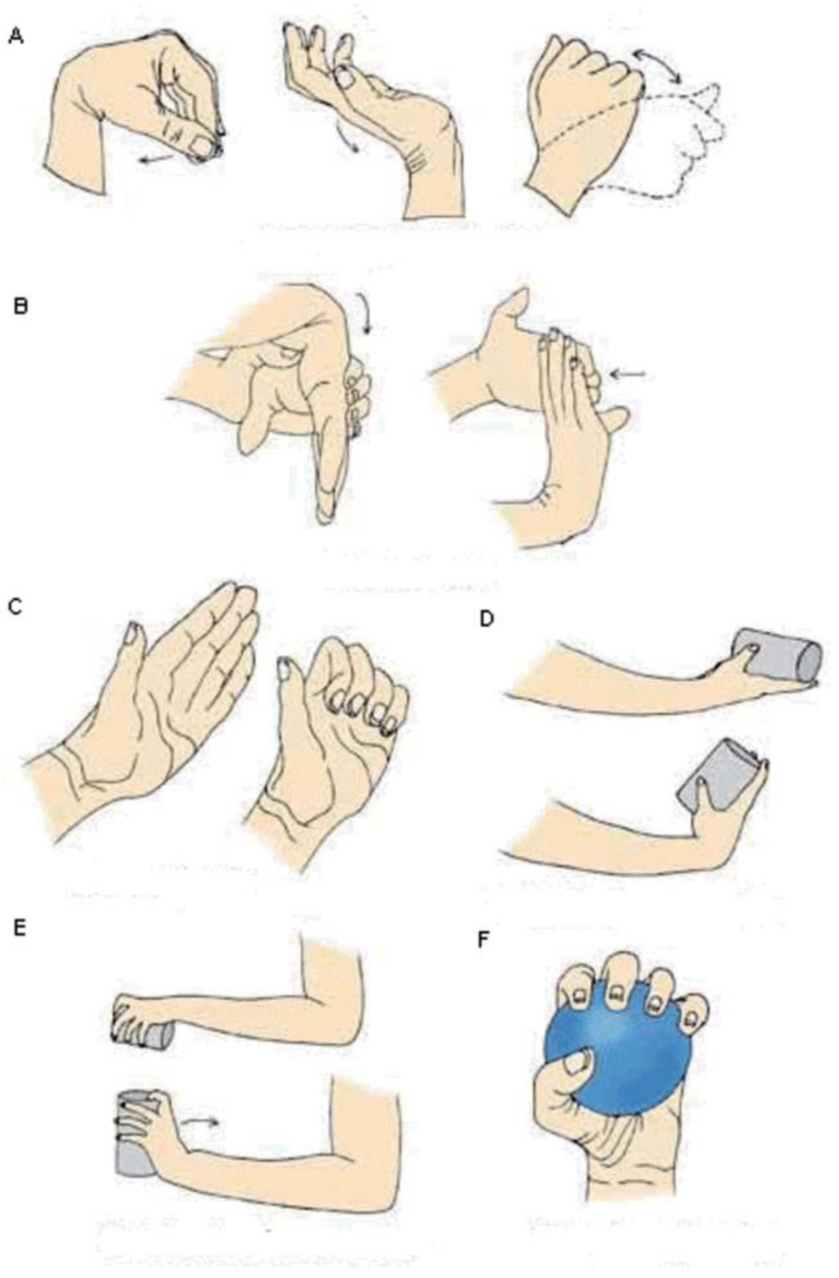


Fig. 17. Wrist exercises:

A – increasing the range of motion,

B – stretching the wrist into flexion and extension,

C – tendon mobilization exercises,

D – wrist flexion while holding a cylinder,

E – wrist extension while holding a cylinder,

F – increasing the grip strength.

Typically, a large proportion of patients receive instructions on how they should exercise and do the assigned exercises on their own at home. According to many authors, there is no significant benefit in conducting the rehabilitation program at the clinic, and that benefits, if any, are mainly due to greater patient satisfaction and decreased pain. Unfortunately, the role of physiotherapy in the treatment of distal epiphyseal fractures of the radius and in quick restoration of the hand function in these patients is still underestimated, which leads to not fully satisfactory outcomes or significant delays in achieving the full limb function [9, 30, 43, 44, 48, 66, 69].

1.4. The Fascial Distortion Model (FDM)

The Fascial Distortion Model (FDM) is a manual therapy method created and developed in the United States by Stephen Typaldos, an osteopath with many years' experience. This technique is also known as TMT (Typaldos Manual Therapy).

The tenets of this technique are based on the knowledge and diagnosis of the types of fascial structural, and consequently functional, abnormalities (distortions). Typaldos considers these distortions to be more significant as the causative factor of pain as well as muscle motor and function limitations than other injuries, such as sprains, luxations, fractures, mechanical muscle injuries. Thus, management of fascial distortions directly affects the other elements of the musculoskeletal system by alleviating pain, reducing movement limitations or edema. This gives the way to quicker and more effective treatment of injuries to other musculoskeletal system structures [75].

1.4.1. Fasciae

Fasciae are fibrous structures composed of connective tissue and located in all parts of the human body – they make up tendons, ligaments, superficial and deep fasciae, pericardium, and other structures the function of which is to join, protect, separate, isolate, and envelop internal organs, muscles and systems of the body.

As a result of their structure, fasciae have poor blood supply. A major portion of oxygen and nutrients as well as metabolites are transported via diffusion between cells and fascial perfusion fluid. This has important consequences in the case of fascial distortions described further in this chapter.

Due to their diverse functions and locations, fasciae differ in structure and mechanical properties. Fascial structures can be divided into the following types:

- fascial bands – including tendons, ligaments, and the iliotibial tract,
- spiral bands – surrounding parts of limbs, trunk, blood vessels, and internal organs,
- folded fasciae – including joint capsules, interosseous membranes and fascial septa,
- smooth fascial bands – lining joints, lining the abdominal cavity beneath other types of fasciae (except folded fasciae).

The function of all fascial types is the protection of various structures. Fascial bands protect joints, blood vessels, tissues, and some areas of the trunk and limbs against perpendicular external forces. Spiral bands of fascia protect extra-articular tissues against harmful effects of traction or compression forces. Bands of irregular, plicated structure are to protect the joints against longitudinal forces, i.e. traction and compression. Finally, smooth fascial bands maintain adequately low level of friction between the different structures, which allows them to easily shift against each other.

Apart from their protective function, fasciae also have a very important function as a structure able to receive mechanical signals. Parallel fibers of connective tissue forming fasciae are excellent transducers of mechanical forces, received by mechanoreceptors located in both the fasciae and adjoining tissues. Mechanoreceptors react both to stretching and compression that affects the pressure in surrounding tissues and in the receptor cell itself. Stimuli received by receptors are transferred to the central nervous system. It is vibration, sensed via single fascial fibers and proportional to the level of external stimulation, that plays a significant role in the reception of stimuli. Moreover, the vibration frequency of fascial fibers determines the characteristics of perceived discomfort: pulling, burning, numbness or pain. This fascial receptor function is used extensively by the central nervous system in controlling the muscle contraction and motion in the joint [75].

1.4.2. Fascial distortions

Fascial distortions can be divided into:

- triggerbands,
- herniated triggerpoints,
- continuum distortion,
- folding distortion,
- cylinder distortion,
- tectonic fixation.

The type of fascial functional abnormality is determined based on medical history. What calls for particular attention is the manner in which the patient shows the painful area and describes the nature of discomfort (burning, stabbing, pulling, etc.). In fascial distortions, it is significant that an injury not only limits the range of motion, diminishes proprioception, and impairs normal muscle function, but it also significantly disturbs fluid transport between fascial laminae, and thus unsettles the chemical balance of the fascia and connecting tissues [75].

Triggerbands

Triggerbands are fascial bands that have been twisted, separated, torn or wrinkled (Fig. 18). The patient reports burning or pulling sensation along the fascial band and shows the pain with a wide movement of his/her hand along the affected fibers. The wider the movement the larger fascial area has been damaged. The pressure of fingers against the skin will be grater with fascia located deeper than with superficial fascial injuries.

The aim of treatment in this type of injury is to break the existing fascial adhesions, which had formed after the injury and changed the band structure (in chronic conditions), and to restore the normal arrangement of fibers. If fascial bands have been twisted, the first action will be to rotate them back the other way. Secondly, the torn or separated fascial bands are approximated to allow for their heeling by restoring their normal anatomy.

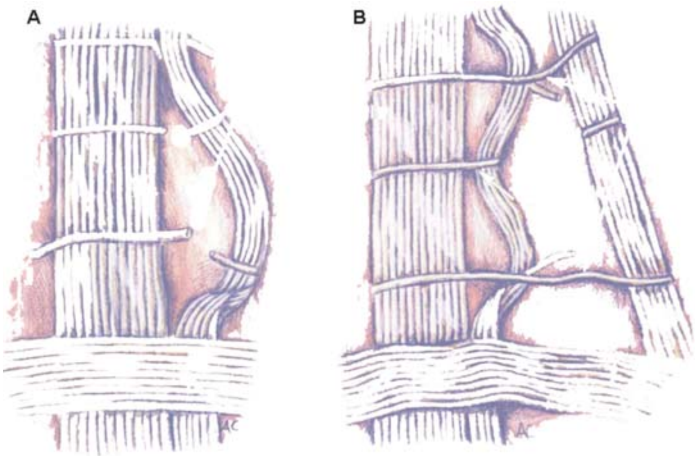


Fig. 18. Acute (A) and chronic (B) fascial band distortion.

Herniated triggerpoints

Herniation of fascial bands occurs when the underlying tissues protrude in an area of weakened connective tissue. This type of injury may cause a number of discomforts such as: pain in the cervical spine, shoulder, abdominal pain or the over-stretching of gluteal muscles. The patient indicates the painful area with one or several fingers pressing the injured site. The range of motion in neighboring joints is limited.

The treatment of herniated triggerpoints is to apply adequate perpendicular force to the injured site in order to "press" the herniated tissues back in and restore their normal anatomical relations.

Continuum distortion

This type of distortion is characterized by structural imbalance in the transition zone between the tendon, ligament or any other fascial structure and bone. As a result of this, the altered transition zone structure becomes more vulnerable to external forces. The structure alteration is mostly due to the growth of bone or tendon tissue that takes over the transition zone. This results in a loss of the transition zone or its significant shift (Fig. 19). Such injuries are mostly acute. These include tarsal joint sprains, over-stretching of neck muscles, and sacroiliac joint pain. In conditions of this type, the patient always indicates the painful site with a single finger. These injuries may be misdiagnosed as minor fascial band disturbances. Diagnosis should be based on the efficacy of a particular treatment technique.

Treatment aims to "shift" the overgrowing tissue (whether tendon or bone) back into place and to "expand" the transition zone to its normal size and position. A complementary treatment of continuum distortion is ice massage, which reduces the general discomfort around the joint.

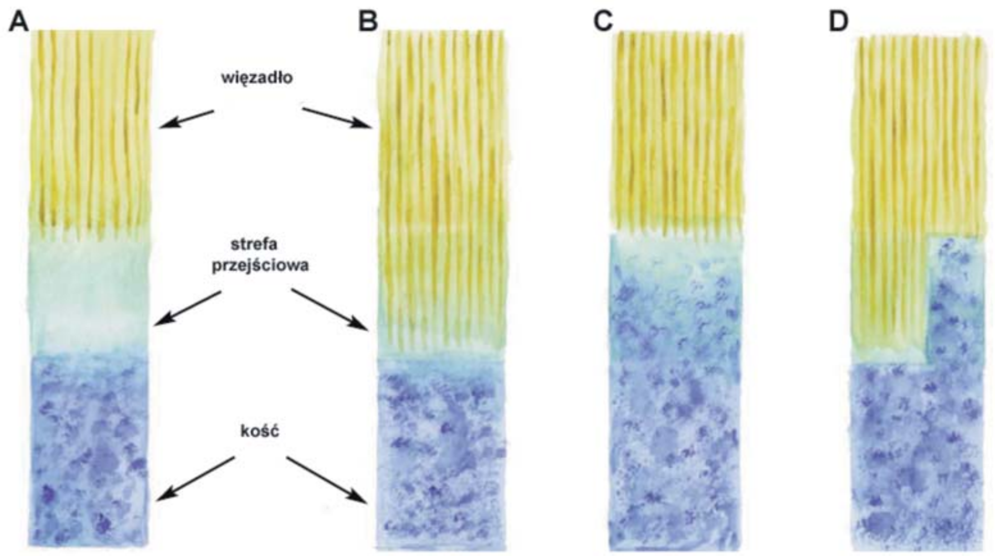


Fig. 19. Transition zone alterations – neutral state (A), ligamentous state (B), bony state (C) and "mixed-state" (continuum distortion) (D).

Folding distortion

Distortion in fascial folds is due to the traction or compression forces that exceed the mechanical resistance of periarticular fascia on which they are exerted. Based on their mechanism, folding distortions can be divided into traction distortions and compression distortions (Fig. 20). The resulting joint pain can easily be relieved by applying the forces in the same direction as those that caused the injury – traction is used in traction-related injuries, and compression is effective in compression injuries. These actions help the overly stretched or compressed tissues to return to their physiological state and the "organized" structure. Treatment also involves the often co-existing structure abnormalities caused by joint rotation at the time of injury.

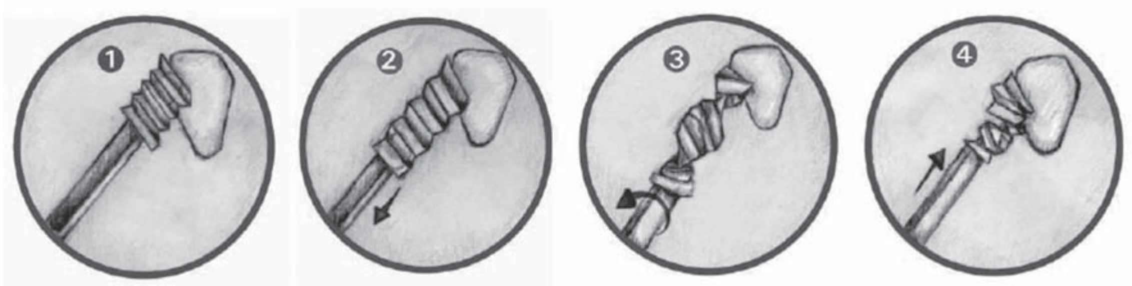


Fig. 20. Fascial distortion mechanism in a joint area following sudden traction and rotation.

Cylinder distortion

This type of distortion affects the fascia cylindrically encircling the individual segments of limbs (excluding the joints), the torso, and internal organs. As a result of compression or traction exceeding fascial resistance, the fibre arrangement shifts causing a disruption in the parallel, organized fascial structure (Fig. 21). Patients characterize their pain as situated deeply, despite the actual superficial location of its cause. More often than not, they are unable to determine the exact location of discomfort. This discomfort may sometimes seem to be neurological due to its character: tingling, numbness or reflex sympathetic dystrophy. While indicating the pain site, the majority of patients repeatedly squeeze the affected soft tissues. The pain may spontaneously relocate with time.

The treatment aims to restore the physiological arrangement of fascial fibers both with respect to each other and to the long axis of the limb. This is achieved by simultaneously twisting and pulling or compressing the damaged fascia. As with the already described treatment of periarticular fascial distortions, the direction of therapeutic force should be opposite to that which had led to the given fascial injury.

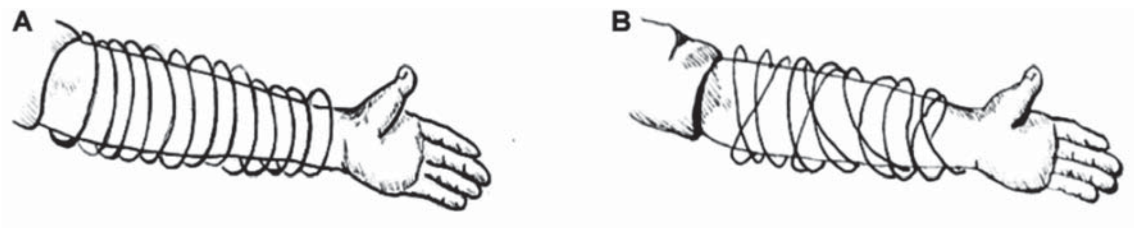


Fig. 21. Normal (A) and distorted (B) structure of spiral fascial fibres of the forearm.

Tectonic fixation

Tectonic fixation (fascial adhesion) occurs as a result of reduction in the amount of fluid produced by smooth fasciae. Adhesions cause limitations of fascial mobility in relation to itself and the surrounding tissues. There are also disturbances in the nourishment of cells incorporated in the fascial structure. Adhesions of the fasciae surrounding the shoulder, hip, and intervertebral joints are the most significant ones from the clinical point of view, as they produce the most severe symptoms.

The treatment of fascial adhesions should first address the other co-existing problems and then focus on increasing the tissue fluid perfusion. The final step of treatment is to restore the fascial mobility in relation to the adjoining tissues by severing the existing adhesions [75].

1.4.3. Treatment techniques

The FDM treatment techniques combine precision and relatively high force that needs to be applied to restore the fascial structure. These techniques can be divided into:

- manipulative techniques performed with the thumb – these include the treatment of triggerbands, herniated triggerpoints, continuum distortions, and some of the techniques used in cylinder distortions. Thumb techniques allow the application of significant force in a single site at a certain angle, which increases the precision of these procedures, however, the area of their application is limited,
- manipulative techniques performed with the whole hand – these are used in the treatment of folding distortions, tectonic fixation, and some cylinder distortions. These techniques are characterized by a smaller degree of precision, however, they allow the use of a greater force applied over a larger affected area; there is also a possibility of applying a traction or compression force to the joint or to extra-articular soft tissues [75].

1.4.4. Contraindications to FDM

The main contraindications to the use of FDM techniques are:

- venous thromboembolism,
- conditions involving bleeding,
- confirmed aneurysm,
- phlebitis,
- other peripheral vascular conditions,
- history of stroke,
- severe oedema,
- open cuts and wounds in the treated area,
- acute bacterial, viral, and fungal infections,
- osteitis,
- septic arthritis,
- fractures,
- connective tissue disorders,
- neoplasm,
- pregnancy (in therapies involving abdominal, pelvic, and lumbosacral spine areas).

Very frequently, these techniques are painful, thus relative contraindications should include low pain threshold or an existing psychiatric condition. In addition, caution should be exercised when applying these techniques in children.

Following the therapy, there may develop erythema, bruising, and other reflex skin reactions in the treated area. Sympathetic reactions such as nausea, vertigo, and vomiting are rare [75].

2. Materials and methods

2.1. Materials

A total of 65 patients (12 men, 53 women) at ages ranging from 22 to 81 were included in this study. They were randomized into the study group (n = 33) and control group (n = 32). Twenty-four patients of the study group underwent all three sessions each, three patients underwent two sessions each, and six patients one session each. Since only patients with all measurements could be included in the statistical evaluation, the effective sample size of the study group is n=24. The two groups do not differ in gender (Fisher's exact p= 0.18) and age (Wilcoxon rank sum test: W=362.5, p=0,73). Descriptive data can be observed in the tables 1 and 2.

Table 1. Study and control group broken down by gender.

		Control Group		Control Group	
dep. Variable		n	%	n	%
Gender	female	28	87,5	17	70,83
	male	4	12,5	7	29,16

Table 2. Study and control group broken down by age.

dep. Variable	Group	Min	Max	Mean	SD	Median	n
Age	total	22	81	61,5	13,3	63,0	56
	Control Group	30	80	61,0	12,7	63,5	32
	Study Group	22	81	62,2	14,2	63,0	24

All study participants suffered a distal radial fracture in the period from February to July 2009. The fractures were more common in the left limb (14 patients from the study group and 22 from control group) than in the right (10 patients in each group). According to a chi-square test, groups do not differ in the affected limb (χ^2=0,27, df=1, p=0,60).

Table 3 shows the types of fractures according to the AO classification. All patients underwent the treatment with Kirschner-wire stabilization and a 6-week cast immobilization.

Table 3. Types of fractures in the study and control groups according to the AO classification.

Fracture type	A			B			C		
Subtype	A1	A2	A3	B1	B2	B3	C1	C2	C3
Number of fractures in the control group	0	5	0	1	1	2	22	1	0
Number of fractures in the study group	2	2	2	0	1	0	5	9	3

Apart from the standard recommendations and exercise instructions, the study group underwent 3 sessions with the use of FDM techniques mentioned above. These therapeutic sessions were conducted once a month. The therapy was adjusted to individual limitations and patient feedback related to pain. The utilized therapeutic techniques included:

- triggerbands,
- herniated triggerpoints,
- continuum distortion,
- folding distortion,
- cylinder distortions,
- tectonic fixation [27, 68, 75].

The selection of therapeutic techniques was based on detailed history and observation of the patient during history-taking. Particular attention was being paid to pain location and the patient's body language when indicating the painful area.

Twenty-four patients underwent three sessions each, 3 patients underwent two sessions each, and 6 patients one session each. The control group received only exercise instructions and recommendations about managing their hand injury.

2.2. Methods

In order to conduct an efficacy analysis of the study therapy, the following were assessed:

- grip strength,
- range of motion at the radiocarpal joint: extension, flexion, adduction and abduction,
- ability to perform daily tasks,
- level of pain.

2.2.1. Grip strength assessment

Grip strength was assessed with the use of the Biometrics Ltd. E-Link H500 dynamometer. Grip strength was defined as a mean of three consecutive measurements and expressed in kilograms approximated to one decimal place [3, 40] (Fig. 22).

Fig. 22. Muscle strength assessment with the H500 dynamometer.

2.2.2. Range-of-motion assessment in the radiocarpal joint

Range of motion in the radiocarpal joint was measured with a manual goniometer according to the established standards (Fig. 23, 24) [29, 67, 80].

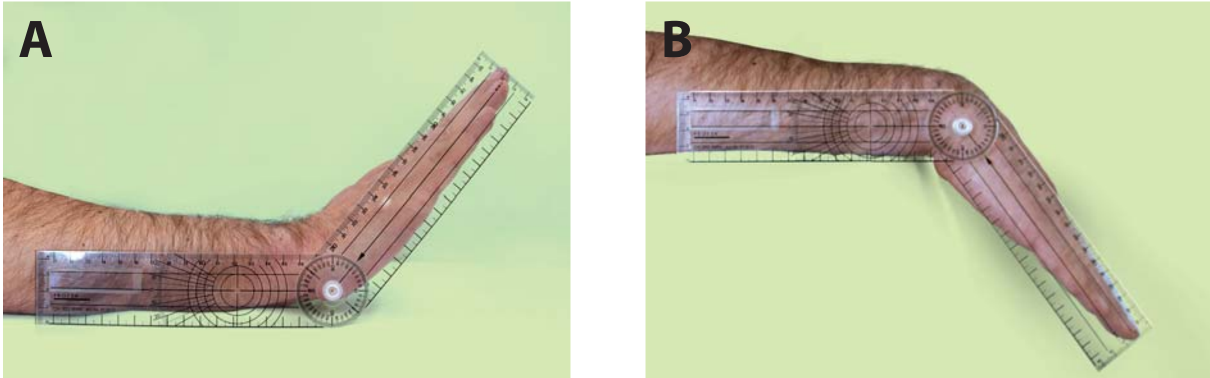


Fig. 23. Measurement of the range of flexion (A) and extension (B) in the radiocarpal joint.

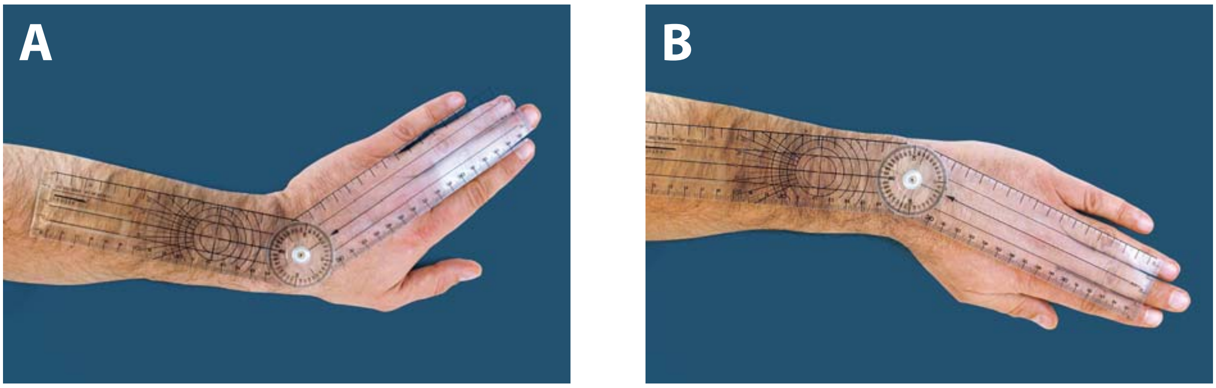


Fig. 24. Measurement of the range of abduction (A) and adduction (B) in the radiocarpal joint.

2.2.3. Assessment of patient's functional performance

A subjective hand function assessment was conducted with the DASH (Disabilities of the Arm, Shoulder and Hand) scale. This scale measures the patient's limitations in performing 23 everyday activities, such as housework, strength tasks, personal hygiene, social life and work, as well as 7 subjectively rated symptoms including pain, limb weakness, spasticity and the impact of these discomforts on sleep. Figure 25 presents the full version of the DASH scale. Each activity is scored from 1 (not at all difficult) to 5 points (unable to perform). The level of pain is rated in a similar manner from 1 (none) to 5 points (unbearable). In order to get the final result, the patient has to answer at least 27 out of 30 questions. The points from each answer are added and divided by the number of answers. For the result to be comparable with those achieved in other scales, the final score should be reduced by 1 and multiplied by 25. This way, the result falls within the 0-100-point range and is called the DASH 100 score. A higher score means greater limb disability [2, 33, 74].

The Disabilities of the Arm, Shoulder and Hand (DASH) Score

Date of completion..

Clinician's name (or ref).. Patient's name (or ref)..

		No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
1.	Open a tight or new jar	1	2	3	4	5
2.	Write	1	2	3	4	5
3.	Turn a key	1	2	3	4	5
4.	Prepare a meal	1	2	3	4	5
5.	Push open a heavy door	1	2	3	4	5
6.	Place an object on a shelf above your head	1	2	3	4	5
7.	Do heavy household chores (eg wash walls, wash floors)	1	2	3	4	5
8.	Garden or do yard work	1	2	3	4	5
9.	Make a bed	1	2	3	4	5
10.	Carry a shopping bag or briefcase	1	2	3	4	5
11.	Carry a heavy object (over 10 lbs)	1	2	3	4	5
12.	Change a lightbulb overhead	1	2	3	4	5
13.	Wash or blow dry your hair	1	2	3	4	5
14.	Wash your back	1	2	3	4	5
15.	Put on a pullover sweater	1	2	3	4	5
16.	Use a knife to cut food	1	2	3	4	5
17.	Recreational activities which require little effort (eg cardplaying, knitting, etc)	1	2	3	4	5
18.	Recreational activities in which you take some force or impact through your arm, shoulder or hand (eg golf, hammering, tennis, etc)	1	2	3	4	5
19.	Recreational activities in which you move your arm freely (eg playing risbee, badminton, etc)	1	2	3	4	5
20.	Manage transportation needs (getting from one place to another)	1	2	3	4	5
21.	Sexual activities	1	2	3	4	5
22.	During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5
23.	During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

	Please rate the severity of the following symptoms in the last week	No difficulty difficulty	Mild difficulty	Moderate difficulty	Severe	Unable
24.	Arm, shoulder or hand pain	1	2	3	4	5
25.	Arm, shoulder or hand pain when you performed any specific activity	1	2	3	4	5
26.	Tingling (pins and needles) in your arm, shoulder or hand	1	2	3	4	5
27.	Weakness in your arm, shoulder or hand	1	2	3	4	5
28.	Stiffness in your arm, shoulder or hand	1	2	3	4	5
29.	During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand?	1	2	3	4	5
30.	I feel less capable, less confident or less useful because of my arm, shoulder or hand problem	1	2	3	4	5

number of responses: DASH total DASH 100:

Fig. 25. The DASH scale.

Moreover, the study group was additionally assessed in terms of pain intensity using the Visual Analog Scale (VAS) of 100 mm in length (with no calibration marks). The level of pain was expressed in millimetres, with 0 indicating no pain, and 100 – worst pain ever (Fig. 26) [13, 76].

Fig. 26. The 100-mm Visual Analog Scale, used for pain assessment.

Measurements were conducted by an independent person, blinded to the patient's group. The patients were not informed as to the expected assessment results.

According to the results of the statistical analysis of the baseline measurements (cf. Table 4), there are significant differences between the two groups in flexion range of motion and DASH100 scores.

Table 4. Results of the Independent Samples t-tests and Wilcoxon Rank Sum Tests of the baseline data with the independent variable "Group".

Baseline	**Indep. Samples t-Test**			**Wilcoxon Rank Sum Test**	
dep. Variable	**t**	**df**	**p (t-Test)**	**Wilcoxon W**	**p**
Age				362,5	0,73
FLEX_rel_1				143,5	**<0,0001**
EXT_rel_1				395,5	0,86
ULN_rel_1				329,5	0,37
RAD_rel_1				451,5	0,27
STR_rel_1				290,5	0,12
DASH100_1	-2,2	50,966	**0,03**		

The baseline data of the variable „FLEX-rel_1 broken down by group are shown in Fig. 27 (mean ±95% confidence intervals and box-and-whisker-plot), descriptive data are presented in Table. 5.

Table 5. Descriptive data for the variable „FLEX_rel_1"(flexion range of motion expressed as percentage of values for the uninjured hand at wire removal) broken down by group (SD... standard deviation).

dep. Var.:	FLEX_rel_1					
Group	n	Min	Max	Median	Mean	SD
Control Group	32	13	89	63,0	58,4	21,2
Study Group	24	50	118	82,0	83,1	18,2

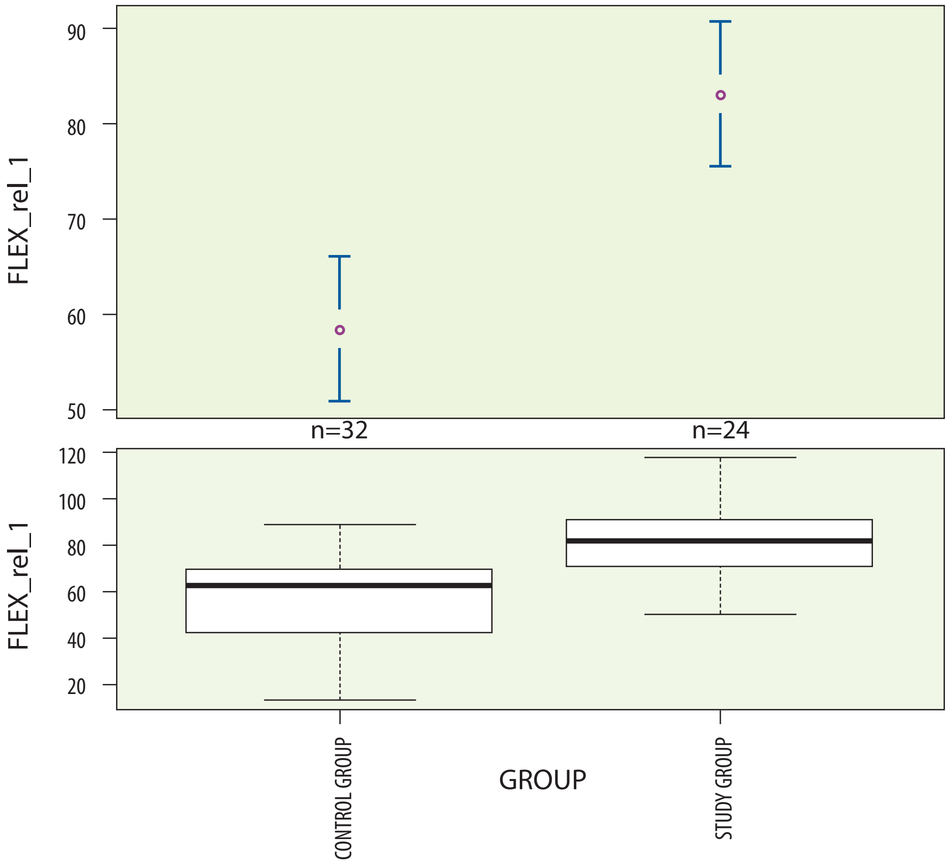


Fig. 27. Mean values ± 95% confidence intervals and box-and-whisker-plot for the variable "FLEX_rel_1" (flexion range of motion expressed as percentage of values for the uninjured hand) broken down by group.

The flexion range of motion is significantly higher in the patients of the study group than in the patients of the control group (Wilcoxon W= 143.5, $p<0.0001$). On average, the patients of the control group achieve 58.4±21.2 % (median: 63.0%) of the range of motion of the healthy hand, the patients of the study group 83.1±18.2% (median: 82.0%).

The baseline data of the variable „DASH100_1" broken down by group are shown in Fig. 28 (mean ±95% confidence intervals and box-and-whisker-plot), descriptive data are presented in Table 6.

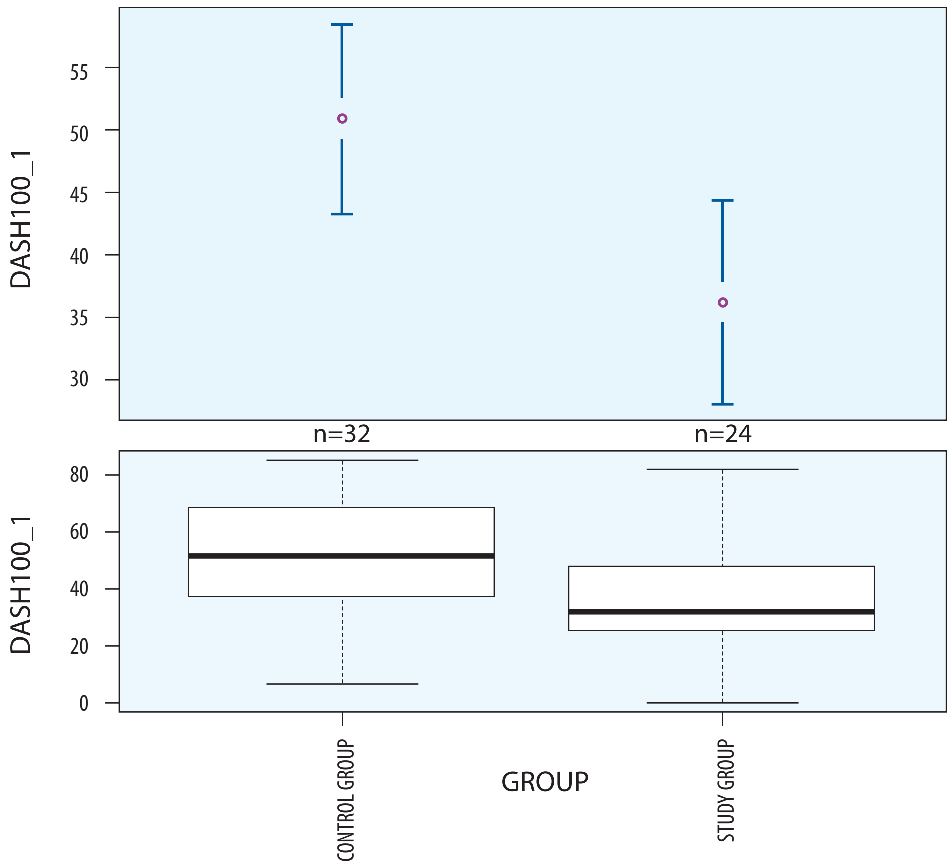


Fig. 28. Mean values ± 95% confidence intervals and box-and-whisker-plot for the variable "DASH100_1" broken down by group.

dep. Var.:	DASH100_1					
Group	n	Min	Max	Median	Mean	SD
Control Group	32	6,7	50,92	85,0	21,14	51,25
Study Group	24	14,2	39,59	81,7	16,63	35,85

Table 6. Descriptive data for the variable „DASH100_1“ (at wire removal) broken down by group (SD... standard deviation)

The patients of the study group are significantly less disabled according to the DASH100 score than the patients of the control group (independent samples t-test: t=2.2, p=50.966, p=0.03).

However, the two groups do not differ in the other variables (cf. Table 4). Range of motion and grip strength at wire removal and broken down by group are summarised in Table 7.

Table 7: Descriptive data for the initial values of the range of motion (extension, adduction and abduction) as well as grip strength ("STR_rel_1") at wire removal. Values are expressed as percentage of values for the uninjured hand (SD... standard deviation).

dep. Variable	Group	Min	Max	Mean	SD	Median	n
Extension (EXT_rel_1)	total	25	120	60,1	22,4	58,5	56
	Control Group	37	120	61,1	23,8	60,0	32
	Study Group	25	111	58,9	20,8	57,0	24
Abduction (RAD_rel_1)	total	25	115	62,6	24,0	65,5	56
	Control Group	25	115	59,9	27,6	63,0	32
	Study Group	25	100	66,0	18,3	67,0	24
Adduction (ULN_rel_1)	total	10	157	70,5	29,9	72,0	56
	Control Group	10	157	73,2	30,0	76,5	32
	Study Group	14	140	66,8	30,0	67,0	24
Grip strength (STR_rel_1)	total	0	89	31,8	20,2	28,0	56
	Control Group	0	89	28,1	19,0	23,0	32
	Study Group	10	77	36,9	21,1	31,5	24

2.3. Statistical Analysis Methods

The statistical analysis of study results was conducted with R 2.12.0. software [81] The level of significance was chosen with $\alpha=0.05$.

Prior to carrying out the data analysis, the Shapiro Wilk test for goodness-of-fit to normal distribution and the Bartlett-test for homogeneity of variances was carried out. With regard to Sachs [82] the level of significance was predefined with $\alpha=0.10$ for the Shapiro Wilk test (results cf. annex).

Due to the results of the test for normal distribution and low sample size nonparametric tests were used for all variables [70, 77].

Differences between the groups in the baselines of the measured parameters was performed by means of Wilcoxon rank sum tests (cf. Table 4 and annex).

Statistical analysis can be differentiated in three parts with the following null hypotheses:

Null hypothesis 1:

There is no linear correlation between the DASH100 score and the

a. range of motion
b. grip strength
c. pain and
d. age

Correlation analysis was performed using Spearman's Correlation Coefficient because of non-normal distribution of presented data.

Null hypothesis 2:

Changes in the

a. range of motion
b. grip strength and
c. disability (according to DASH100 scores)

between the pre- and post-FDM measurement are identical in the study- and control group. I.e., there is no significant effect of the FDM technique on these parameters.

Analysis of variance (ANOVA), which is considered as being robust against violations of normality and homogeneity requirements was performed in order to study the effect of FDM technique on the mobility- strength and pain parameters in comparison to a control group. Since the design is unbalanced, a REML approach (restricted maximum likelihood method for mixed effect models) was chosen, defining "patient" as random factor, "measurement" as within-subject factor and "group" as between-subject factor.

Baseline data of the variables "FLEX_rel_1" and "DASH100_1"of the two groups differ significantly, wherefore these variables were defined as covariates in order to control the effect of the initial state on the changes in the dependent variables.

For the non-parametric assessment of differences between study and control group in the changes within the 3-month period between the measurement at wire removal and 3 months later, the differences of the values of the two measurements were calculated for each patient. The differences between groups in these new variables were analysed with the Wilcoxon rank sum test.

Null hypothesis 3:

Differences between the results of the measurements of the

a. range of motion
b. grip strength
c. pain and
d. disability (according to DASH100 scores)

before and after the single FDM-sessions (in the study group only) are equal 0.

Intra-group statistics in the study group were evaluated using Friedman's ANOVA test and subsequently Wilcoxon signed rank tests.

Since only complete data sets were evaluated, the effective sample size of the study group is n=24, results of the control group base on n=32 patients.

Range of motion and grip strength values were expressed as percentage of values for the uninjured hand of the same patient.

3. Results

3.1. Correlation analysis

The data was analyzed for correlation between the study parameters and the DASH100 score (cf. Table 8). The correlation of the DASH100 score with the range of motion expressed as percentage of that in the healthy limb was moderate and ranged from –0.39 to –0.45 ($p < 0.05$). The linear relationship between the functional performance assessment score (DASH100) and the level of pain assessed on the VAS scale and the grip strength (as percentage of the strength in the healthy hand) is more distinct with Spearman's correlation coefficients of 0.52 and –0,69, respectively ($p < 0.0005$). No correlation of the DASH100 score could be observed with age ($p=0.29$).

*Table 8. Outcomes of the Spearman's rank correlation test of the DASH100 score and the other dependent variables and age (study group data at wire removal and at the follow-up assessment 3 months later; * study and control group data at wire removal).*

Var. vs. DASH100	n	S	p	ρ
FLEX (Flexion)	44	20557.68	0.0022	-0.45
EXT (Extension)	44	19931.34	0.0064	-0.41
ULN (Adduction)	44	20298.47	0.0035	-0.43
RAD (Abduction)	44	19689.65	0.0093	-0.39
STR (Grip strength)	44	23931.74	<0.0001	-0.69
VAS (Pain level)	43	6373.042	0.00036	0.52
Age	54*	22410.45	0.29	0.15

3.2. Results of the overview analyses

Results of the Friedman tests are summarised in Table 9 showing the presence of significant differences of at least two results of grip strength-, range of motion-, and functional performance assessment within the study group (maximum $p<0.001$).

Table 9. Results of the Friedman tests for differences in the value distributions in the dependent variables between the single measurements within the study group.

Dep. Var	Friedman χ^2	df	p
FLEX (Flexion)	77.6933	5	**<0.0001**
EXT (Extension)	62.328	5	**<0.0001**
ULN (Adduction)	38.2	5	**<0.0001**
RAD (Abduction)	37.3342	5	**<0.0001**
STR (Grip strength)	87.2002	5	**<0.0001**
VAS (Pain level)	13.8667	2	**0.00097**

These results indicate at least one significant difference in the value distributions of the six (variable "VAS" three) measurements of each variable.

The results of the REML analyses for the comparison between the study- and control group are summarised in Table 10. According to the results of ANOVA and ANCOVA, respectively, there are significant differences in the change of the extension-, flexion-, and adduction range of motion (apparent in the significant effect of the "Group:Measurement"-interaction). Additionally, there might be hints, that grip strength (p=0.10) is influenced by the FDM technique, too. No effect of FDM at all can be observed in the abduction range of motion and DASH100 score.

Table 10. Results of the REML analysis for the model describing the outcomes of the dependent variables at wire removal and after the three month period with the random factor "patient", the within-subject factor "measurement" and the between-subject factor "group". Additional covariates "FLEX_rel_1" and "DASH100_1", respectively, were defined for the according variables "FLEX_rel" and "DASH100", as baseline data differ significantly between the two groups.

Dep. Var.	Factor	numDF	denDF	F-value	p-value
Extension (EXT_rel)	(Intercept)	1	54	630.1742	<0.0001
	Group	1	54	0.1321	0.72
	Measurement	1	54	124.2002	**<0.0001**
	Group: Measurement	1	54	11.1121	**0.0016**
Abduction (RAD_rel)	(Intercept)	1	54	560.0321	<0.0001
	Group	1	54	0.3146	0.58
	Measurement	1	54	56.5122	**<0.0001**
	Group: Measurement	1	54	1.3740	0.25
Adduction (ULN_rel)	(Intercept)	1	54	420.9248	<0.0001
	Group	1	54	0.3217	0.57
	Measurement	1	54	48.5389	**<0.0001**
	Group: Measurement	1	54	10.3062	**0.0022**
Grip strength (STR_rel)	(Intercept)	1	54	307.10390	<0.0001
	Group	1	54	5.76892	**0.020**
	Measurement	1	54	144.90340	**<0.0001**
	Group: Measurement	1	54	2.72868	0.10

Dep. Var.	Factor/Covariate	numDF	denDF	F-value	p-value
Flexion (FLEX_rel)	(Intercept)	1	54	5561.822	<0.0001
	Group	1	53	183.574	**<0.0001**
	Measurement	1	54	121.714	**<0.0001**
	FLEX_rel_1	1	53	277.172	**<0.0001**
	Group: Measurement	1	54	5.209	**0.026**
DASH100 score (DASH100)	(Intercept)	1	51	1169.5747	<0.0001
	Group	1	51	16.8515	**0.0001**
	Measurement	1	50	151.6880	**<0.0001**
	DASH100_1	1	51	173.3109	**<0.0001**
	Group: Measurement	1	50	1.0592	0.31

Because significantly different DASH100 scores in study- and control group might have an effect on other variables, too, data analysis was repeated with the additional covariate "DASH100_1", representing the baseline values of the DASH 100 score (cf. Table 11).

Table 11. Results of the REML analysis for the model describing the outcomes of the dependent variables at wire removal and after the three month period with the random factor "patient", the within-subject factor "measurement" and the between-subject factor "group" and the covariate "DASH100_1", as baseline data of the DASH100 scores differ significantly between the two gro

Dep. Var.	Factor/Covariate	numDF	denDF	F-value	p-value
Flexion (FLEX_rel)	(Intercept)	1	52	865.0967	<0.0001
	Group	1	51	30.9491	**<0.0001**
	Measurement	1	52	121.3674	**<0.0001**
	DASH100_1	1	51	0.0007	0.98
	Group:Measurement	1	52	6.6055	**0.013**
Extension (ULN_rel)	(Intercept)	1	52	641.5893	<0.0001
	Group	1	51	0.0816	0.78
	Measurement	1	52	113.7908	**<0.0001**
	DASH100_1	1	51	6.1342	**0.017**
	Group:Measurement	1	52	10.2590	**0.0023**
Abduction (EXT_rel)	(Intercept)	1	52	565.1168	<0.0001
	Group	1	51	0.4495	0.51
	Measurement	1	52	58.0939	**<0.0001**
	DASH100_1	1	51	4.5894	**0.037**
	Group:Measurement	1	52	0.7546	0.39
Adduction (RAD_rel)	(Intercept)	1	52	396.7773	<0.0001
	Group	1	51	0.2362	0.63
	Measurement	1	52	47.7939	**<0.0001**
	DASH100_1	1	51	1.4592	0.23
	Group:Measurement	1	52	11.5469	**0.0013**
Grip strength (STR_rel)	(Intercept)	1	52	376.2548	<0.0001
	Group	1	51	5.5259	**0.023**
	Measurement	1	52	139.2399	**<0.0001**
	DASH100_1	1	51	18.0199	**0.0001**
	Group:Measurement	1	52	3.1751	0.081

The initial DASH100 score shows a significant effect on extension- and abduction range of motion and on grip strength, only. There is no general difference in the predication of these results compared to the results shown in table 10.

3.3. Descriptive Statistics

3.3.1. Flexion Range of Motion

Changes within the study group

According to the results of the Friedman test, there is at least one significant difference in the value distributions of the six measurements of the flexion range of motion within the study group ($p<0.001$).

Mean values and 95% confidence intervals of the flexion range of motion in the six measurements of the three therapeutic sessions are presented in Fig. 29, mean differences and results of the Wilcoxon signed rank tests of each subsequent pair of measurements are summarised in Table 12.

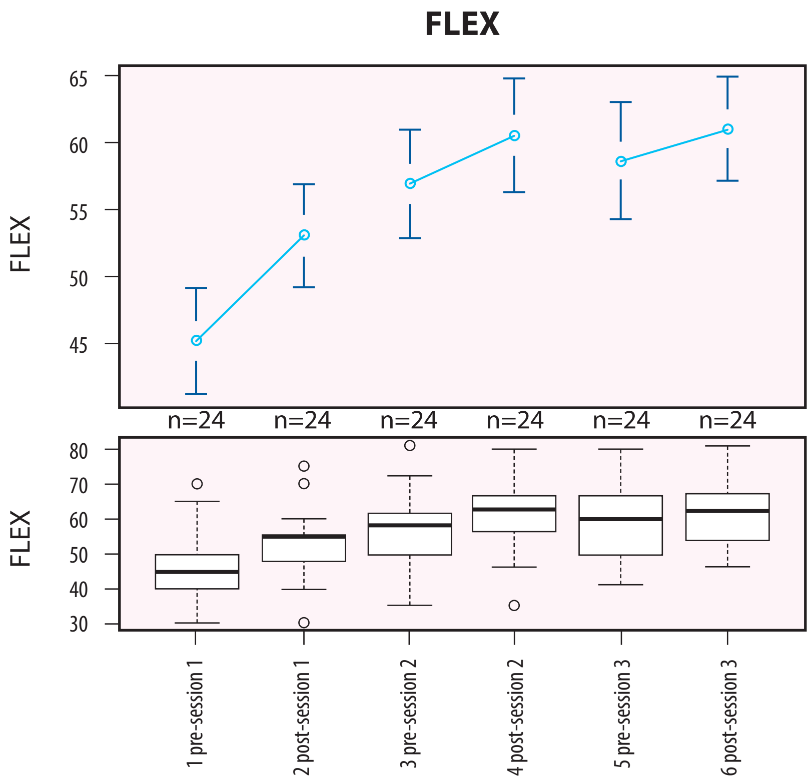


Fig. 29. Mean values and 95% confidence intervals of the flexion range of motion in the six measurements of the three therapeutic sessions [°].

Table 12. Mean differences± standard deviation (SD) of the flexion range of motion [°] measured before and after each of the three FDM sessions and results of the Wilcoxon signed rank tests of the data of consecutive measurements.

FLEX	n	Mean Diff	SD (Diff)	Wilcoxon signed rank test
1post - 1pre	24	7.9	5.3	V = 0, p-value <0.0001
1pre - 2 post	24	3.8	6.0	V = 37.5, p-value = 0.0069
2post - 2pre	24	3.7	3.4	V = 5, p-value = 0.00013
2pre - 3post	24	-1.9	5.0	V = 194, p-value = 0.090
3post - 3pre	24	2.4	3.9	V = 37.5, p-value = 0.0067

These results show, that the application of FDM technique has a significant effect on the flexion range of motion. Differences between post and pre-FDM measurements are generally higher than the differences between the single sessions. The highest effect can be observed in the first session with an improvement of 7.9±5.3% (absolute).

Comparison of the study- and control group outcomes

The means of the variable „FLEX_rel" (Flexion range of motion as percentage of values for the uninjured hand) broken down by group and measurement are shown in Fig. 30, differences between the two measurements (mean ±95% confidence intervals and box-and-whisker-plot) in Fig. 31. The descriptive data are presented in Table 13.

Table 13. Descriptive data for the variable „FLEX_rel"at wire removal (_1) and at the follow-up assessment 3 months later (_3a) broken down by group (Values are expressed as percentage of values for the uninjured hand, SD... standard deviation)

dep. Variable	Group	Min	Max	Mean	SD	Median	n
FLEX_rel_1	total	13	118	69,0	23,3	69,0	56
	Control Group	13	89	58,4	21,2	63,0	32
	Study Group	50	118	83,1	18,2	82,0	24
FLEX_rel_3a	total	29	158	92,9	28,8	94,5	56
	Control Group	29	101	78,0	23,0	87,0	32
	Study Group	75	158	112,8	23,5	113,0	24

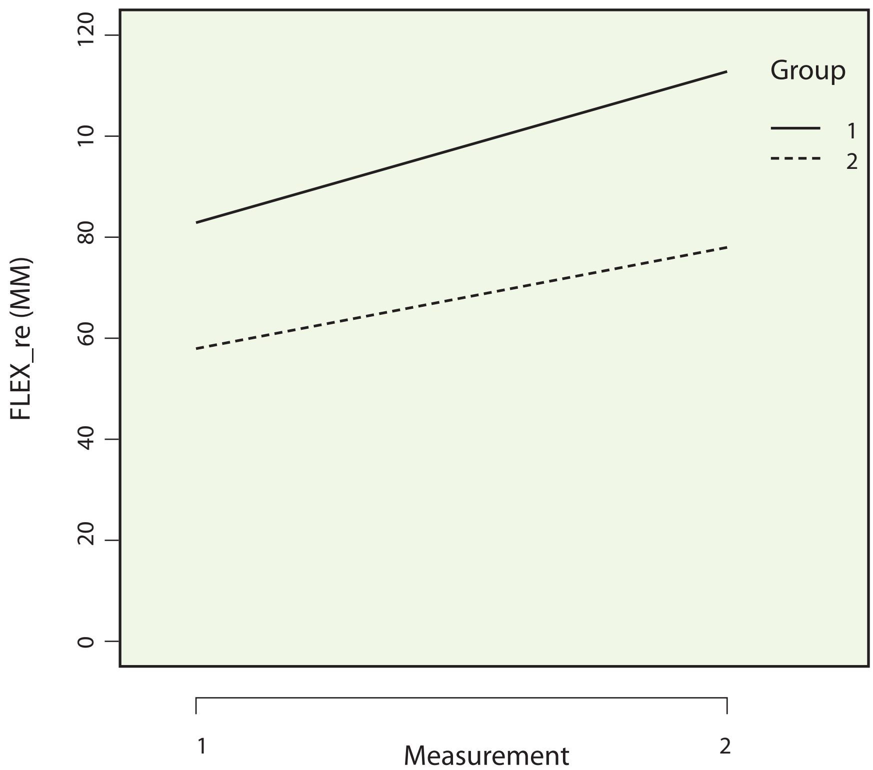


Fig. 30. Mean values of the flexion range of motion broken down by group and expressed as percentage of the values of the uninjured hand at wire removal (1) and at the follow-up assessment 3 months later (2). (Group 1: evaluation group, Group 2: control group, values are expressed as percentage of values for the uninjured hand).

The evaluation group achieved a more distinct improvement of the flexion range of motion than the control group. Means increase from 83.1±18.2 to 112.8±23.5% (median: from 82.0 to 113.0), whereas in the control group an improvement from 85.4±21.2 to 78.0±23.0% (median: from 63.0 to 87.0) could be observed.

The mean difference in the control group is D=19.7±17.0% (absolute) and differs significantly from the according value D= 29.7±15.4 in the evaluation group (Wilcoxon rank sum test: W=225.5, p= 0.009). Under consideration of the different baseline values in the study- and control group, ANCOVA results in p=0.026, indicating a significant effect of the FDM technique, too.

Mean values (± 95% confidence intervals) and the distribution of the FLEX_rel_D-values can be observed in Fig. 31.

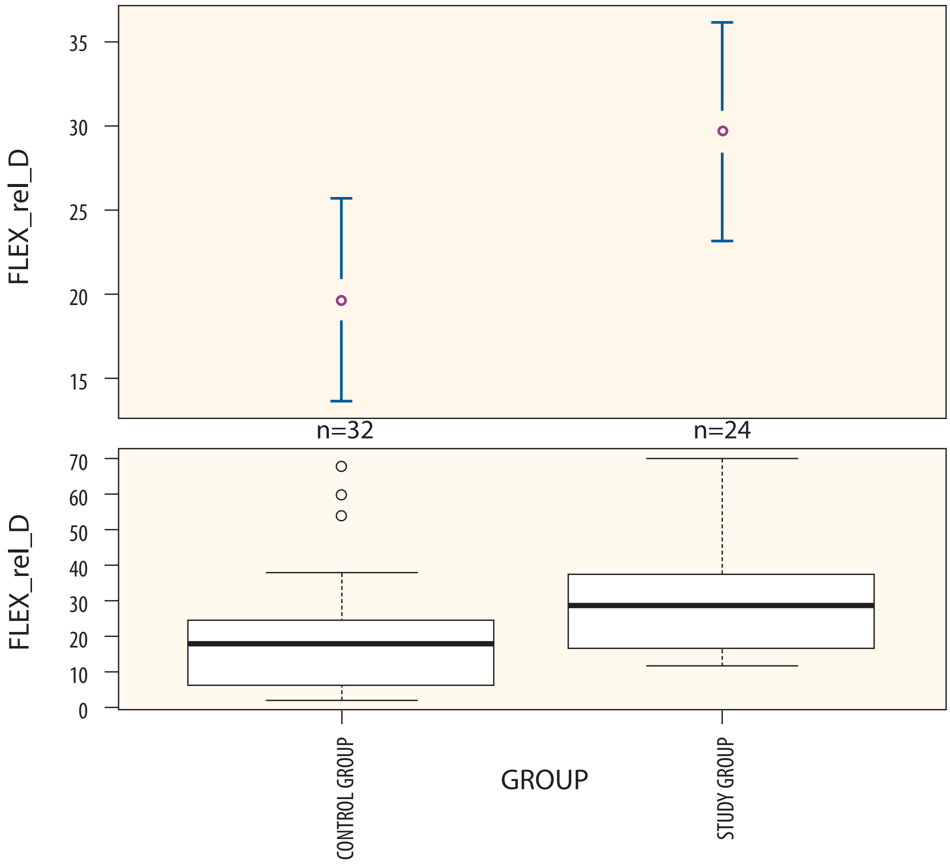


Fig. 31. Mean values ± 95% confidence intervals and box-and-whisker-plot for the variable "FLEX_rel_D" (difference FLEX_rel_3-FLEX_rel_1) broken down by group.

3.3.2. Extension Range of Motion

Changes within the study group

According to the results of the Friedman test, there is at least one significant difference in the value distributions of the six measurements of the flexion range of motion within the study group ($p<0.001$).

Mean values and 95% confidence intervals of the extension range of motion in the six measurements of the three therapeutic sessions are presented in Fig. 32, mean differences and results of the Wilcoxon signed rank tests with the data of each pair of consecutive measurements are summarised in Table 14.

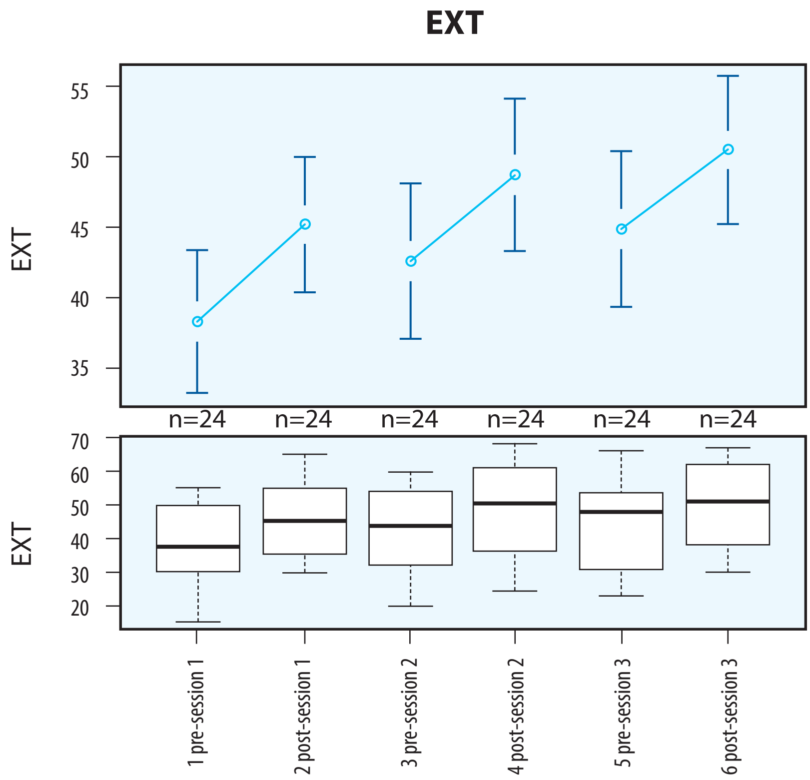


Fig. 32. Mean values and 95% confidence intervals of the extension range of motion in the six measurements of the three therapeutic sessions [°].

Table 14. Mean differences±standard deviation (SD) of the extension range of motion [°] measured before and after each of the three FDM sessions and results of the Wilcoxon signed rank tests of the data of consecutive measurements.

EXT	n	Mean Diff	SD (Diff)	Wilcoxon signed rank test
1post - 1pre	24	6.9	6.2	V = 0, p-value = **0.00029**
1pre - 2 post	24	-2.6	8.3	V = 190.5, p-value = 0.11
2post - 2pre	24	6.1	3.9	V = 1.5, p-value <**0.0001**
2pre - 3post	24	-3.8	5.3	V = 219.5, p-value = **0.0026**
3post - 3pre	24	5.6	4.5	V = 1.5, p-value <**0.0001**

Again, the application of FDM technique has a significant effect on the range of motion. Extension range of motion increases significantly between the pre- and post-FDM measurements, whereas a decrease of the extension between the single sessions can be observed.

Comparison of the study- and control group outcomes

The means of the variable „EXT_rel“ (Extension range of motion as percentage of values for the uninjured hand) broken down by group and measurement are shown in Fig. 33, differences between the two measurements (mean ±95% confidence intervals and box-and-whisker-plot) in Fig. 34. The descriptive data are presented in Table 15.

dep. Variable	Group	Min	Max	Mean	SD	Median	n
EXT_rel_1	total	25	120	60,1	22,4	58,5	56
	Control Group	37	120	61,1	23,8	60,0	32
	Study Group	25	111	58,9	20,8	57,0	24
EXT_rel_3a	total	47,0	125,0	73,72	18,17	68,00	56
	Control Group	58,0	125,0	71,12	18,78	62,00	32
	Study Group	47,0	116,0	77,19	17,09	80,50	24

Table 15. Descriptive data for the variable „EXT_rel" at wire removal (_1) and at the follow-up assessment 3 months later (_3a) broken down by group (Values are expressed as percentage of values for the uninjured hand, SD... standard deviation).

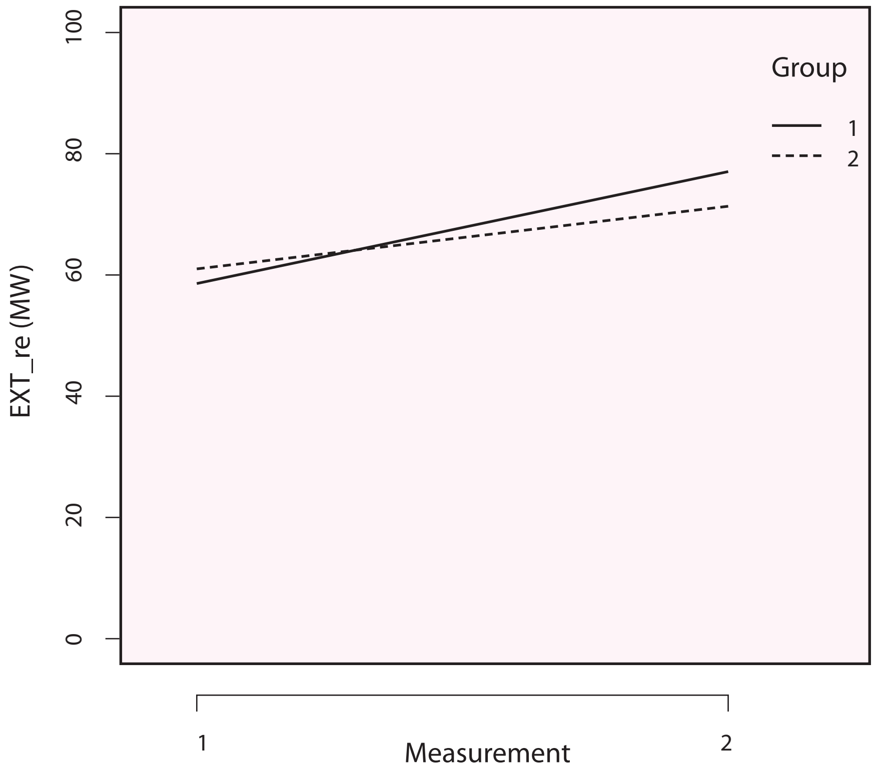


Fig. 33. Mean values of the extension range of motion broken down by group and expressed as percentage of the values of the uninjured hand at wire removal (1) and at the follow-up assessment 3 months later (2). (Group 1: evaluation group, Group 2: control group, (Values are expressed as percentage of values for the uninjured hand).

The mean value of the extension range of motion of the study group patients increases from 58.9±20.8 to 77.2±17.1% (median: from 57.0 to 80.5), whereas a distinctly lower improvement can be observed in the control group (means ± standard deviation: 61.1±23.8 to 71.1±18.8% (median: from 60.0 to 62.0).

The mean difference in the control group is D=10.1±8.0% (absolute) and differs significantly from the according value D= 18.3±10.3 in the evaluation group (Wilcoxon rank sum test: 193.5, p= 0.002).

Mean values (± 95% confidence intervals) and the distribution of the EXT_rel_D-values can be observed in Fig. 34.

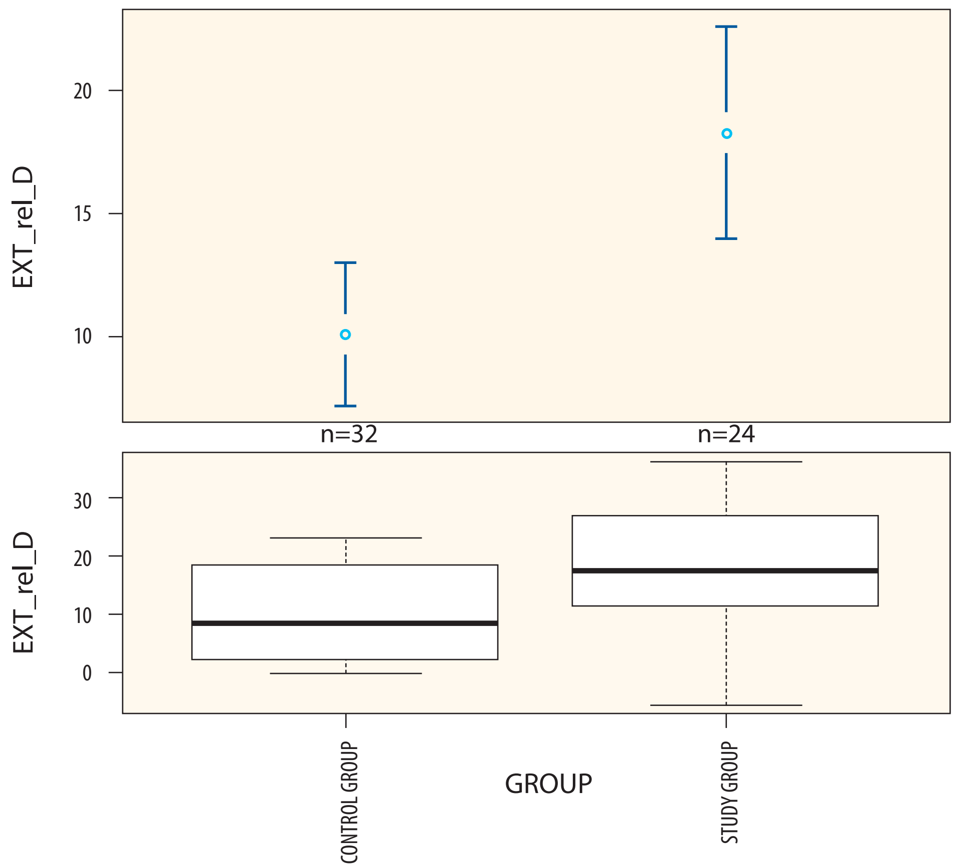


Fig. 34. Mean values ± 95% confidence intervals and box-and-whisker-plot for the variable "EXT_rel_D" (difference EXT_rel_3-EXT_rel_1) broken down by group.

3.3.3. Abduction Range of Motion

Changes within the study group

According to the results of the Friedman test, there is at least one significant difference in the value distributions of the six measurements of the abduction range of motion within the study group ($p<0.001$).

Mean values and 95% confidence intervals of the abduction range of motion in the six measurements of the three therapeutic sessions are presented in Fig. 35, mean differences and results of the Wilcoxon signed rank tests of the results of each pair of consecutive measurements are summarised in Table 16.

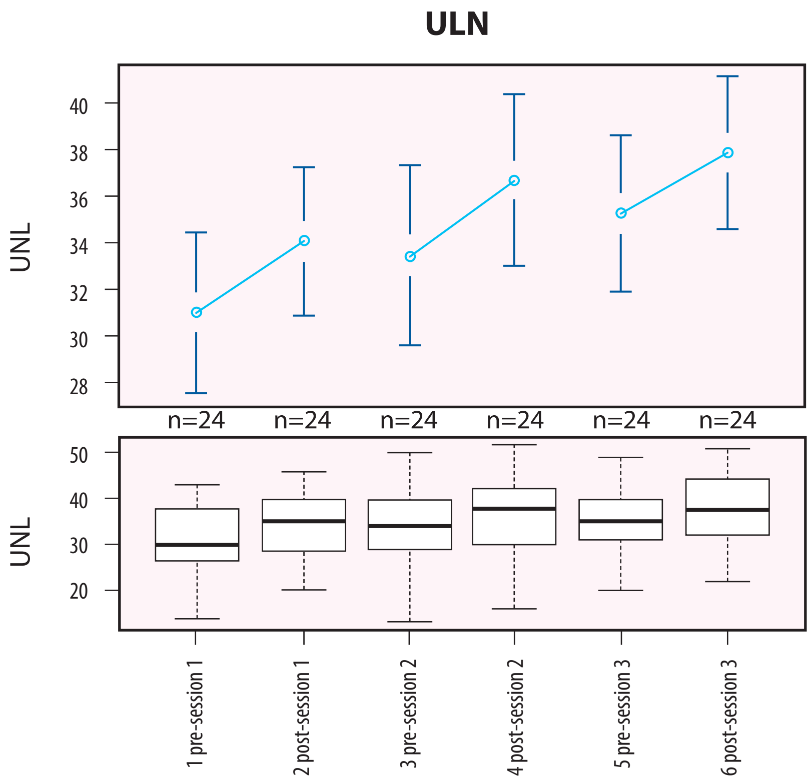


Fig. 35. Mean values and 95% confidence intervals of the abduction range of motion in the six measurements of the three therapeutic sessions [°].

Table 16. Mean differences± standard deviation (SD) of the abduction range of motion [°] measured before and after each of the three FDM sessions and results of the Wilcoxon signed rank tests of the data of consecutive measurements.

ULN	n	Mean Diff	SD (Diff)	Wilcoxon signed rank test
1post - 1pre	24	3.1	5.1	V = 18, p-value = **0.0049**
1pre - 2 post	24	-0.63	4.42	V = 144.5, p-value = 0.57
2post - 2pre	24	3.3	3.138125	V = 15.5, p-value = **0.00020**
2pre - 3post	24	-1.5	4.4	V = 171.5, p-value = 0.15
3post - 3pre	24	2.6	3.4	V = 18, p-value = **0.0020**

These results show, that the application of FDM technique has a significant effect on the abduction range of motion, too. Abduction range of motion increases significantly between the pre- and post-FDM measurements only, whereas the abduction range decreases between the single FDM sessions.

Comparison of the study- and control group outcomes

The means of the variable „ULN_rel“ (Abduction range of motion as percentage of values for the uninjured hand) broken down by group and measurement are shown in Fig. 36, differences between the two measurements (mean ±95% confidence intervals and box-and-whisker-plot) in Fig. 37. The descriptive data are presented in Table 17.

Table 17. Descriptive data for the variable „ULN_rel“ at wire removal (_1) and at the follow-up assessment 3 months later (_3a) broken down by group (Values are expressed as percentage of values for the uninjured hand, SD... standard deviation).

dep. Variable	Group	Min	Mean	Max	SD	Median	n
ULN_rel_1	Total	25	62,6	115	24,0	65,5	56
	Control Group	25	59,9	115	27,6	63,0	32
	Study Group	25	66,0	100	18,3	67,0	24
ULN_rel_3a	Total	14	79,7	123	23,8	83,5	56
	Control Group	14	79,4	123	29,4	84,5	32
	Study Group	55	80,1	104	13,8	81,0	24

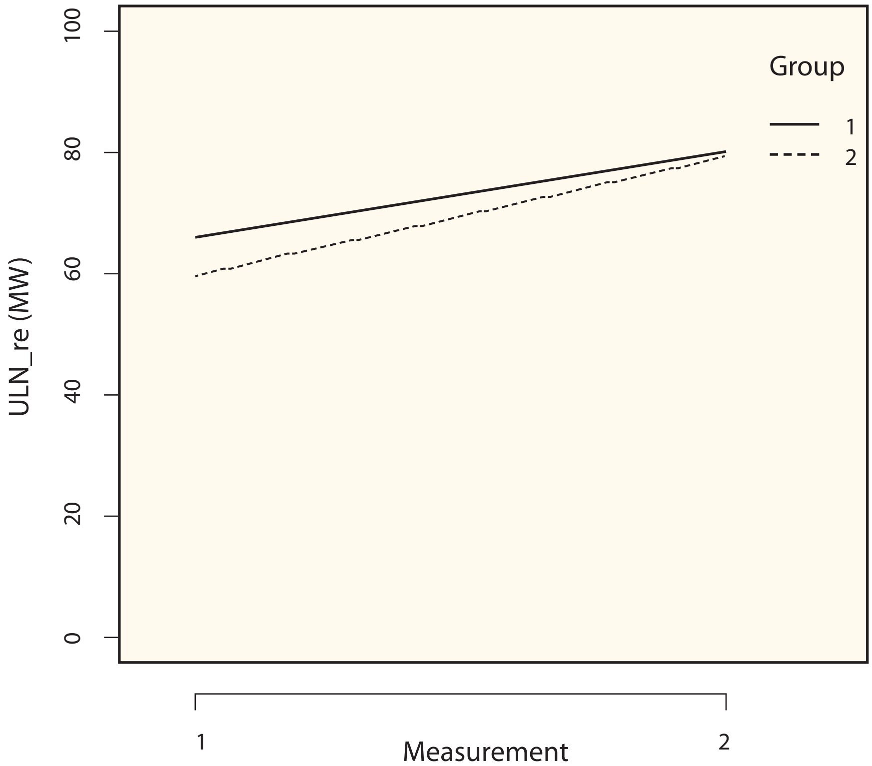


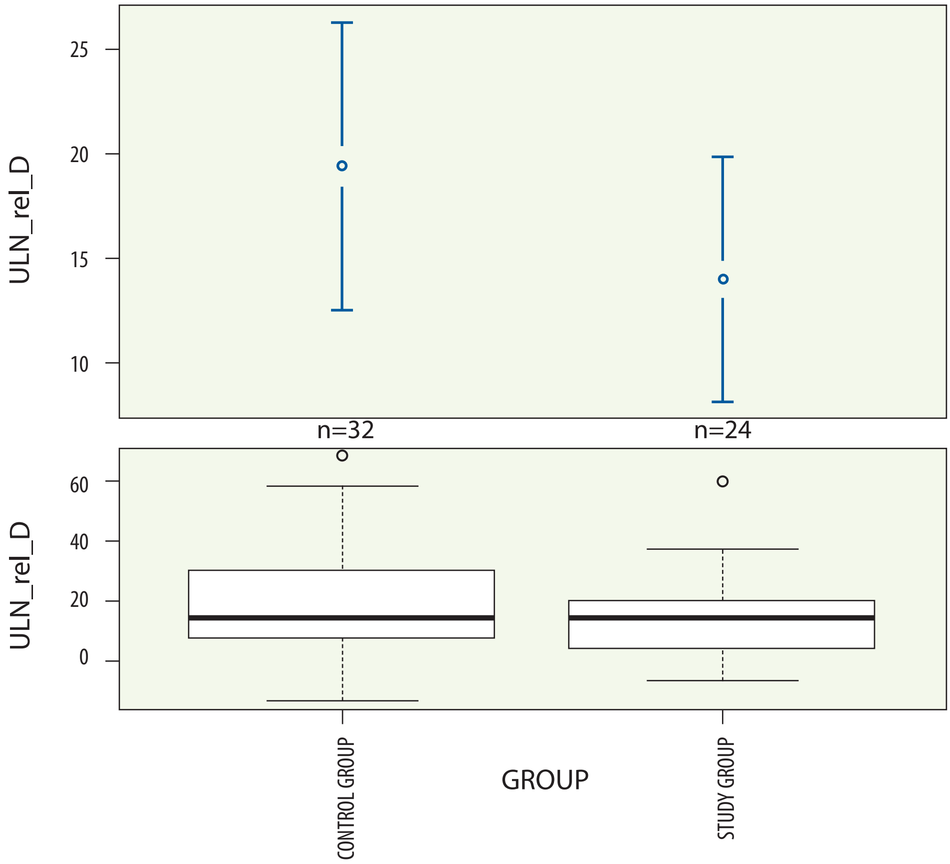
Fig. 36. Mean values of the abduction range of motion broken down by group and expressed as percentage of the values of the uninjured hand at wire removal (1) and at the follow-up assessment 3 months later (2). (Group 1: evaluation group, Group 2: control group, values are expressed as percentage of values for the uninjured hand).

In the study group, the mean abduction range of motion increases from 66.0±18.3 to 80.1±13.8% (median: from 67.0 to 81.0), whereas in the control group a distinctly higher improvement was observed (means ± standard deviation: 59.9±27.6 to 79.4±29.4% (median: from 63.0 to 84.5).

The mean difference in the control group is D=19.4±19.0% (absolute) and does not differ significantly from the according value D= 14.0±13.9 in the evaluation group (Wilcoxon rank sum test: W=443, p= 0.33).

Mean values (± 95% confidence intervals) and the distribution of the ULN_rel_D-values can be observed in Fig. 37.

Fig. 37. Mean values ± 95% confidence intervals and box-and-whisker-plot for the variable "ULN_rel_D" (difference ULN_rel_3-ULN_rel_1) broken down by group.



3.3.4. Adduction Range of Motion

Changes within the study group

According to the results of the Friedman test, there is at least one significant difference in the value distributions of the six measurements of the adduction range of motion within the study group ($p<0.001$).

Mean values and 95% confidence intervals of the adduction range of motion in the six measurements of the three therapeutic sessions are presented in Fig. 38, mean differences and results of the Wilcoxon signed rank tests of the results of pairs of consecutive measurements are summarised in Table 18.

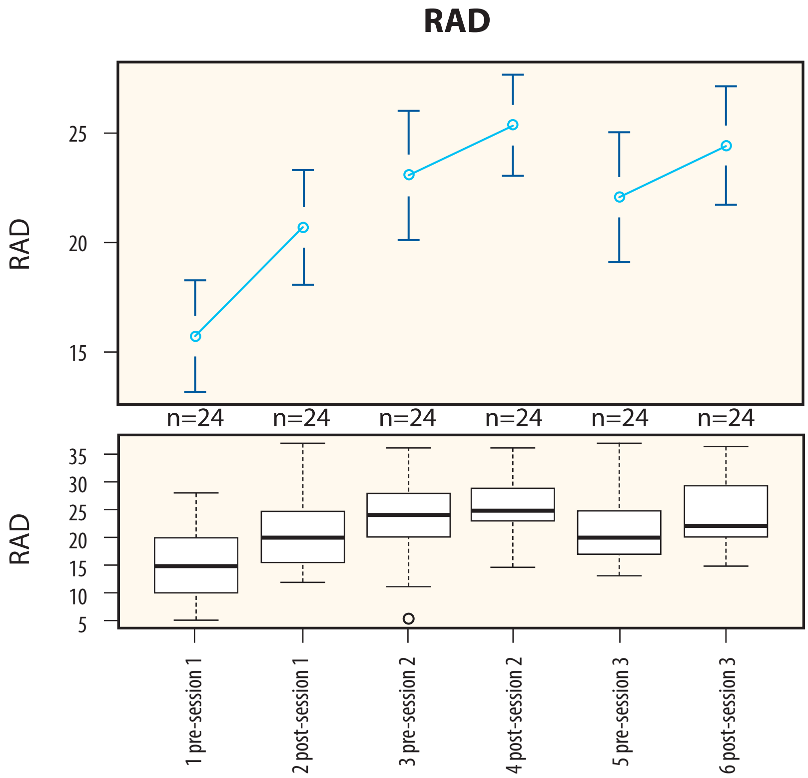


Fig. 38. Mean values and 95% confidence intervals of the adduction range of motion in the six measurements of the three therapeutic sessions [°].

Table 18. Mean differences± standard deviation (SD) of the adduction range of motion [°] measured before and after each of the three FDM sessions and results of the Wilcoxon signed rank tests of the data of consecutive measurements.

RAD	n	Mean Diff	SD (Diff)	Wilcoxon signed rank test
1post - 1pre	24	5.0	5.8	V = 0, p-value = **0.00046**
1pre - 2 post	24	2.4	7.6	V = 83, p-value = 0.16
2post - 2pre	24	2.3	4.5	V = 45.5, p-value = **0.027**
2pre - 3post	24	-3.3	4.7	V = 232, p-value = **0.0044**
3post - 3pre	24	2.3	3.1	V = 20, p-value = **0.0026**

Again, the application of FDM technique has a significant effect on the range of motion. Adduction range of motion increases significantly between the pre- and post-FDM measurements. A considerable increase in the range of motion can also be observed between session 1 and 2, whereas the range of motion is reduced at the pre-FDM measurement of session 3 compared to the post-FDM measurement of session 2.

Comparison of the study- and control group outcomes

The means of the variable „RAD_rel“ (Adduction range of motion as percentage of values for the uninjured hand) broken down by group and measurement are shown in Fig. 39, differences between the two measurements (mean ±95% confidence intervals and box-and-whisker-plot) in Fig. 40. The descriptive data are presented in Table 19.

Table 19. Descriptive data for the variable „RAD_rel“ at wire removal (_1) and at the follow-up assessment 3 months later (_3a) broken down by group (Values are expressed as percentage of values for the uninjured hand, SD... standard deviation).

dep. Variable	Group	Min	Max	Mean	SD	Median	n
RAD_rel_1	total	10	157	70,5	29,9	72,0	56
	Control Group	10	157	73,2	30,0	76,5	32
	Study Group	14	140	66,8	30,0	67,0	24
RAD_rel_3a	total	14	220	94,2	35,5	97,5	56
	Control Group	14	128	87,5	30,9	97,5	32
	Study Group	51	220	103,1	39,8	98,0	24

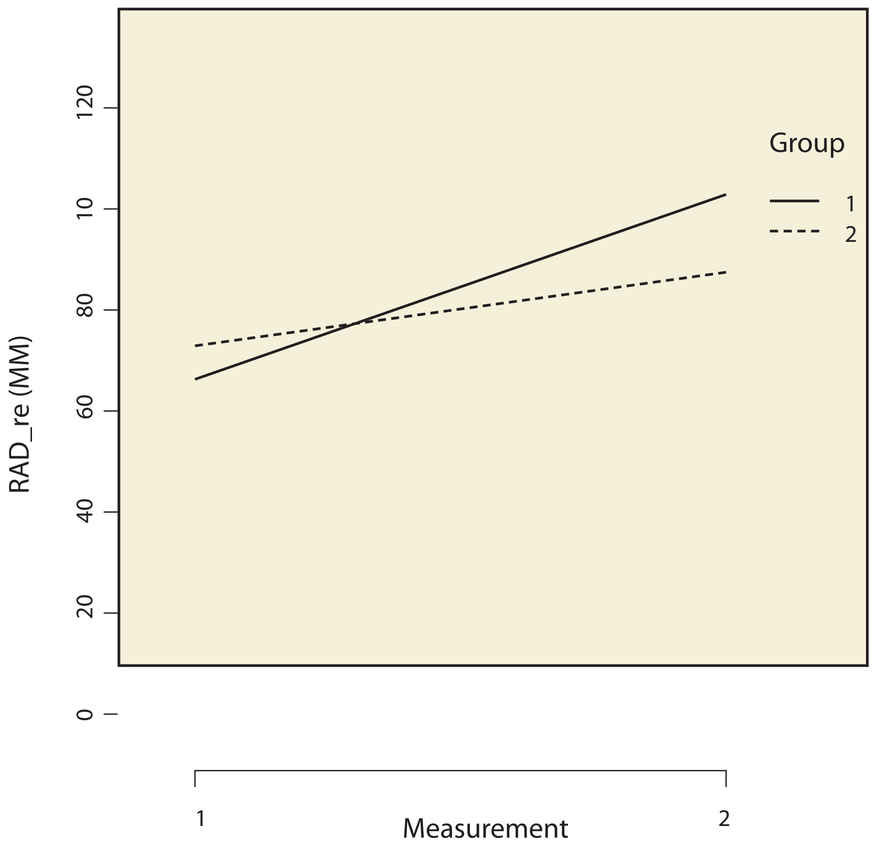


Fig. 39. Mean values of the adduction range of motion broken down by group and expressed as percentage of the values of the uninjured hand at wire removal (1) and at the follow-up assessment 3 months later (2). (Group 1: evaluation group, Group 2: control group, values are expressed as percentage of values for the uninjured hand).

The mean adduction range of motion of the evaluation group patients increases from 66.8±30.0% to 103.1±39.8% of the values for the uninjured hand (median: from 67.0 to 98.0), whereas a distinctly lower improvement was observed in the control group (means ± standard deviation: 73.2±30.0 to 87.5±30.9%, median: from 76.5 to 97.5).

In the control group, the mean difference is D=14.2±14.8% (absolute) which differs significantly from the according value D= 36.2±34.9 in the evaluation group (Wilcoxon rank sum test: W= 202,5, p= 0,003).

Mean values (± 95% confidence intervals) and the distribution of the "RAD_rel_D"-values can be observed in Fig. 40.

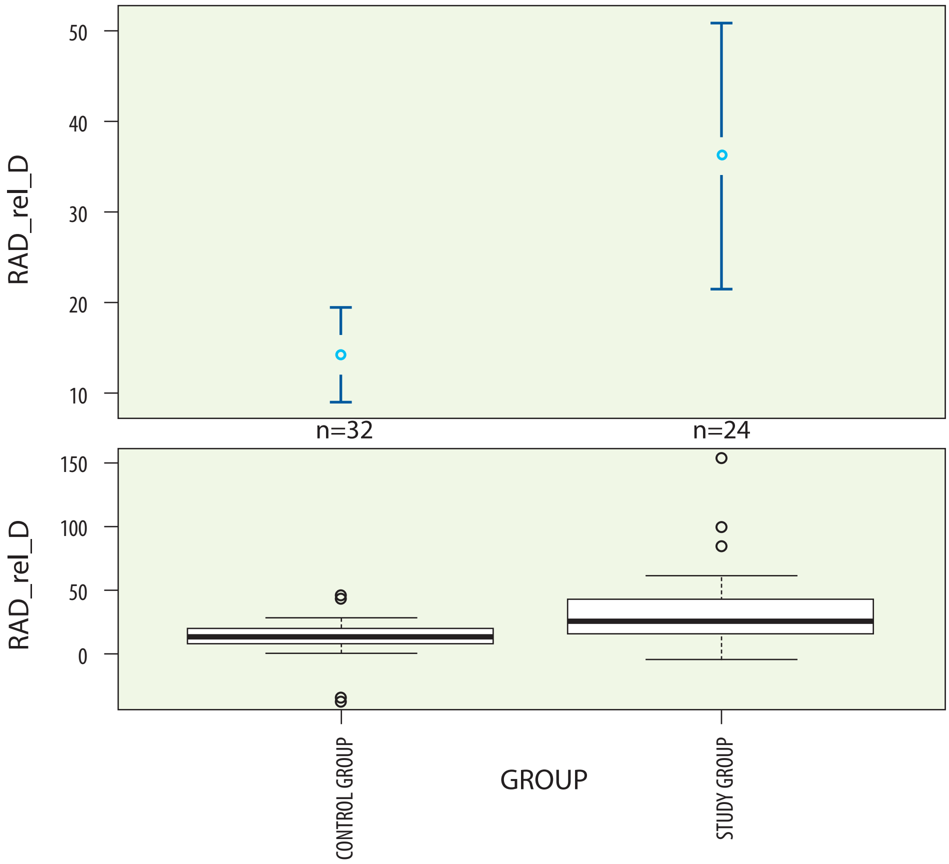


Fig. 40. Mean values ± 95% confidence intervals and box-and-whisker-plot for the variable "RAD_rel_D" (difference RAD_rel_3-RAD_rel_1) broken down by group.

3.3.5. Grip Strength

Changes within the study group

According to the results of the Friedman test, there is at least one significant difference in the value distributions of the six measurements of the grip strength within the study group ($p<0.001$).

Mean values and 95% confidence intervals of the grip strength in the six measurements of the three therapeutic sessions are presented in Fig. 41, mean differences and results of the Wilcoxon signed rank tests of each pair of consecutive measurements are summarised in Table 20.

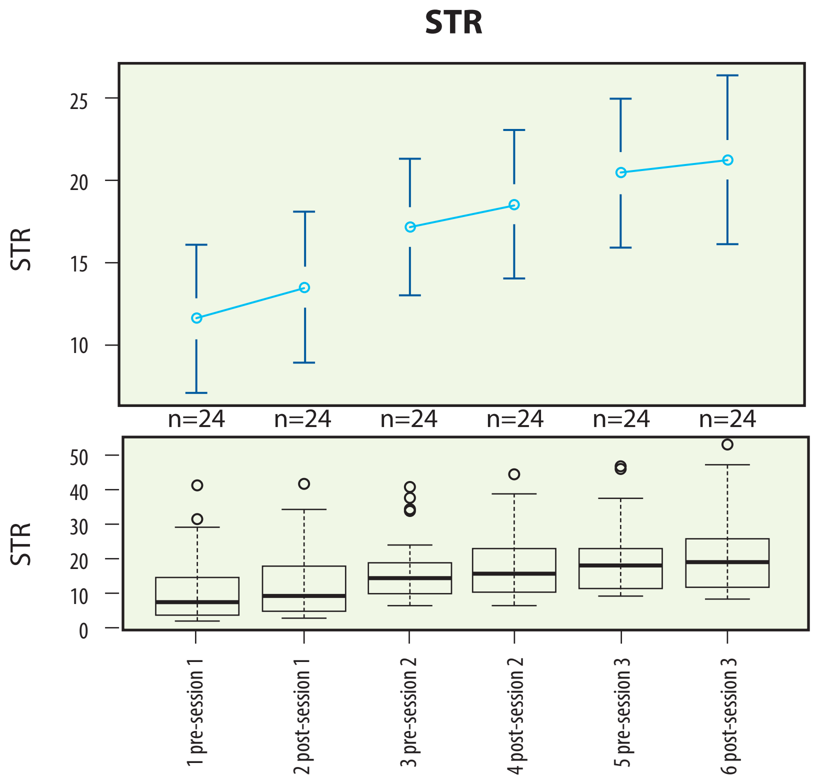


Fig. 41. Mean values and 95% confidence intervals of the grip strength in the six measurements of the three therapeutic sessions [kg].

Table 20. Mean differences± standard deviation (SD) of grip strength [kg] measured before and after each of the three FDM sessions and results of the Wilcoxon signed rank tests of the data of consecutive measurements.

STR	n	Mean Diff	SD (Diff)	Wilcoxon signed rank test
1post - 1pre	24	1.9	2.3	V = 25.5, p-value = **0.00040**
1pre - 2 post	24	3.7	4.1	V = 29, p-value = **0.00058**
2post - 2pre	24	1.4	2.6	V = 61, p-value = **0.020**
2pre - 3post	24	1.9	2.3	V = 29.5, p-value = **0.0010**
3post - 3pre	24	0.79	1.87	V = 61.5, p-value = 0.063

The main increase in grip strength happens between the single FDM-sessions. However, a significant immediate positive effect of the first and second treatment can be observed, too. The improvement by the third session is less distinct (p=0.06).

Comparison of the study- and control group outcomes

The means of the variable „STR_rel“ (Grip strength as percentage of values for the uninjured hand) broken down by group and measurement are shown in Fig. 42, differences between the two measurements (mean ±95% confidence intervals and box-and-whisker-plot) in Fig. 43. The descriptive data are presented in Table 21.

Table 21. Descriptive data for the variable „STR_rel“ at wire removal (_1) and at the follow-up assessment 3 months later (_3a) broken down by group (values are expressed as percentage of values for the uninjured hand, SD... standard deviation).

dep. Variable	Group	Min	Mean	Max	SD	Median	n
STR_rel_1	total	0	31,8	89	20,2	28,0	56
	Control Group	0	28,1	89	19,0	23,0	32
	Study Group	10	36,9	77	21,1	31,5	24
STR_rel_3a	total	15	64,8	149	26,9	60,5	56
	Control Group	15	57,1	122	25,2	51,5	32
	Study Group	30	75,1	149	26,1	78,0	24

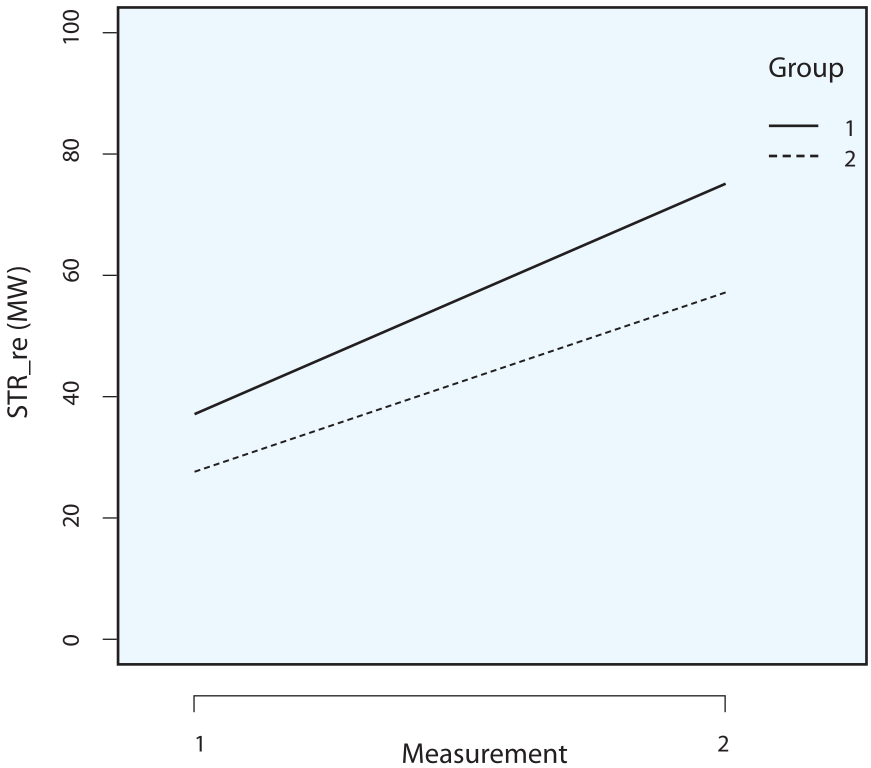


Fig. 42. Mean values of the grip strength broken down by group and expressed as percentage of the values of the uninjured hand at wire removal (1) and at the follow-up assessment 3 months later (2). (Group 1: evaluation group, Group 2: control group, values are expressed as percentage of values for the uninjured hand).

The evaluation group achieved a more distinct improvement in the grip strength than the control group. The mean grip strength of the evaluation group patients increases from 36.9±21.1 to 75.1±26.1% (median: from 31.5 to 78.0), whereas a distinctly lower improvement was observed in the control group (means ± standard deviation: 28.1±19.0% to 57.1±25.2 (median: from 23.0 to 51.5).

The mean difference in the control group is D=29.1±13.8% (absolute) and does not differ significantly from the according value D= 38.2±25.9 in the evaluation group (Wilcoxon rank sum test: W= 330, p= 0.38).

Mean values (± 95% confidence intervals) and the distribution of the STR_rel_D-values can be observed in Fig. 43.

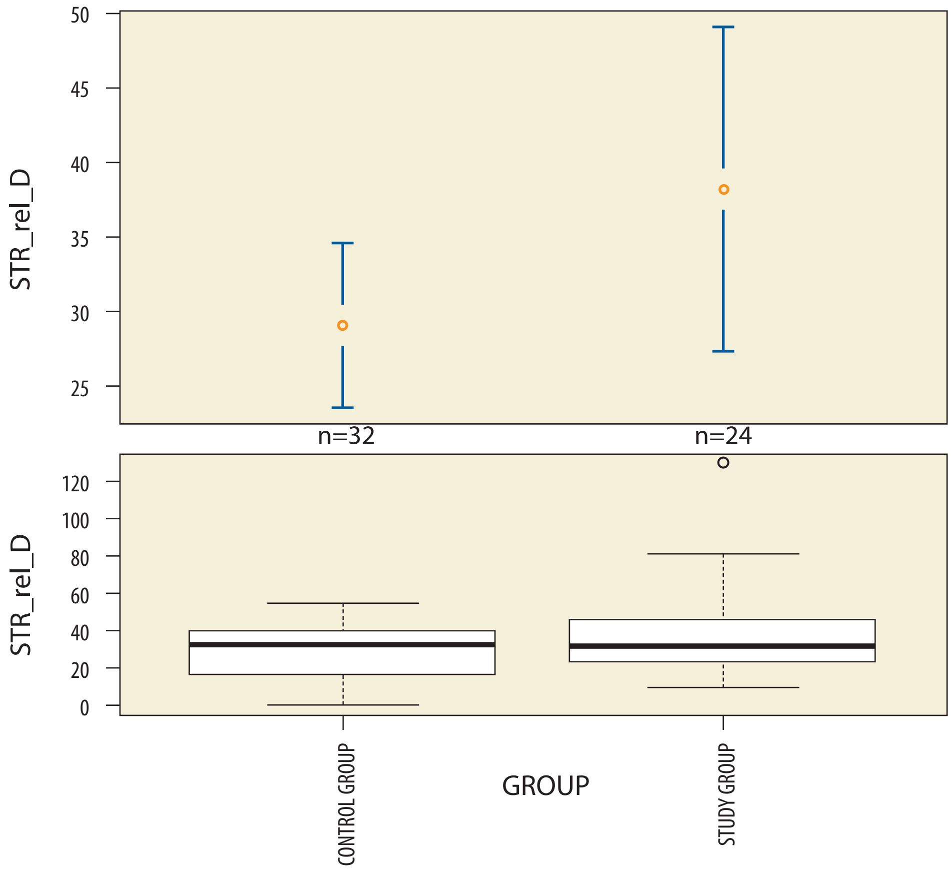


Fig. 43. Mean values ± 95% confidence intervals and box-and-whisker-plot for the variable "STR_rel_D" (difference STR_rel_3-STR_rel_1) broken down by group.

3.3.6. Level of disability in everyday life (DASH100 score)

Changes within the study group

The DASH100 score was assessed only twice (in advance of the first and the last treatment). The Wilcoxon signed rank test of the study group data results in V = 199, p= 0.00010, showing a significant difference between the two measurements. Further descriptive details are presented below.

Comparison of the study- and control group outcomes

The means of the variable „DASH100" broken down by group and measurement are shown in Fig. 44, differences between the two measurements (mean ±95% confidence intervals and box-and-whisker-plot) in Fig. 45. The descriptive data are presented in Table 22.

Table 22. Descriptive data for the variable „DASH100" at wire removal (_1) and at the follow-up assessment 3 months later (_3a) broken down by group (SD... standard deviation).

dep. Variable	Group	Min	Max	Mean	SD	Median	N
DASH100_1	total	6,7	85,0	46,30	20,06	46,25	54
	Control Group	6,7	85,0	50,92	21,14	51,25	32
	Study Group	14,2	81,7	39,59	16,63	35,85	22
DASH100_3a	total	0,0	55,8	21,58	13,63	19,10	54
	Control Group	0,0	55,8	24,32	14,39	22,90	32
	Study Group	0,8	44,6	17,60	11,37	15,85	22

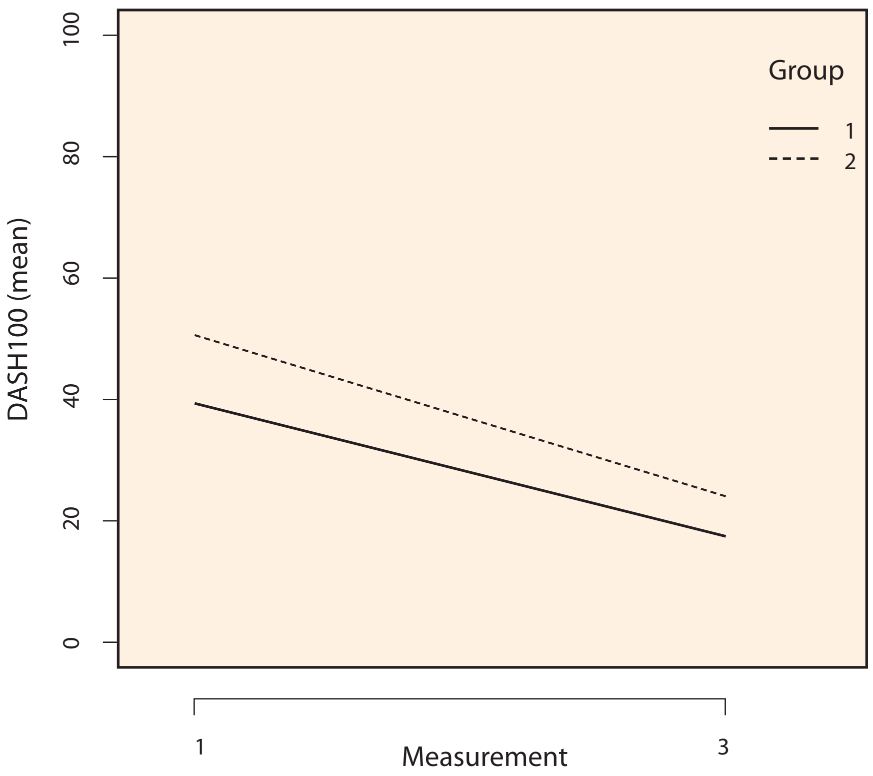


Fig. 44. Mean values of the DASH100 scores broken down by group at wire removal (1) and at the follow-up assessment 3 months later (3) (Group 1: evaluation group, Group 2: control group).

The mean DASH100 score of the study group patients decreases from 39.6±16.6 to 17.6±11.4 (median: from 35.9 to 15.9), whereas an improvement from 50.9±21.1% to 24.3±14.4 (median: from 51.3 to 22.9) was observed in the control group.

The mean difference within the control group D=-26.6±15.1% (absolute) does not differ significantly from the according value D= -22.6±19.9% in the evaluation group (Wilcoxon rank sum test: W= 346.5, p= 0.62).

Under consideration of the covariate "DASH100_1", REML analysis of the dependent variable "DASH100" results in a p-value of p=0.31, indicating either, that differences between the two groups are not signficant.

Mean values (± 95% confidence intervals) and the distribution of the DASH_D-values can be observed in Fig. 45.

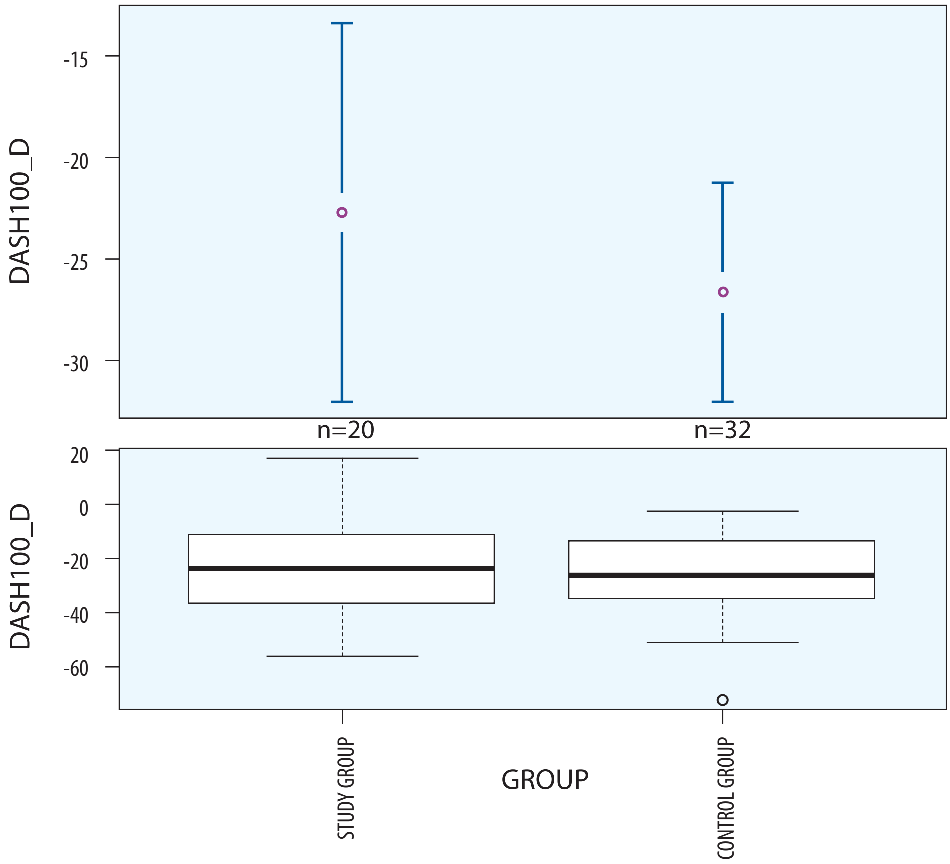


Fig. 45. Mean values ± 95% confidence intervals and box-and-whisker-plot for the variable "DASH_D" (difference DASH100_3-DASH100_1) broken down by group.

3.3.7. Level of Pain

Changes within the study group

According to the results of the Friedman test, there is at least one significant difference in the value distributions of the three measurements of the level of pain within the study group ($p<0.001$).

Mean values and 95% confidence intervals of the level of pain assessed in advance of the three therapeutic sessions are presented in Fig. 46, mean differences and results of the Wilcoxon signed rank tests of the data of each pair of consecutive measurements are summarised in Table 23.

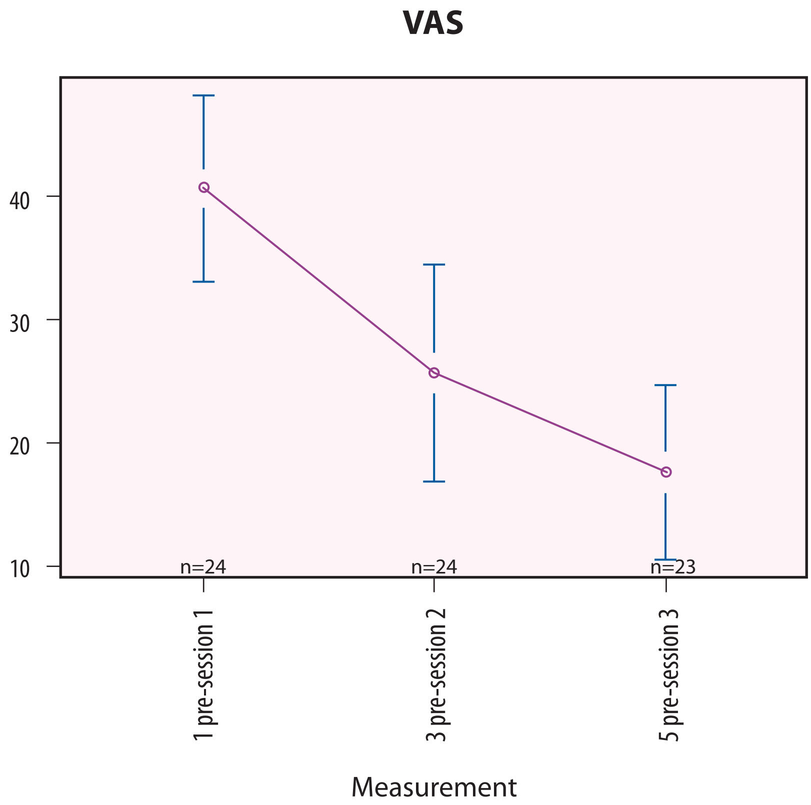


Fig. 46. Mean values and 95% confidence intervals of the level of pain assessed in advance of the three therapeutic sessions.

Table 23. Mean differences± standard deviation (SD) of the level of pain assessed before the three FDM sessions and results of the Wilcoxon signed rank tests of the data of consecutive measurements.

VAS	n	Mean Diff	SD (Diff)	Wilcoxon signed rank test
session 2 – session 1	24	-15.0	22.7	V = 247.5, p-value = **0.0056**
session 3 – session 2	23	-9.3	24,7	V = 165, p-value = 0.088

A significant reduction of the level of pain can be observed in advance of the second session. The difference in the VAS scores between the second and third session are less distinct (p=0.09).

Comparison of the study- and control group outcomes

The level of pain was assessed in the study group, only. Therefore, no comparative data of the control group are available.

4. Discussion

Distal radial fractures constitute approximately 14% of all fractures. In younger people, these fractures result from high-energy injuries, such as sports injuries, falls from a height and direct mechanism injuries, such as a blow with a hard object. In the older population, over 60 years of age, the main cause of this typical forearm fracture is a low-energy injury, such as a fall from the standing height [20, 26, 41, 57, 61, 62]. Fractures of the distal radius occur more frequently in women than men. This relationship is most pronounced in the older population, where these fractures are more common than in younger people. The incidence of fractures is also greater in the left upper limb than in the right [28, 42, 49]. A similar relationship was found in individuals qualified to participate in this study. Women constituted as much as 80% of the study group (88% of the evaluation group and 71% of the control group). The left limb was fractured in 58% patients from the evaluation group and in 69% of controls (overall, in 64% of all study participants).

Therefore, the sample can be considered as being representative for the population.

The two groups do not differ significantly in these aspects, either. However, randomisation brought along a significant group-difference in the baseline data of the flexion range of motion and of the DASH100 scores, whereas groups do not differ in the other variables. It has to be considered, that in both variables, the initial control group status is worse than the study group status.

Patients with a lower impairment of the injured hand (in the sense of a higher range of motion and/or a lower level of disability in everyday life, but also generally), might use this hand more extensively leading to an acceleration of the healing- and training process. However, according to this theory, also other variables might be affected by a different status in the level of disability.

The present study showed the existence of correlations between the DASH score and the level of pain assessed with the VAS scale ($p=0.00036$) as well as the grip strength ($p<0.0001$). Lower level of pain allows the patient to perform many everyday activities more easily. In addition, improved grip strength means that objects can be without a doubt handled with the use of the injured hand. The study showed a less distinct, but also significant relationship between the DASH 100 score and the wrist range of motion ($p<0.05$). Lucado et al. showed such correlations in studies evaluating the efficacy of dynamic railing in distal radial fracture patients [47], whereas Board et al. indicated a relationship between the functional assessment values and the surgically accomplished positioning of the radius: radial inclination, palmar tilt, and radial height in relation to the ulna [4]. Studies by Moore et al. including nearly 100 distal radial fracture patients indicate a significant relationship between the level of disability based on the DASH scale on one hand and the age of the patients as well as their fracture-related use of medications (usually analgesics) on the other [51]. The study presented here does not demonstrate any correlation between the DASH score and the patient age ($p=0.29$). However, this might be a result of a too small sample size and considerable diversity of ages within the study population. Another fact that is very likely to play a role here is that the studies by Moore et al. were conducted on the average 17 months after the injury and were retrospective in nature [51].

Due to the significant correlation of the DASH100 scores and the range of motion and especially grip strength, and the significant differences in the initial DASH100 scores, this was being considered in the statistical analysis of the effect of the FDM technique by adding the baseline data of the DASH100 scores as covariate. The ANCOVA results indicate an effect of the FDM technique on the flexion- ($p=0.013$), extension- ($p=0.0023$), and adduction range of motion ($p=0.0013$). Additionally, there is a tendency towards an effect of FDM on grip strength ($p=0.081$). The abduction range of motion and the DASH100 scores were not affected anyway ($p=0.39$ and $p=0.31$, respectively).

The mean grip strength in the evaluation group increases from 36.9±21.1 to 75.1±26.1% of that in the healthy hand (median: from 31.5 to 78.0%), whereas in the control group a distinctly lower improvement was observed (means ± standard deviation: 28.1±19.0% to 57.1±25.2, median: from 23.0 to 51.5). However, the mean difference in the control group of D=29.1±13.8% (absolute) does not differ significantly from the value D= 38.2±25.9 achieved in the evaluation group (Wilcoxon rank sum test: W= 330, p= 0.38).

A mean level of strength at 75% of that in the healthy hand, as reached in the study group, is considered normal and this difference may be a result of differences between the dominant and the non-dominant limb, which can be considerable in the case of grip strength. It is worth noting that in some patients the grip strength in the injured hand was substantially greater (by nearly 50%) than that in the healthy hand. This suggests a high efficacy of FDM treatment. This greater strength may also be a result of pre-existing limitations in the healthy limb that might be reduced with the FDM technique (due to probably the same origin of limitations in both limbs).

Three months after wire removal, the mean grip strength of the control group patients was at a level of only 57% of that in the healthy hand. However, studies by Krischak et al. confirm this result, as the authors reported a similar level of improvement in the group of patients exercising on their own at home [37]. The increase in strength in both, the evaluation and control group is doubtlessly a result of spontaneous healing following immobilization removal. This process is induced by everyday activities, where the patient, despite the limitations, uses his/her injured limb to perform tasks at home and at work or to exercise recreational activities. This is consistent with study results of various authors who have demonstrated that, irrespective of the type of treatment used following the removal of immobilization (giving instructions to exercise at home or providing active physiotherapy versus exercising under the supervision of a therapist or exercising alone), the return of grip strength occurs at a similar rate [30, 37, 48]. This rate may be slower in the elderly [31]. In spite of significant improvements by the single FDM sessions, observable in the results of grip strength assessment before and after application of this technique, the main increase takes place in the period between the FDM sessions.

Thus, the use of FDM technique, which seems to accelerate this process, may be an effective way of achieving a quicker restoration of strength. However, further research would be necessary in order to confirm this effect.

While grip strength predominantly can be affected only in an indirect way by the applied FDM technique, there is a direct effect of the FDM technique on the range of motion.

Significant immediate effects of the FDM technique are observable on all four variables (flexion, extension, abduction and adduction). The results of the pre- and post-FDM measurements in each session differ significantly (Wilcoxon signed rank tests: $p<0.05$).

However, this improvement of extension and abduction range of motion is not sustainable and pre-FDM values of the subsequent session are worse than post-FDM values of the actual one.

A higher sustainability of the improvement could be observed in flexion- and adduction range of motion. The range of motion improves further after the first session, however, pre-FDM measurements of the third session show, that the effect of the second session gets almost (flexion) of totally (adduction) lost.

Compared to the control group, FDM has a significant effect on flexion-, extension-, and adduction- range of motion. In contrary, the improvement in abduction range of motion is lower than in the control group.

The mean flexion range of motion increases from 83.1±18.2 to 112.8±23.5% of the values of the healthy limb (median: from 82.0 to 113.0) and the mean differences between the values at wire removal and three months later differ significantly between the study and the control group (30% abs. vs. 20%abs., Wilcoxon rank sum test: W=225.5, p= 0.009). Under consideration of the different baseline values in the study- and control group, ANCOVA results in p=0.026, indicating a significant effect of the FDM technique, too.

The mean extension range of motion increases from 58.9±20.8 to 77.2±17.1% of the values of the healthy limb (median: from 57.0 to 80.5) after the application of the FDM technique. The mean differences between the values at wire removal and three months later differ significantly between the study and the control group (18% abs. vs. 10%abs., Wilcoxon rank sum test: W=193.5, p= 0.002).

The mean of the adduction range of motion increases from 66.8±30.0% to 103.1±39.8% of the values of the healthy limb (median: from 67.0 to 98.0%). The mean differences between the values at wire removal and three months later differ significantly between the study and the control group (36% abs. vs. 14%abs., Wilcoxon rank sum test: W=193.5, p= 0.002).

Only the abduction range of motion is not positively affected by FDM. While the mean of the study group increases from 66.0±18.3 to 80.1±13.8% (median: 67.0 to 81.0) of the values of the healthy hand, patients of the control group improve better from 59.9±27.6 to 79.4±29.4% (median: from 63.0 to 84.5).

The mean differences between the values at wire removal and three months later do not differ significantly between the study and the control group (14% abs. vs. 19%abs., Wilcoxon rank sum test: W=443, p= 0.33).

Three months after wire removal, the mean range of flexion in the evaluation group was greater by approximately 13% and the mean range of adduction by approx. 3% than the respective ranges of motion in the opposite healthy wrist. After the 3-month period following immobilization removal, there was also an improvement in the range of motion in the control group, however, this improvement was not as distinct as that in the group receiving FDM treatment. This improvement was probably a result of the process described above, where spontaneous heeling and rehabilitation occur through exercising and performing everyday activities.

The significantly greater range-of-motion improvement in the evaluation group (except in abduction) may be a result of the specificity of Fascial Distortion Model technique, where range-of-motion limitations caused by fascial distortion are taken into account. Knowing the fascial structure and physiology, one is entitled to state that injuries presented in section 1 are very likely, with almost 100% certainty, to occur in patients with a distal radius fracture and limit the range of motion in these patients. Thus, treatment with the use of FDM techniques may, through correction of the normal fascial structure, effectively accelerate the return of the full range of motion.

Similarly to the objective measurements, the subjective functional assessment in the study group revealed a significant improvement after the 3-month period between the assessments. However, the improvement in the study group patients is not significantly different to the improvement gained in the control group, where an even higher reduction of the DASH100 scores could be observed. The mean DASH100 score in the study group decreases from 39.6±16.6 to 17.6±11.4 points (median: from 35.9 to 15.9 points).

The mean differences between the values at wire removal and three months later do not differ significantly between the study and the control group (-23 vs. –27 points, Wilcoxon rank sum test: W= 346.5, p= 0.62). Under consideration of the different baseline values in the study- and control group, ANCOVA results in a p-value of p=0.31, indicating no significant difference in the change in the DASH scores between two groups, either.

The results achieved in the control group were higher than those reported by other authors (19 points in studies by Lucado et al. and 18.3 points in studies by Abramo et al.) [1, 46]. This might be due to a relatively lower rate of restoring the hand function that was caused by a lack of regular controlled physical therapy (the control group only received instructions but compliance was not verified).

According to different authors, these results are 13–14 points (DASH 100) [45, 46, 58]. In some studies, the results differ considerably – from 7.5 points in the Abramo study to 25 points in the study by Figl at 12 months after injury [1, 17]. According to various authors, functional assessments of the wrist with the use of DASH scale may be partly unreliable, due to the potential influence of other discomforts on the obtained result [19, 49]. However, there seams to be very little influence of the patient's psychological state on the results, as shown by slight or moderate correlation of the DASH score and the various psychological scales [54]. It should be borne in mind that achieving good and very good functional assessment score is a more important goal of conducted physical therapy than increasing the range of motion or muscle strength. Reducing the level of pain seems to be equally important, as it improves the patient's quality of life and the subjective assessment of patient's health. All these factors influence one another. However, functional assessment seems to be a reliable tool for measuring the efficacy of therapeutic method.

There are few literature reports about the efficacy of osteopathic procedures after distal radius fractures, and the available ones usually relate to short-term treatment outcomes [49]. We would like to emphasize that no report on the use of osteopathy or manual therapy in radial fractures or injures has been found in the Medline/PubMed database. The more abundant literature reports on the use of osteopathic procedures in the carpal tunnel syndrome indicate short-term efficacy of these procedures [11, 23, 59]. The results presented here indicate very high efficacy of the FDM as a therapeutic technique rapidly improving the range of motion and also – with restrictions - the muscle strength in the affected joint. It is worth noting that during each therapeutic session all patients achieved a significant improvement in the measured parameters. Better hand performance means a more extensive use of the limb in everyday activities, which may lead to quicker recovery and a full return of function. This is reflected in the results presented above, achieved after 3 months following the removal of immobilization. During the present study or during the FDM therapeutic sessions, none of the patients developed complications following the surgery or the study therapy that negatively affected the final treatment outcome. Failure to complete the 3 therapeutic sessions by patients assigned to the evaluation group was caused by reasons other than a poor response to study treatment.

5. Conclusions

1. The Fascial Distortion Model (FDM) technique presented here has an impact on immediate and significant improvement in the wrist range of motion and grip strength in patients treated for a distal radial fracture.
2. In comparison with the control group, patients treated with the use of the FDM tended to achieve higher improvement in flexion, extension and adduction than patients who had not undergone these procedures. Improvement of the mobility range of the abduction did not differ as considerable. Hand function after FDM therapy did not improve significantly better than in the group of patients who had not undergone manual therapy procedures, either.
3. Our study results seem to indicate that the FDM technique might be a beneficial alternative in treatment of patients with limited range of motion and diminished muscle strength.
4. For further studies, shorter intervals between the single FDM sessions might be adviceable.
5. Extended studies involving patients with other musculoskeletal disorders are needed in order to confirm the effectiveness of the FDM therapeutic techniques.

Summary

Functional performance of the hand is a crucial factor in the ability to carry out many everyday activities. The radiocarpal joint together with the midcarpal and both radioulnar joints allow movement in all three planes – sagittal, frontal and transverse. This means a great capacity in maneuvering objects, reaching, and performing complex manual tasks, which are indispensable for effective performance in today's world [22, 29]. Distal metaphyseal fractures of the radius may severely disrupt the patient's everyday functioning. Both the conservative and surgical treatments are usually associated with an approximately 6-week-long immobilization period of the injured limb [7]. A direct result of this local hypokinesis is limited range of motion due to the formation of tissue adhesions and tissue remodeling. This condition is exacerbated by the earlier injury of those structures and any surgical intervention. Immobilization is also the main reason behind diminished muscle strength and disuse atrophy. These effects of immobilization decrease functional motor performance. The patient is virtually unable to perform a number of activities [7, 43]. For many years now there has been a search for therapeutic methods that would quickly and permanently restore patient's performance, especially in everyday functioning. Previous attempts to compile different exercise and physiotherapy programs have been unsatisfactory, as their effectiveness did not differ from the effects of exercises performed by the patients on their own. There is still little knowledge about the effects, especially long-term effects, of manual therapy on the recovery process in post-immobilization patients [30, 44, 49]. The FDM technique presented in this article is based on the knowledge of fascial structure, function, and pathophysiology. According to this, fasciae can be divided into four categories, and their possible injuries as well as treatment methods into six types. Patient evaluation based on pain history as well as observation helps make a correct treatment-oriented diagnosis [75]. Patient evaluation results presented and discussed in this dissertation indicate the effectiveness of the FDM technique, which brings an immediate improvement in the range of motion and grip strength. The results achieved between the sessions and after the mobilization period are promising – the patients undergoing FDM treatment are sooner able to return to normal everyday functioning.

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STATISTICAL DATA

		Shapiro-Wilk-Test				Bartlett -Test														
dep. Variable		W	p (SW)	normal distr.	mult. normality	K²	df	p	homogeneous	G txt ID	GID	G1	G2	G2 Wert	G3	G3 Wert	G4	G4 Wert	Ordinal	Scale
	total	0,937	0,005797	no						6	31									
Age	Control Group	0,9408	0,07902	no	no	0,3193	1	0,572	yes	7	95	Group								x
	Study Group	0,9093	0,03401	no						7	96	Group								x
	total	0,9597	0,05861	no						26	7									
FLEX_rel_1	Control Group	0,897	0,005199	no	no	0,5706	1	0,45	yes	27	47	Group								x
	Study Group	0,9736	0,7544	yes						27	48	Group								x
	total	0,9659	0,1132	cond.						28	8									
FLEX_rel_3a	Control Group	0,8432	0,0002962	no	no	0,0107	1	0,9176	yes	29	49	Group								x
	Study Group	0,9696	0,6575	yes						29	50	Group								x
	total	0,9136	0,0006829	no						30	9									
EXT_rel_1	Control Group	0,8597	0,000677	no	no	0,4722	1	0,492	yes	31	51	Group								x
	Study Group	0,9516	0,2931	yes						31	52	Group								x
	total	0,9144	0,0007324	no						32	10									
EXT_rel_3a	Control Group	0,7161	1,526e-06	no	no	0,2279	1	0,6331	yes	33	53	Group								x
	Study Group	0,9569	0,3796	yes						33	54	Group								x
	total	0,9514	0,0246	no						34	11									
ULN_rel_1	Control Group	0,9123	0,01295	no	no	4,0977	1	0,0429	no	35	55	Group								x
	Study Group	0,9712	0,6968	yes						35	56	Group								x
	total	0,9482	0,01763	no						36	12									
ULN_rel_3a	Control Group	0,9186	0,01904	no	no	12,7066	1	0,0004	no	37	57	Group								x
	Study Group	0,9756	0,8026	yes						37	58	Group								x
	total	0,9602	0,06215	no						38	13									
RAD_rel_1	Control Group	0,9186	0,01905	no	no	1e-04	1	0,9928	yes	39	59	Group								x
	Study Group	0,978	0,8558	yes						39	60	Group								x
	total	0,933	0,003943	no						40	14									
RAD_rel_3a	Control Group	0,8972	0,005253	no	no	1,6735	1	0,1958	yes	41	61	Group								x
	Study Group	0,8747	0,006513	no						41	62	Group								x
	total	0,9167	0,0008887	no						42	15									
STR_rel_1	Control Group	0,8476	0,0003678	no	no	0,2051	1	0,6506	yes	43	63	Group								x
	Study Group	0,9268	0,08275	no						43	64	Group								x
	total	0,9686	0,1523	cond.						44	16									
STR_rel_3a	Control Group	0,9506	0,1495	cond.	cond.	0,0312	1	0,8598	yes	45	65	Group								x
	Study Group	0,955	0,3458	yes						45	66	Group								x
	total	0,977	0,3814	yes						46	17									
DASH100_1	Control Group	0,9731	0,5896	yes	yes	1,3583	1	0,2438	yes	47	67	Group								x
	Study Group	0,945	0,2506	yes						47	68	Group								x
	total	0,9539	0,03676	no						48	18									
DASH100_3a	Control Group	0,9545	0,1938	cond.	no	1,6646	1	0,197	yes	49	69	Group								x
	Study Group	0,9644	0,5835	yes						49	70	Group								x
	total	0,9238	0,001681	no						56	23									
FLEX_rel_D	Control Group	0,8627	0,0007901	no	no	0,2316	1	0,6303	yes	57	79	Group								x
	Study Group	0,9128	0,04053	no						57	80	Group								x
	total	0,9632	0,08533	no						58	24									
EXT_rel_D	Control Group	0,8506	0,000427	no	no	1,3923	1	0,238	yes	59	81	Group								x
	Study Group	0,9759	0,8096	yes						59	82	Group								x
	total	0,9259	0,002026	no						60	25									
ULN_rel_D	Control Group	0,9447	0,1021	cond.	no	2,469	1	0,1161	yes	61	83	Group								x
	Study Group	0,89	0,01328	no						61	84	Group								x
	total	0,7728	6,515e-08	no						62	26									
RAD_rel_D	Control Group	0,8759	0,001594	no	no	18,5587	1	2E-05	no	63	85	Group								x
	Study Group	0,8068	0,0003808	no						63	86	Group								x
	total	0,8641	1,495e-05	no						64	27									
STR_rel_D	Control Group	0,9569	0,2257	yes	no	7,0594	1	0,0079	no	65	87	Group								x
	Study Group	0,8036	0,0003369	no						65	88	Group								x
	total	0,991	0,9627	yes						66	28									
DASH_D	Control Group	0,9506	0,1502	cond.	cond.	1,8028	1	0,1794	yes	67	89	Group								x
	Study Group	0,9732	0,8213	yes						67	90	Group								x

dep. Var	Obs. (dep.)	indep. Var	Obs (indep.)	n (valid)	% (valid)
Group	Control Group		total	32	57,14
	Study Group			24	42,85
Sex	female		total	45	80,35
	male			11	19,64
	female	Group	Control Group	28	87,5
	male			4	12,5
	female		Study Group	17	70,83
	male			7	29,16
Inj_h	left		total	36	64,28
	right			20	35,71
	left	Group	Control Group	22	68,75
	right			10	31,25
	left		Study Group	14	58,33
	right			10	41,66

dep. Variable	Group	Min	Mean	Max	SD	Median	n	c21 (KW-Te	df	p (KW-Test	normalvertei	G txt ID	id	G1	NV p
	total	22	61,5	81	13,3	63,0	56				nein	6	56647	gesamt	0,005797
Age	Control Group	30	61,0	80	12,7	63,5	32	0,127	1	0,72	nein	7	56709	Group	0,07902
	Study Group	22	62,2	81	14,2	63,0	24	0,127	1	0,72	nein	7	56710	Group	0,03401
	total	13	69,0	118	23,3	69,0	56				nein	26	56623	gesamt	0,05861
FLEX_rel_1	Control Group	13	58,4	89	21,2	63,0	32	15,897	1	<0,0001	nein	27	56663	Group	0,005199
	Study Group	50	83,1	118	18,2	82,0	24	15,897	1	<0,0001	ja	27	56664	Group	0,7544
	total	29	92,9	158	28,8	94,5	56				bedingt	28	56624	gesamt	0,1132
FLEX_rel_3a	Control Group	29	78,0	101	23,0	87,0	32	21,531	1	<0,0001	nein	29	56665	Group	0,0002962
	Study Group	75	112,8	158	23,5	113,0	24	21,531	1	<0,0001	ja	29	56666	Group	0,6575
	total	25	60,1	120	22,4	58,5	56				nein	30	56625	gesamt	0,0006829
EXT_rel_1	Control Group	37	61,1	120	23,8	60,0	32	0,036	1	0,85	nein	31	56667	Group	0,000677
	Study Group	25	58,9	111	20,8	57,0	24	0,036	1	0,85	ja	31	56668	Group	0,2931
	total	47,0	73,72	125,0	18,17	68,00	56				nein	32	56626	gesamt	0,0007324
EXT_rel_3a	Control Group	58,0	71,12	125,0	18,78	62,00	32	3,354	1	0,07	nein	33	56669	Group	1,526e-06
	Study Group	47,0	77,19	116,0	17,09	80,50	24	3,354	1	0,07	ja	33	56670	Group	0,3796
	total	25	62,6	115	24,0	65,5	56				nein	34	56627	gesamt	0,0246
ULN_rel_1	Control Group	25	59,9	115	27,6	63,0	32	0,816	1	0,37	nein	35	56671	Group	0,01295
	Study Group	25	66,0	100	18,3	67,0	24	0,816	1	0,37	ja	35	56672	Group	0,6968
	total	14	79,7	123	23,8	83,5	56				nein	36	56628	gesamt	0,01763
ULN_rel_3a	Control Group	14	79,4	123	29,4	84,5	32	0,484	1	0,49	nein	37	56673	Group	0,01904
	Study Group	55	80,1	104	13,8	81,0	24	0,484	1	0,49	ja	37	56674	Group	0,8026
	total	10	70,5	157	29,9	72,0	56				nein	38	56629	gesamt	0,06215
RAD_rel_1	Control Group	10	73,2	157	30,0	76,5	32	1,252	1	0,26	nein	39	56675	Group	0,01905
	Study Group	14	66,8	140	30,0	67,0	24	1,252	1	0,26	ja	39	56676	Group	0,8558
	total	14	94,2	220	35,5	97,5	56				nein	40	56630	gesamt	0,003943
RAD_rel_3a	Control Group	14	87,5	128	30,9	97,5	32	0,485	1	0,49	nein	41	56677	Group	0,005253
	Study Group	51	103,1	220	39,8	98,0	24	0,485	1	0,49	nein	41	56678	Group	0,006513
	total	0	31,8	89	20,2	28,0	56				nein	42	56631	gesamt	0,0008887
STR_rel_1	Control Group	0	28,1	89	19,0	23,0	32	2,401	1	0,12	nein	43	56679	Group	0,0003678
	Study Group	10	36,9	77	21,1	31,5	24	2,401	1	0,12	nein	43	56680	Group	0,08275
	total	15	64,8	149	26,9	60,5	56				bedingt	44	56632	gesamt	0,1523
STR_rel_3a	Control Group	15	57,1	122	25,2	51,5	32	7,154	1	0,007	bedingt	45	56681	Group	0,1495
	Study Group	30	75,1	149	26,1	78,0	24	7,154	1	0,007	ja	45	56682	Group	0,3458
	total	6,7	46,30	85,0	20,06	46,25	54				ja	46	56633	gesamt	0,5993
DASH100_1	Control Group	6,7	50,92	85,0	21,14	51,25	32	6,295	1	0,01	ja	47	56683	Group	0,5896
	Study Group	14,2	39,59	81,7	16,63	35,85	22	6,295	1	0,01	ja	47	56684	Group	0,7848
	total	0,0	21,58	55,8	13,63	19,10	54				nein	48	56634	gesamt	0,03342
DASH100_3a	Control Group	0,0	24,32	55,8	14,39	22,90	32	3,724	1	0,05	bedingt	49	56685	Group	0,1938
	Study Group	0,8	17,60	44,6	11,37	15,85	22	3,724	1	0,05	ja	49	56686	Group	0,363
	total	2	23,9	70	16,9	19,5	56				nein	56	56639	gesamt	0,001681
FLEX_rel_D	Control Group	2	19,7	68	17,0	18,0	32	6,899	1	0,009	nein	57	56693	Group	0,0007901
	Study Group	12	29,7	70	15,4	29,0	24	6,899	1	0,009	nein	57	56694	Group	0,04053
	total	-5,5	13,58	36,0	9,74	12,50	56				nein	58	56640	gesamt	0,08533
EXT_rel_D	Control Group	0,0	10,06	23,0	7,98	8,50	32	9,975	1	0,002	nein	59	56695	Group	0,000427
	Study Group	-5,5	18,27	36,0	10,27	17,50	24	9,975	1	0,002	ja	59	56696	Group	0,8096
	total	-13	17,1	67	17,1	14,5	56				nein	60	56641	gesamt	0,002026
ULN_rel_D	Control Group	-13	19,4	67	19,0	14,5	32	0,955	1	0,33	bedingt	61	56697	Group	0,1021
	Study Group	-6	14,0	59	13,9	14,5	24	0,955	1	0,33	nein	61	56698	Group	0,01328
	total	-37	23,7	153	27,6	18,5	56				nein	62	56642	gesamt	6,515e-08
RAD_rel_D	Control Group	-37	14,2	45	14,8	12,5	32	9,054	1	0,003	nein	63	56699	Group	0,001594
	Study Group	-4	36,2	153	34,9	25,5	24	9,054	1	0,003	nein	63	56700	Group	0,0003808
	total	0	33,0	130	20,2	32,5	56				nein	64	56643	gesamt	1,495e-05
STR_rel_D	Control Group	0	29,1	55	13,8	32,5	32	0,8	1	0,37	ja	65	56701	Group	0,2257
	Study Group	9	38,2	130	25,9	32,5	24	0,8	1	0,37	nein	65	56702	Group	0,0003369
	total	-72,5	-25,08	17,1	17,04	-25,90	52				ja	66	56644	gesamt	0,4625
DASH_D	Control Group	-72,5	-26,60	-2,5	15,12	-25,90	32	0,7	1	0,4	bedingt	67	56703	Group	0,1502
	Study Group	-55,9	-22,64	17,1	19,91	-23,75	20	0,7	1	0,4	ja	67	56704	Group	0,2148

Control Group vs. Study Group					
Baseline	Indep. Samples t-Test			Wilcoxon Rank Sum Test	
dep. Variable	t	df	p (t-Test)	Wilcoxon W	p
Age				362,5	0,73
FLEX_rel_1				143,5	<0,0001
EXT_rel_1				395,5	0,86
ULN_rel_1				329,5	0,37
RAD_rel_1				451,5	0,27
STR_rel_1				290,5	0,12
DASH100_1	-2,2	50,966	0,03		
Differences M3a - M1	Indep. Samples t-Test			Wilcoxon Rank Sum Test	
dep. Variable	t	df	p (t-Test)	Wilcoxon W	p
FLEX_rel_D				225,5	0,009
EXT_rel_D				193,5	0,002
ULN_rel_D				443	0,33
RAD_rel_D				202,5	0,003
STR_rel_D				330	0,38
DASH_D	0,763	32,573	0,45	346,5	0,62

Written consent to participate in a clinical Study

- Please read this form carefully.
- Please ask if you want something do not understand or know.

Study title:	
Patient: Name and first name:	
Date of Birth:	

☐ Male ☐ Female

- I was by the undersigned orally and in writing about the objectives, informed by the end of the study andthe anticipated possible risks.
- I study delivered to the above written patientinformation of [date] have read and understood. Myquestions in connection with participation in this studyhave been satisfactorily answered me. I can keep thewritten patient information and receive a copy of mywritten consent.
- I was aware of possible treatments and othertreatments
- I have enough time to make my decision was.
- I am aware that insurance covers damage, if anyoccur in the study.
- I know that my personal data will only be usedanonymously to outside institutions for researchpurposes.
- I volunteered for this study. I can at any time andwithout stating any reasons my consent to participate,without the disadvantages incurred by me because ofthe additional medical care. In this case I was being investigated for my final medical safety.

Place, date Signature of patient