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Relationship between stability of external fixator device and healing process of pilon fracture: Biomechanics perspective

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Abstract

The fracture of distal tibia bone is one of the most serious cases in the world, especially pilon fractures type. This is due to fact that the ankle joint involve soft tissue problems (cartilage and ligaments) and can cause to long-term disability. The treatment of pilon fractures are depending on several aspects where this may lead to complications. Different types of pilon fractures may not use similar treatment and the choices can be included several internal and external fixators. Therefore, this recent article is reviewing the principles of external fixator in treating pilon fractures. The use of this system with properly applied allows bony stability and increasing soft tissue care monitoring after fixation is achieved. The review discusses about the basic configurations of external fixator, stability of the external fixator and healing process. The findings will provide an additional information to medical doctors and engineers to decide the best configurations for patients associated with pilon fractures.
1.0 Introduction

Pilon fractures can be refer to traversing the weight bearing to the articular surface of the distal tibia [1]. This type of fracture often involved displacement of articular cartilage at the ankle joint, comminution of the distal tibia bone and injury on soft tissue such as skin and muscle [2]. In clinical research, there were reports that this injury usually caused by road traffic accidents, sports injuries, high velocity gunshot wounds and high energy falls from a height [3-21]. Based on previous research articles, pilon fractures can be occurred due to rotational of tibia bone and high compression forces to the human leg [1, 18]. The complexity of ankle fractures is due to the fact that when the foot is planted on the ground, the body applies excessive torque on the ankle [22]. To best knowledge of authors, the pilon fractures is a combination of compression, shear, bending and rotation load from external [10, 16, 18, 23-24]. To date, the pilon fracture injuries contribute at least 10% of lower limb fractures for males in the world [3, 18, 25-27].

Numerous classification systems of tibia pilon or plafond fractures exist and are published. Back in 1979, two scholars; Ruedi and Allgower have proposed several types of pilon fractures. This was based on their own findings and experts. From that, Ruedi and Allgower classified pilon fractures into three categories. The first is Type I where there is an intra-articular fracture of the distal tibial plafond without displaced or minimal displacement. The second is Type II where this type of fracture involved an intra-articular displacement that could be with or without minimal comminution. The last is Type III has significant comminution and impaction of the intra-articular surface with displacement [19, 27-30]. This classification is commonly reported in the literature [4, 8-9, 11, 16, 19-20, 24, 31-41]. Gustillo and Anderson have proposed their pilon fracture classification on the basis of clinical studies of 1025 open fractures [42]. They described three types; Type I is clean wound of less than 1cm is size associated with open fracture, Type II is open fracture with skin laceration longer than 1cm but without extensive soft tissue damage, and Type III is extensive soft tissue damage with compromised vascularity with or without severe wound contamination [43]. These classifications have been used previously in orthopaedics research [14, 21, 38, 41, 44-48]. Another classification is Arbeitsgemeinschaft fur Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA). According to AO/OTA, the fractures of the distal segment tibia or fibula are divided into three types; A: extra-articular
fracture, B: partial articular fracture, and C: complete/intra-articular fracture [27-29]. AO/OTA classifications also have been used by many authors [5, 12-13, 15-16, 35, 41, 44, 49-59].

Medical experts aims a better treatment for pilon fractures where their intention is to make sure that the fractures can be fully reconstructed and ensure the anatomical conditions can be return to normal condition that include fast soft tissue healing, minimally soft tissue invasive, recreation of the joint surfaces, early function and restoration of the ankle joint alignment [54-55, 60-61]. These may be achieved by using open reduction internal fixation (ORIF), minimally invasive plate osteosynthesis (MIPO) or external fixation [18, 54, 57, 62]. Normally type I and type II (Ruedi and Allgower) were treated with internal fixation (with or without external fixation) such as screws, K-wires and plates [13, 16, 35, 39, 60, 63-67] and even external fixation alone has been used [36-37]. The treatment of type I and type II pilon fractures are easy and the results are generally very good without any complications [35, 64]. However, there is an ongoing debate and new treatment approach towards type III fractures, since these fractures are induced by high-energy, and the treatment outcome is poor and associated with high rate of complications [4, 8]. The increased rate of complications after immediate open reduction and internal fixation of pilon fractures type II and III include partial- and full-thickness skin necrosis, wound healing problems, dehiscence, increases infections, inflammation, arthrodesis, second surgery, bone loss, nonunion, malunion, deformity and even amputation have been reported in the literature [26, 32, 49, 68-76]. Furthermore, the internal fixation such as plate and screws will not stabilize the fracture [9]. Therefore, the use of external fixator can overcome the issues to maintain ankle and foot alignment. Previous study also shows that researchers who are used internal fixation for early treatment need second surgery to reconstruct anatomical position [75, 77].

For treatment of type III, researchers have proposed various methods for treating such fracture in either internal or external fixation. Popular method to treat this particular type of pilon fracture is two stages operative management [25-26, 31, 44, 49, 62, 78-82]. The first stage is regarding applying external fixator and/without fibular fixation in order to reduce the incidence of soft tissue-related complications as well as to stabilize and align the ankle joint. The second stage is open reduction internal fixation after several weeks of external fixation mobilization. The purpose of the second stage was to achieve and maintain the anatomical reduction of
articular and peri-articular fragments. In the first stage treatment, various types of external fixator have been recommended in the previous clinical study. These include bridge or spanning fixator with rods and clamps, dynamic system, articulated device that allow movement or a ring frame include of tensioned wires with or without rods may be used [4, 11, 25, 49-50, 52, 83]. Medical experts strongly suggested to use external fixator as this medical device can minimize complications as compared with conventional ways in using screws and plates [50, 53, 71, 81, 84-86]. For clinical practices, the ideal method in treating pilon fractures is measured by maintaining patient’s ankle alignment and position where the stability of medical device to fix the bone is one of the important things. To be noted that the complications such as non-union and mal-union of bone that involved in clinical practices are due to the fact that lacking of stability [9, 31].

Outcome of the treatment can be altered by many factors. Not only from the treatment method (internal or external fixator) used by medical experts, it is also based on fractures type, the time taken for ankle to immobilize, fixation stability and medical experiences [30, 33, 87-89]. Moreover, the use of external fixator is depending on the surgeon’s experiences, soft tissue injury pattern and fracture conditions [58, 90]. Improper uses of external fixation may also be associated with a high incidence of complications, with pin infection and loosening in up to 50% of cases and ma-lunion rates of up to 45% [35]. Recently, there is no evidence in the literature to indicate which type of external fixator is better for tibia pilon fractures. Researchers have their own suggestion in the treatment of these fractures based on fracture pattern, experience, equipment and skill. Therefore, this recent article is reviewing the basic configurations of external fixator for ankle, stability of external fixator and healing process.
2.0 Methods

Several search engines were utilized to search related publication. This include ScienceDirect, Medline, Web of Science, Scopus, Pubmed, IEEE Explorer and Google Scholar. The keywords used for the searching were “pilon fracture” and specific words “ankle”, “biomechanics”, “mechanics”, “external fixation”, “internal fixation” and “lower limb”.

3.0 External Fixator Configurations

The configurations of any external fixator can be modified depends on the expertise and experience from the medical surgeons. Normally, different fracture uses different type of fixator. Fractures which heal slowly impose demands on external fixators to maintain their biomechanical characteristics over extended periods of time.

3.1 Monolateral/uniplanar

Monolateral or uniplanar is a simple configuration that uses a small numbers of pins, clamps and rods. Some configuration consists of one rods, two clamps and two pins. Other construction can be a combination of two rods and several numbers of clamps and pins. This will be depending on medical experiences and fractures type. Basically, the unilateral external fixator configurations made of 4.0 until 6.0 mm Schantz screws. Some of medical experts used single half pins. Both screws and pins penetrating the bone through the tibial anterodiaphysis proximal to the fracture, the medial calcaneus or metatarsals suffices for the temporary fixation [27, 58, 68, 71, 86]. Another position of pin placement is in the medial neck of talus [68]. The big advantages of this frame is that it has high flexibility. The simple monolateral or uniplanar frame can be converted into another configurations during the treatment where the position of pins remains at similar places as at the beginning [46, 54].

3.2 Multiplanar/biplanar/delta

Unlike uniplanar or unilateral frame where it is a simple configuration, a multiplanar external fixator is more complex construct. The construct can be either two or more planar configuration [5, 49]. As mentioned from previous published reports, a number of pins will be inserted into the bone where the locations are different depending on type of fractures [91]. Generally, the multiplanar configuration applied several number of clamps, pin clamps and some
different sizes of half pin (4.5 or 5.0 mm) [92]. For the pilon fractures, normally the pins will be fixated at tibia, metatarsal, cuneiform and calcaneus bone. The existence of additional pin at metatarsal bone is to avoid forefoot equinus [44, 49, 93-94]. Another configuration that proposed by Salton et al. where there are two pins placed at the tibia, one at talus and another pin at calcaneus bone [78]. The pin placement for calcaneus bone must be between medial to lateral through the posterior-plantar aspect of the calcaneal tuberosity. Many authors preferring to construct a multiplanar or namely as delta frame for treating pilon fractures [91].

3.3 Articulated/hinged

There is a type of external fixator that can be flexible in movement namely as articulated or hinged frame. This external fixator is constructed by a number of clamps and rod where one hinge element is introduced to allow ankle movement during a period of treatment [18]. Instead of the hinged or articulated configuration, some scholars name it as dynamic fixator [46, 50]. To date, Orthofix external fixator is the one of hinged frame that recently used by medical surgeons to treat pilon fractures [40, 46, 50]. Not only using the existing product, the hinged frame can be transformed from the unilateral frame [54]. For this type, normally the external fixator consists several number of 5 mm screws of pin where two of them is fixed at the tibia, one pin at the neck of talus and another pin fixated at the calcaneus bone where a ball-joint is introduced to the configuration and manually locked for beginning [18, 47, 50, 95]. However, some medical surgeons uses three pins at tibial diaphyseal [31] and some of them apply two pin at calcaneus bone [40]. Nevertheless, it is suggested that the articulated or hinged external fixator should be in appropriated angles and location due to the fact that the hinge axis will affect the ankle movement during intervention period. The hinge axis must be aligned with the normal ankle axis to avoid any complications [96]. Valgus deformity is one of the complications that may occurred if medical surgeons poorly choose the position of hinge axis of the external fixator [40].

3.4 Hybrid

As its name, the hybrid frame in general is a combination of the conventional rods and clamps with circular concept. For this construct, several number of periarticular tensioned fine wire is applied to a ring with conventional method of pins, rods and clamps [27, 91]. In treating pilon fractures, the patient’s foot will be fixed with transfixion pin i.e. pin passing through the
calcaneus and talus bone that attached with a circular ring [27, 38]. For the tibia bone, the conventional method is applied where several screws and pins are placed in the tibial diaphysis and the position should be proximal to the fracture site [59, 97]. Due to clinical experiences, some surgeons may introduce two tensioned olive wires to fix the distal fixation in which additional wires and screws may be used [38, 59]. To avoid complications such as equines deformity, a removable foot support that will attach with distal ring is applied [38]. The important of wires fixation should be in safe corridors as shown in the previous study [98] in order to reduce pin tract infections. For hybrid frame, the ACE-Fisher® Frame (DePuy ACE, Indiana, USA) and the Tenxor™ Frame (Stryker Trauma, Geneva, Switzerland) was more recently used [6].

3.5 Circular

The famous configuration used by many medical surgeons is Ilizarov frame that made up from several number of rings and wires. The frame consists of two-level fixation; first level is the rings configuration and second is wires configurations [9]. Ideally, a normal Ilizarov configuration is a combination of four connected rings where the two center rings are close to the broken bone and the other two rings are located far away [9, 51]. Each ring is secured to the bone with two tensioned wires (1.5 or 2.0 mm); or a combination of wires and threaded pins (3.5 or 4.0 mm) [19, 50]. As far as the stability is concern, a stiff frame that consists of more than four rings can be constructed to allow high protection of multi-fragmentary ankle fracture such as pilon fractures [9, 99]. Based on some medical experts, two or three rings were fixed to the tibia diaphysis, a half ring to the calcaneus with 1.8 mm tensioned K-wires fixed to the rings [9, 14, 17, 20, 50-51, 56]. Meanwhile, Israelite et al. [36] reported that the Ilizarov construct consists of three proximal fill rings along the shaft of the tibia with the most proximal ring tensioned with wires, connected to the tensioned calcaneal half-ring. Generally, two wires are placed proximally to the fracture, with three wires placed in the distal fracture just above and parallel to the ankle joint.
4.0 Overall construct stability

Early motion of ankle joint is necessary to avoid many complications. This can be achieved by constructing a stable frame of external fixator to fix the lower limb of ankle joint [9, 23]. The essential to restore the proper axial alignment are using modern external fixator techniques, versatile and stable fixator [38]. One study have proved that the healing time is significantly related to fixation stiffness in which the highest stability of external fixator will promote healing rate in short of period of time [100]. For pilon fractures, there are two type of treatment; internal and external fixation. As far as the biomechanical aspect is concern, the internal fixation can only be used if the fixation is stable to fix the ankle joint [101]. Other than the configuration of external fixator, it should be noted that the material used is the one of factors that contribute to the fixation stability. As to date, stainless steel material is highly recommended by medical experts where it can provide rigid fixation as compared to titanium alloy. However, the use of titanium alloy can allow high flexibility that creating lower stress at the pin-bone interface and also allowing patients to experience early weight bearing during a treatment [57, 66]. For the pilon fractures treatment, the reduction of the fractures and alignment of ankle joint is a big challenge to medical surgeons [67]. The operations of reduction and alignment by using external fixator should be performed by experienced surgeons to avoid many complications [13].

4.1 Uniplanar, biplanar or delta

For the uniplanar, biplanar and delta, the optimal insertion point for the second pin was either the navicular, medial cuneiform or first metatarsal [78]. This was suggested by the medical experts in considering the complications of pilon fractures. While for the dynamic fixation with two convergent pins through the proximal fragment of the tibia, 1 or 2 pins through the calcaneus, and one through the base of the first metatarsal bone [54]. Stability of the conventional method of this external fixator can be improved by considering several parameters. Those parameters are including number of screws or pins, pins diameter, rods diameter, the distance of connecting rods as well as the number of rods in a particular external fixator [102-103]. Stiffness and stability can be optimized by adding additional pin from two to three pins in one clamp and minimize the distance between the connecting rod and skin [104]. For the articulated or hinged design, it is recommended to be constructed by allowing early movement with minimal disturbance to the soft tissues of human [40]. It is important when applying spanning external fixator that the hind
foot and mid foot be positioned in neutral of slight valgus alignment [92]. Another method in increasing the stiffness and stability of external fixator is by increasing a number of rods in different plane [91].

4.2 Ring or circular and hybrid

The ring or circular external fixator is involving several special configurations such as rod, plate and peri-articular fine wires. To be noticed that the peri-articular fine wires allow rigid fixation of small pieces of cancellous bone and intra-articular fractures, minimal soft tissue disruption, easy wound surveillance, early joint mobilization and weight bearing [6]. At the same time, the application of hybrid external fixator is relatively technically easy, restoration of the joint congruity cannot be achieved without at least minimal intervention [59]. The advantages of hybrid external fixator can control trial of motion compared to rigid immobilization with a mobile of locked hinge is possible [52]. As compared with other frames, the Ilizarov fixator is found to be low stiffness where it could not fix well the long bone such as tibia and tibia bone, nevertheless it can fix the smallest bone such as talus, calcaneus and metatarsals with the use of tensioned K-wires [9, 105]. This is due to fact that the Ilizarov fixator can allow patients to experience early movement and partial weight bearing [45]. Even though the Ilizarov method is not promising high stiffness, however this method can accomplishes the aim of pilon fractures treatment where to reduce the multi-fragmentary broken bone, allow weight-bearing and aligning the ankle position to normal one [11, 99]. For increasing the stability of Ilizarov fixator, the main contribution is a number of wires, optimize the wires configuration, appropriate tension of the wires, wires diameter and ring size [99]. From previous published reports, the smallest diameter of wires can increase the stability of construct without preventing the healing process of callus [27, 59]. The major advantage to use these type of frame (ring, circular of hybrid) is that some motion can be maintained with the fixator in place, offer adequate stability for fracture union and keeps the pins away from the fracture site [27, 59].
5.0  Time of fixation associated with healing process

The time and healing process is a very subjective where it can be depending on patient’s condition, medical experts and environmental condition. However, there was some evidence to suggest that early weight bearing after ankle fixation may result in faster rehabilitation of patients’ and result in an earlier return to work. Possibility of fracture displacement is the one of factors of surgeons not allowed early weight bearing [109-110]. To be noted, early fixator removal can lead to a gradual varus collapse because the fibula is quicker to heal or is intact from the start [27]. Therefore, an appropriate time of fixation should be plan by medical experts to ensure the treatment is success.

Early weight bearing is the aims to decrease the joint stiffness, articular cartilage degeneration, and bony atrophy [111-112]. Many surgeons mentioned that spanning any joint more than 15 weeks raises concerns over the potential for increased stiffness of the joint [31]. A full weight bearing would only appropriate for patients who had fractures that fixed at the time of operation such as anatomical reduction, good quality bone, and minimal comminution [111]. In general, Foxworhty et al. mentioned preliminary evaluation of healing time in relation to the timing of dynamization suggested that early release (before 30 days) was associated with a quicker healing time [46]. The healing rate can be significantly improved by dynamizing before 4 weeks after injury. After many months of non-weight bearing, a foot can have midfoot varus and cavus deformity, which need to be addressed when considering foot position [113].

5.1  Monolateral/uniplanar

Monolateral or uniplanar configurations can promote healing process. It is a subjective outcomes where the healing process can be taken according to patient’s condition, medical experts, external fixator configurations and environmental condition. Previous case study by Williams et al. study [68] found that the average of time fixation is thirteen weeks while Mitkovic et al. [54] mentioned that weight bearing was gradually introduced after three weeks depending on the degree of comminution and fracture instability. Another case study by Lee et al. [106] stated that postoperative care includes keeping the patient non-weight bearing for 8 weeks or longer depending on the clinical situation. In other case reported by Prayson et al. [27]
suggested that the patient should return between 5 days and 2.5 weeks to remove external fixator and proceed to internal fixation.

5.2 Multiplanar/biplanar/delta

Not only unilateral can promoting the healing process of the pilon fractures, delta configurations are also give a positive outcomes of the treatment. This can be proved by Cheema et al. [49] where they found that the delta frame external fixator is used for only 12 days in order to finish first stage of operative procedure. Two other studies are also found similar findings where the medical experts to remove the delta frame an average of 11.2 days [78] and 17.4 days (range of 11-25 days) [44]. One study by Bacon et al. [5] mentioned that the delta fixation was removed at 6-8 weeks.

5.3 Articulated/hinged

The timing of fixator removal was determined by treating surgeon based on radiographic appearance and clinical progress of the patient. In this case, the use of articulated of hinged fixation found that the time is between 8 and 12 weeks (average 11.7 weeks). The study also shows that uses of external fixator with motion given longer times fixation and the author suggests the movement through the hinge may delay fracture healing. Partial weight bearing was allowed at 8 weeks mostly still in the frame and was progressed to full weight bearing at 12 weeks after injury [52]. The study by Okcu et al. [50], the patients were not allowed full weight bearing for at least three months, depending on the progress of healing. The patients wore the fixator for a mean of $17.2 \pm 2.9$ weeks. Dickson et al. [31] mentioned the removal of external fixator was at 16 weeks after first and second stage protocol. After 12 weeks from the first surgery, the patients were allowed weight bearing. Saleh et al. [40] stated that the articulated external fixator were removed after 58 to 112 days (mean 88 days) and partial weight bearing was started between 30 and 130 days (mean 93 days). Marsh et al. [47] stated that the patient were allowed to bear partial weight at an average of nine weeks (range four to twelve weeks) after the injury and full weight at an average of thirteen weeks (range six to twenty-four weeks) after the injury. The external fixator was removed an average of twelve weeks (range five to twenty-two weeks). Another study by Marsh et al. [21] found that the fixator dynamized at an
average of 9.3 weeks. Fixators were removed between 12-50 weeks (average, 24.6) after application.

5.4 Hybrid

In general, the average duration of hybrid external fixation to be fixed at bone was 4 months [6]. However, the fastest duration was found from previous published by Kumar et al. [45] where that partial weight bearing with support was started within 2 weeks of fixation. This situation shows that the healing process was took earlier. In a study by El-Shazly et al. [38], they mentioned that partial weight bearing was allowed after 3 weeks progressing to full weight at 6 weeks. Fixator removal was determined according to the radiological appearances and performed in the out-patient clinic without anaesthesia. Removal of fixator and unprotected weight-bearing was ranged 3.5 to 21.5 months (mean 9.4 months). Leung et al. [56] stated that the pilon fractures patients were kept non-weight bearing for at least 8 weeks. The fixator was removed at an average of 15 weeks post-operatively (range 10 to 20 weeks).

In the meantime, two studies by two different scholars; Prayson et al. [27] and Babis et al. [59]. The former one suggested that ranges from 2.5 to 4 months in most cases while the later one suggested external fixator can be removed after adequate healing was confirmed and a below knee synthetic walking cast was applied. The patient can be instructed to full weight bear and approximately 4 weeks later the cast was removed. The fixator is suggested to be removed at an average of 2.8 months (range 2-5 months). Other study by Manca et al. [48] stated progressive weight-bearing was allowed between the eighth and twelfth week, depending on the radiographic appearance of the fracture. The external fixator was removed between fifteen and twenty-one weeks after surgery.

5.5 Circular exfix

For the clinical cases using circular external fixator, several case studies were analysed in this paper. Kapukaya et al. [4] removed the frame from the limbs after averaged 4.25 (3-6) months for fractures type III (Ruedi and Allgower) and the entire external fixator was removed 10 months later in one patient and 8 months later in the other. Another study by Kapukaya et al. [9], partial weight bearing with crutches was started on the seventh postoperative day and full weight bearing was started after the third week. The calcaneal half ring was removed after 8 to 12 weeks.
The external fixators were removed after approximately 15 weeks (ranged 11 to 21 weeks). For a study that involved type III pilon fracture, the patients were not allowed full weight bearing for at least three months, depending on the progress of healing[51]. In intra-articular fractures, the calcaneal half ring was removed after 4-5 weeks and ankle range of motion were then started. After union of the fractures, frames were dynamized for two to three weeks before removal. The average time for healing was 4.5 months (range 2.5-6 months).

**Conclusion**

The successful of pilon fractures treatment can be achieved by applying correct configurations of external fixator. This was proved scientifically by previous researchers, however the healing process is depending on how medical experts fix the external fixator, patient’s condition, complications and many more. Based on these findings, it can be concluded that there is no specific configuration to treat pilon fractures. It will be based on the demand and experts by the medical surgeons. Nevertheless, comfortable and healing to the patients is the priority in treating pilon fractures.

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References


