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The damage control in tibial pilon open fractures with a new external fixator delta frame

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ABSTRACT

Objective: To evaluate the effectiveness of the damage control, in emergency to treat the open tibial pilon fractures with Dolphix® External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy). **Methods:** From January 2017 to August 2017, at the Department of Orthopedics and Traumatology of Vito Fazzi Hospital Lecce, we treated 23 open tibial pilon fractures with Dolphix® External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy). The evaluation criteria of the case series were: the time needed to assemble the external fixator; the time taked to treat the ankle associated lesions; the time of skin healing; the ankle alignment; the subjective/objective Ovadia and Beals score; and complications. The Endpoint assessment was set at the days of the definitive surgery. **Results:** The results in terms of alignment, biomechanical stability of the frame, healing of soft tissue, complications were as good as the objective and subjective results according Ovadia and Beals score. **Conclusion:** Pilon fractures are complex and often present complications; the damage control treatment, in emergency, with Dolphix® External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy) permits a stable osteotaxis with minimal soft tissue damage and permit the repair of muscles, blood vessels and nerves with a stable bone and the soft tissue healing with vaccum therapy.

1. Introduction

Distal tibia fractures, located within 5 cm from the articular line, are about 1% of all lower limb fractures and about 5% to 7% of the tibial fractures [1,2]. Although relatively rare, these injuries, currently on the rise, pose a serious challenge to the orthopedic surgeon because the muscular layer is not adequate, the pilon is poorly vascularized, and often there is a comminution of the fragments and joint involvement. Most of these fractures are secondary to a high-energy trauma, such as falling from a height, traffic accidents with metaphyseal sinking, crushing of soft tissues or even exposure of the fracture. Low-energy trauma (*eg.* Skiing accidents), instead, cause spiral (torsion) fractures, less complicated with modest soft

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tissue damage [3,4]. They are often associated with open wounds or serious closed soft tissue involvement, with metaphyseal or articular comminution or shaft extension [4]. The damage control with external fixation was the gold standard to treat this injures[3,4].

The purpose of this prospetic cases series was to evaluate the effectiveness of the damage control, in emergency to treat the open tibial pilon fractures with Dolphix® External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy, Figure 1A).

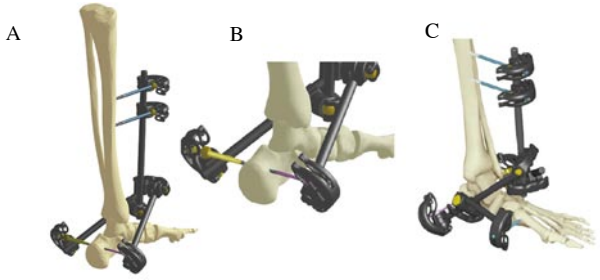

Figure 1. An example of Dolphix External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy).

2. Materials and methods

From January 2017 to August 2017, at the Department of Orthopedics and Traumatology of Vito Fazzi Hospital Lecce, we treated 23 open tibial pilon fractures with Dolphix® External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy, Figure 1). The average age of the study population was 47.4 (range 16-90), the sex ratio was 3.6 to 1 in favor of males (men: 18 *vs.* women: 5). All fractures were classified according to the A.O.. The three groups were represented by 11 patients (47.83%) for the Type A; 2 patients (8.69%) for Type B and 10 patients (43.48%) for Type C. The working sector most represented was the Primary and Secondary industry sector (10, 43.48%), followed by the Tertiary industry (3, 13.04%). The most common causes of tibial pilon fractures were work accidents (15 patients, 65.22%). Other causes were Fall from High (5 patients, 21.74%) and Car Accident (3 patients, 13.04%). All fractures are open. According to the Gustilo Anderson classification, the open fractures were: Type I, 2 patients (8.69%); Type II, 4 patients (17.39%); Type III A, 5 patients (21.74%); Type III B,11 patients (47.83%); Type III C, 1 (4.35%).

All patients were treated with the Dolphix® External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy). The muscles (3, 13.04%), nerve (1, 4.35%) and bone injuries (2, 8.69%) associated with tibial pylon fractures were observed. All the ankle damages were repaired in emergency after the bone fixation by Dolphix® External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy). All patients were associated a supra-transidesmosic peronaeal fracture that was fixated in all cases with K wire. All patients were treated with vacuum therapy (ActiV.A.C.® Therapy Unit, Acelity; L.P. Inc., San Antonio, Texas, USA) to have the healing of the soft tissue damage.

All patients were informed in a clear and exhaustive way about the variuos types of treatment and the corresponding surgical alternatives. Patients were treated according to the ethical standards of the Declaration of Helsinki and were invited to read, understand and sign the informed consent form. The follow-up was carried out with clinical and radiographic tests at after the surgery to 15 days after the surgery, and the day before the definitive fixation.

The evaluation criteria of the case series were: the time needed to assemble the external fixator; the time taked to treat the ankle associated lesions; the time of skin healing; the ankle alignment[5]; the subjective/objective Ovadia and Beals score[6]; and complications. The Endpoint assessment was set at the days of the definitive surgery.

2.1. Resveratrol(RSV)

To implant the Dolphix®, the patient should place supine radiotransparent bed without calcaneal trans-skeletal traction. After doing a sterile surgical field, under the knee and the heel should be placed a soft support as surgical towels.

Dolphix® Tibial Pilon Kit contents: 2 Bone Screw clamp pre-assembled with bone screw ø6 mm, L. 160 mm; 2 Dolphix® Rod to Rod clamp; 1 Radiolucent Rod ø12 mm, L. 200 mm; 2 Radiolucent Rod ø12 mm, L. 280 mm; 1 hand drill; 1 Dolphix® Bone Screw Clamp for Transfixing bone screw, yellow part; 1 Dolphix® Bone Screw Clamp for Transfixing bone screw, pink part; 1 Transfixing Bone Screw, L. 220 mm, thread length ø5 mm;1 hand drill. The Dolphix® Transfixing Bone Screw Clamps are applied to the corresponding colored part of the transfixing bone screw.

Frame stability is obtained by inserting a transfixing 5 mm bone screw through the calcaneus and two bone screws anteriorly in the tibia. Following insertion of the transfixing bone screw, the two Dolphix® clamps for transfixing bone screws were applied; these are attached to the bone screw in relation to their corresponding colored part, yellow and violet.

The clamp with the yellow part should be locked first. Before locking the clamp with the violet part apply a protection cap to the tip of the transfixing bone screw (Figure 1B).

Use of some component the Dolphix® Base Kit to achieve more biomechanical stability of the Delta External Frame (Figure 2). Dolphix® Base Kit contents: 4 Dolphix® Bone Screw clamp pre-assembled with bone screw ø6 mm, L. 160 mm; 2 Dolphix® Rod to Rod clamp; 1 Radiolucent Rod ø12 mm, L. 150 mm; 2 Radiolucent Rods ø12 mm, L. 200 mm; 1 hand drill.

Use of the Dolphix® Metatarsal Accessory Kit in ankle fractures-dislocations and in complex tibial pilon type C

Figure 2. A 73-year-old male patient, traffic accident car *vs.* motorbike(own) with fracture.

(A) 43-B2 fracture according AO/OTA and open fracture Type IIIB according to Gustilo-Andreson associated with bone loss (B). After stabilization with Dolphix® External Fixator Frame, we found lesions of postero-medial compartment muscle (C) after wound exploration. Long Tibial calcaneal bridging external fixation due to skin lesions of the anterior-medial tibial part. Using Supplements from Base Kit (D-E) to achieve more biomechanical stability. The postoperative X-rays control shows a good reduction in sagittal plane, valgus deformity at the frontal plane (F). Stabilization of supra-sindesmosis fracture with K (F) wire.

fracture (Figure 1C). Dolphix® Metatarsal Accessory Kit contents: 1 Bone Screw Dolphix® pre-asesmbled with bone screw ø5 mm, L. 120 mm; 1 Dolphix® Rod to Ropd clamp-1 Radiolucent Rod ø12 mm, L. 130 mm.

In the fractures previously described the Dolphix® Metatarsal Accessory Kit is an option to give greater stability to the system. The bone screw can be manually inserted in the first metatarsal and it is to be connected with a short bar and a rod to rod clamp in the medial rod of the delta implant(Figure 1C).

2.2. Indomethacin and healing skin prothocol

To applicate the Vaccum Therapy on External Fixation we should cover adequately the skin wound with sponge or gauze, apply a moldable hydrocolloid strip around the pins approximately above 1.27 cm above the level of wound, wrapping it around the pin, ensuring the snug fit. After the cuted the drape to appropriate sized and apply to the wound. The vacuum pressure was in the range of 45-75 mmHg. We change the Vacuum Medication every 3 days and we eventually did with plastic surgeon the escharotomy. The medication around the external fixation were done by the Bisaccia prothocol[7].

3. Results

We needed to assemble the Dolphix® external fixator frame an average time in minutes of 23.6 minutes (range: 15.3-45.6 minutes). To repair the associated Ankle's injures we need and average times in minutes of 48.3 minutes(range 15.2-93.5 minutes). The skin healing was achieved in average time of 46 days (range 21-76 days). The definitive treatment with hybrid external fixator or plate and wires have done an average time of 46 days(range 21-76) after the dame control (Figure 2). The excellent radiographic alignment of the Talar Tilt and Shenton's line occurred in 20 (86.96%) patients after the damage control while 18(78.26%) patients the day before the definitive surgery(Figure 2). 1 out of 23 patients (4.35%) had excellent subjective results and the 4.35% (1 of 23) had excellent results from the objective point of view, too; Good 2(8.69%) in subjective and objective 2(8.69%); Discrete 15(65.22%) in subjective

and objective 15(65.22%) objective; Insufficient 5 (21.74%) in subjective and objective (21.74%).

During the follow-up period of about 46 days(range 21-76), we had 13 complications: 6(26.09%) Ankle's Ostheoarthritis, 2(8.69%) Skin Infection; 1(4.35) Bad alignment Pro Curved/Retro curved <10; 4(17.39%) Bad alignment in Var / Valgus> 5 (Figure 2).

4. Discussion

Pilon fractures are still a major challenge for the orthopedic surgeon. Their management is guided by the state of the soft tissues, the joint injury and the comminution of the fracture fragments [1-4]. The primary objective to be achieved, regardless of the method of synthesis, is to obtain good anatomical reduction of the fracture with the possibility of early weight bearing and avoid more serious consequences [1-4]. Not always is possible to do in emergency a definitive fixation[8].

Tang *et al*[9] reported their experience in temporary external fixation in closed tibial fracture due to the soft tissue swelling. This patients underwent the surgery from the 10 days to 3 weeks postinjury after the soft tissue swelling subsided. The funtional result are not good in the postponed group. If soft tissue conditions are acceptable, early ORIF for treating closed type C pilon fractures can be safe and effective, with similar rates of wound complication, fracture union, and final good functional recovery but shorter operative time, union time, and hospital stay. These results favorably compare with delayed ORIF treatment[9]. Temporary external fixators are often used to stabilize fractures when definitive fracture surgery must be delayed. Sometimes, external fixators are left in place during repeat operations, including definitive internal fixation of tibial pilon and tibial plateau fractures[10]. It is unknown how well current surgical preparation sterilizes these devices, which become part of the surgical field[10]. According to Hardeski *et al*[10] the application of fast assemble kit external fixation did not increase a rate of culture-positive environments on external fixators at the time of surgical skin incision.

From Bosnian War, Grubor *et al*[11] reported the use of vacuum therapy to recover the soft tissus injures. In 2014 Lavini *et al*[12] reported in their two stage treatment of tibial pilon fracture: the temporary external fixation in high-energy trauma and fracture-dislocation of the ankle enables soft tissue to be restored, which facilitates postoperative assessment of bone fragments by CT scan. The complication rate in this study was 5% in patients with malleolar fractures and 20% in patients with pilon fractures. The maintenance of temporary external fixation after ORIF synthesis during the entire first stage of bone healing seems to be a good method of treatment that has a low rate of soft tissue complications[12]. Some experts authors in External Fixation suggested to use the definitive external fixation like a manner to reduce the risk of soft tissue damages, thanks to his minimally invasive approach; hybrid external fixation systems had additional advantages, because these are modular, easy to apply and allow early mobilization[3,4,13,14]. These authors showed the primary stabilization of clsed or open tibial pilon fractures should be quick and easy, but it must stabilize the skeletal lesion to neutralize the stress on the soft tissues. The "tripolar" [15] configuration demonstrates to fully carry out these requirements in cases of tibial pilon fracture, both isolated or with fibula fracture; in fact, this configuration allows the facilitation of nursing and next diagnostic as CT scan and therapeutic procedures as vacuum therapy[15]; The time of surgical lenght can be reduced with a simple sedation and intraoperative fluoroscopy in the emergency room, if the lesion is closed not requires an aggressive surgical debridement[16,17]. The Delta external fixator was found to be the most stable external fixator for treating not stable as type III according AO/OTA's classification[18]. Axial loads of 350 N and 70 N were applied at the tibia to simulate the stance and the swing phase of a gait cycle. To prevent rigid body motion, the calcaneus and metatarsals were fixed distally in all degrees of freedom. The results indicate that the model with the Delta frame produced the lowest relative micromovement (0.03 mm) compared to the Mitkovic (0.05 mm) and Unilateral (0.42 mm) fixators during the stance phase. The highest stress concentrations were found at the pin of the Unilateral external fixator (509.2 MPa) compared to the Mitkovic (286.0 MPa) and the Delta (266.7 MPa) frames[18]. The treatment of Gustilo Anderson type 3B open fracture tibia is a major challenge and it needs aggressive debridement, adequate fixation[19]. Tibial open fracture needs a stable rigid fixation before flap coverage should be treated with high priority of radical early debridement[19-21]. From our preliminary data we can concluded Pilon fractures are complex and often present complications; the damage control treatment, in emergency, with Dolphix® External Fixator Frame(CITIEFFE®, Calderara di Reno, Bologna, Italy) permits a stable osteotaxis with minimal soft tissue damage and permit the repair of muscles, blood vessels and nerves with a stable bone and the soft tissue healing with vaccum therapy.

Human and animal right

For this type of study any statement relating to studies on humans and animals is not required. Patients gave her informed consent prior to being included in the study. All procedures involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments.

Conflict of interest statement

All authors disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

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