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ITTF - TEMPORARY IMMOBILIZER WITH PROXIMAL FEMUR TRACTION: DEVICE DESCRIPTION AND POTENTIALITIES

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Abstract: Trauma is considered a public health problem. Femur fractures in the adult population have an epidemiological characteristic of being bimodal. The use of immobilizers in lower limbs in pre-hospital care is consensus and aims to recover the anatomy, stabilize the fracture focus, reduce pain stimulus and the progression of hemorrhage due to trauma. The use of traction associated with immobilizers can represent a gain in these parameters. **Objective:** to describe and analyze the potential of the temporary immobilizing device for the proximal femur in trauma, radiolucent, patented in 2022. **Methodology:** This is a descriptive and comparative analysis of the patented device in the initial technological maturity process, using the descriptors and scientific search platforms (BIREME, PUBMED, SCIELO and GOOGLE PATENTS) in English, Portuguese and Spanish; as well as between the last 5 years. Using searches in the databases with the descriptors "femur fracture"; "restraints"; "trauma"; "pre-hospital care". **Result:** among the current devices found on the market, the present invention stands out for having a radiolucent presentation, in addition to allowing traction maintained without the use of mechanisms external to the device. **Conclusion:** Given the differences and potential of the immobilizer with traction, it may be possible to keep it on the patient from pre-hospital care to imaging exams in the emergency room.

Keywords: Femur fracture; traction immobilization, pre-hospital care

INTRODUCTION

In the femur, the strongest bone in human anatomy, large muscles are attached and established between two powerful joints: the hip and the knee. The femur is a long bone, divided into a proximal portion (femoral head, neck, trochanters and subtrochanteric), femoral diaphysis (body of the bone) and distal portion (condylar and articular regions are distal) (Stubbs AJ, 2014). Conceptually, a fracture is the loss of bone continuity, being the partial or complete rupture of the cortical surfaces (Thematic Glossary, 2012).

The fragments are usually pulled by the powerful muscles of the hip and thigh (BARBOSA DE TOLEDO LOURENÇO; PIRES, 2016), causing deviations of the fractured bone portions in flexion by the iliopsoas muscle, reducing the angle of the fracture; abduction, mainly by the gluteus medius, moving the fragment away from the long axis of the bone; and external rotation, by the external rotator muscles, in the proximal fragment of the femur (Lima et al, 2017). Distally in the femur, the adductors are responsible for the varus deformity (Gösling T, 2019), compromising the central line of the limb; and the deviation in the sagittal plane occurs by the action of the quadriceps femoris, hamstrings and gastrocnemius. Associated with these deviations, shortening of the fractured limb may occur.

Trauma is considered a public health problem, especially in large urban centers, and is the third leading cause of mortality (Antunes P de SL, 2021), and orthopedic sequelae can lead to reduced quality of life and functional capacity (Houwen T, 2022).

Femur fractures in the adult population have an epidemiological characteristic of being bimodal (Court-Brown CM, Caesar B, 2006) in relation to age, sex, and energy involved in the trauma. Thus, young male adults are more associated with high-kinetic-energy accidents

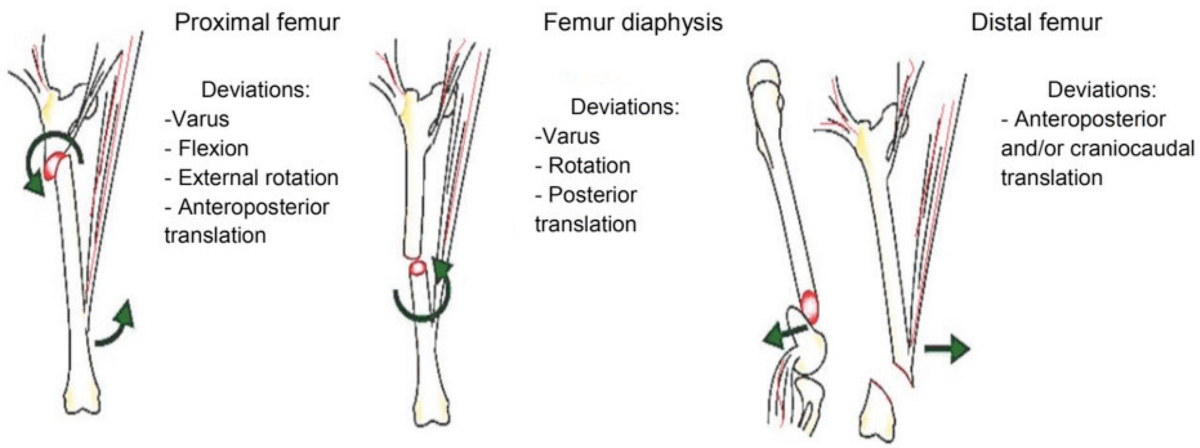

Figure 1

with polytrauma (Abarbanell NR, 2001), while elderly females are more associated with lower-energy traumas (Tittel, S et al, 2020), usually focal trauma. It is important to highlight that there is an increase in life expectancy, with a consequent decrease in bone quality (TONINI; NAZÁRIO, 2021), as well as in the incidence of trauma in people over 65 years of age (Parreira JG et al 2013). In Brazil, between 2015 and 2020, 224,697 cases were reported in elderly people over 70 years of age and 58,367 in young people, between 20 and 29 years of age (Antunes P de SL, 2021). In the initial trauma care protocols (Level 3 guideline on the treatment of patients with severe/multiple injuries, 2018); (Fire Department of the State of Rio de Janeiro, 2018), the fracture focus must be stabilized and the victim removed using long boards and accessory immobilizations (AMERICAN COLLEGE OF SURGEONS, 2018), always with the aim of providing fast and safe transportation, without delaying in-hospital care (HARMSEN, A. M. K. et al, 2015).

The Advanced Trauma Life Support – ATLS (AMERICAN COLLEGE OF SURGEONS, 2018) recommends that, after the initial trauma care protocol, bone alignment must be restored and the fractured lower limb must be lengthened through immobilization and traction for removal to the nearest emergency department. Positioning that is as similar to pre-trauma anatomy as possible aims to reduce the risk of fracture complications such as pain, neurovascular damage, and hemorrhage control by decreasing the space formed in the soft tissue envelope and the fractured bone surface (Runcie H, Greene M, 2015) (Level 3 guideline on the treatment of patients with severe/multiple injuries, 2018). The average volume of hemorrhage in diaphyseal fractures is approximately 1.5 liters, which is equivalent to approximately 30% of the circulating blood volume in a 70-kg adult individual (MITCHNIK et al., 2022). Immobilization of the affected region in trauma is an important pre-hospital intervention and must be performed before transport (DAVIS et al., 2020).

Mobilization for transport of the victim must be performed after stabilization of the fractured limb, with the use of long boards and accessory immobilizations (16) (DAVIS et al., 2020.) (Level 3 guideline on the treatment of patients with severe/multiple injuries, 2018). Immobilization with or without traction is already established in pre-hospital care (Howland IR et al 2019). The use of traction has the advantage of reducing muscle spasm near the fracture site, generating pain relief (ELLERTON, J. et al, 2019) (AMERICAN COLLEGE OF SURGEONS, 2018).

(SYME, K, 2020). An important fact that contraindicates the use of immobilizers with or without traction is the lack of training of first responders (CAMPAGNE et al., 2020). This may even delay rescue, generating risks to the patient (AMERICAN COLLEGE OF SURGEONS, 2018). It is necessary to assess the neurovascular risk in traction of the affected limb. In polytraumas, due to high energy, there is direct injury to the tissues and there may be secondary injuries through the fractured bone surfaces, generating a greater risk of vascular damage (Pottecher J et al 2021) (NATIONAL ASSOCIATION OF EMERGENCY MEDICAL TECHNICIANS (U.S.), 2022).

In the journey of the individual victim of trauma from the scene to the first hospital care, the pain caused by the fracture is relevant in the patient's experience (SYME, K, 2020). Pain, on the analog scale (0 - 10), reported upon arrival at the care unit due to suspected/fractured hip, was on average 7.2 points, and was also attributed to transport (Wennberg P et al 2018). Comparatively, in diaphyseal fractures of the femur, only 22% of 170 patients required intravenous analgesia (Nackenson J, 2017). The use of immobilizers with traction was superior to those without traction in the parameter of pain control in the first and sixth hours after placement (p=0.0001) (IRAJPOUR, A. et al 2012). The use of immobilization in an appropriate manner, in itself, brings comfort to the patient ((NATIONAL ASSOCIATION OF EMERGENCY MEDICAL TECHNICIANS (U.S.), 2022) by reducing manipulation at the fracture site and restoring the anatomy prior to the trauma in the fractured limb. The most commonly used immobilizations with traction are originally for diaphyseal fractures ((AMERICAN COLLEGE OF SURGEONS, 2018)), in the middle third of the femur (Salminen ST et al, 2000).

The concept of immobilization for transport associated with traction was introduced in 1870, by Hugh O Thomas, and was widely used successfully for the rescue and initial care of trauma in World War I and subsequent non-surgical treatment due to its stabilization capacity and practicality (Agrawal Y, 2009). The Sager model, developed a century later, is better suited for fractures of the proximal femur, using an external mechanism for traction with a reference of 10-15% of the patient's body weight (Davis DD et al, 2023).

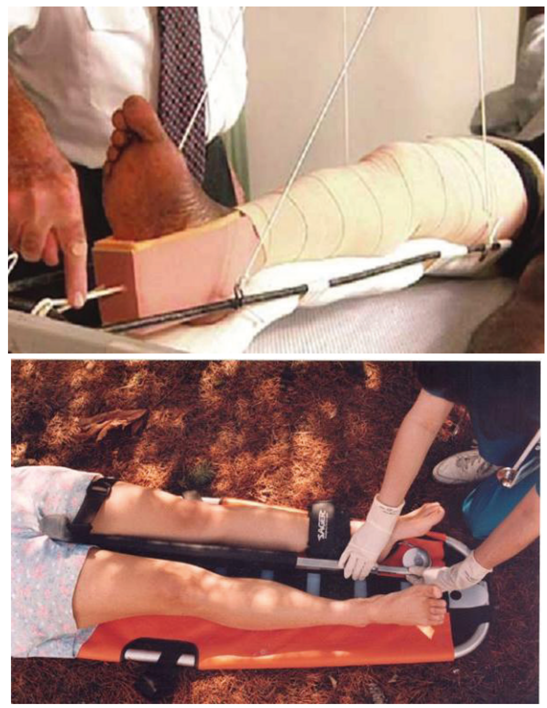

Figure 2: Immobilization developed by: a) Thomas (https://media.aofoundation.org/-/jssmedia/surgery/32/32_p010_i340.png?w=620); b) Sager (https://sagersplints.com/wp-content/uploads/2020/02/301-2.jpg)

METHODOLOGY

Analytical study of a temporary proximal femur immobilization device developed and patented under number BR 10 2022016107 0 at the National Institute of Industrial Property-INPI, with maturity level II, for trauma care in out-of-hospital settings, during removal and initial hospital care

For comparison, a literature review was carried out, based on a comprehensive search of scientific articles and relevant studies related to advances in temporary immobilization and traction techniques of the proximal femur. From the scientific databases PUBMED and SCIELO, with the keywords, being descriptors in health sciences (DeCS) "trauma", "femur immobilization", "femur traction", "pre-hospital care".

The initial selection of studies was carried out based on titles and abstracts, excluding articles that were clearly not related to the topic of interest or that were duplicates. Then, the remaining articles were subjected to a complete reading to assess their relevance for the review. Studies that specifically addressed techniques for temporary immobilization of the proximal femur by traction in pre-hospital care were included in the review. The languages were English, Portuguese and Spanish. Relevant data from the included studies were systematically extracted, allowing a comparative analysis of the results between them and with the patented model, in addition to a synthesis of the main scientific evidence available.

RESULTS

The Temporary Immobilization Device with Traction for Femur – ITTF, with emphasis on proximal femur fractures and the possibility of being used for lower limb fractures, is composed of a fixed portion (1) formed by the base plate (1a), an intermediate plate (1b), an upper plate (1c) and a mobile portion, the extension plate (2). It has a plurality of holes (2a) and longitudinal slits (2b) and two lower supports that level it.

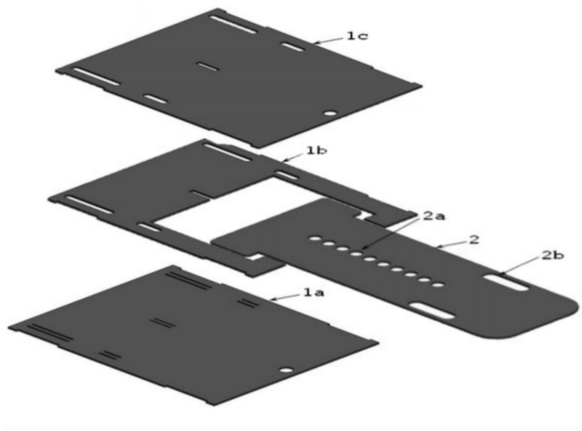

Figure 3: Initial assembly diagram of the device and its components

Source: the author

This retractable device is pre-assembled, with the length varying according to the size of the components. Designed for use on adults, the fixed plate (1) is 40 cm to 80 cm by 50 cm to 80 cm wide and the extension plate (2) is 70 cm to 100 cm long and 20 cm to 40 cm wide. The thicknesses are approximately 20 mm. The plates have grooves and recesses so that the self-adhesive fabric strips can be passed through to attach the victim to the device and the entire assembly to the long transport board.

The rigid parts of the temporary removal device are made of thermoplastic polypropylene (PP) material, chosen due to its radiotransparency, machinability, high chemical and solvent resistance, affordable cost and satisfactory mechanical properties to be subjected to traction with low deformation and low risk of fatigue fracture. Furthermore, it is recyclable, which guarantees the sustainability of the product (FILHO, P, 2023).

For attachment to the trauma victim, the device has straps made of self-adhesive material such as Velcro®, including a pelvic strap (3) measuring 20 mm wide and 1.5 m long; two internal straps (4), two external straps (5) and at least two foot straps (7) made of 15 mm by 1.5 m Velcro; at least two foam pads (8) in the ankle and hindfoot support area and a support base (9) fixed to the extension plate (2). After traction is applied, it will be maintained using the locking pin (6).

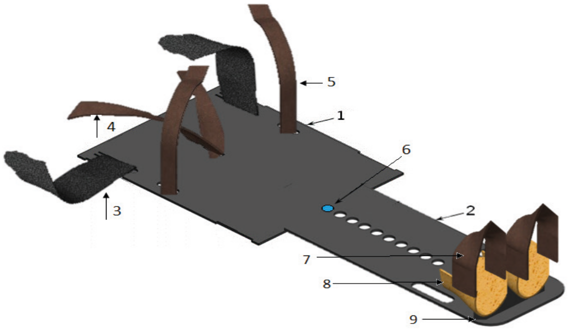

Figure 4: Temporary Immobilizer with Traction for Femur – ITTF and its components

Source: the author

The choice of self-adhesive strips of material forms an efficient support point to stabilize the pelvic girdle and proximal thigh region on the medial and lateral sides. In addition, the arrangement of the medial strips tends to promote the correction of rotation forces, keeping the lower limbs in neutral. The minimum width of 15 mm on the strips aims to increase the contact area, reducing local pressure and preventing injuries. Velcro ® or similar strips are easily found at a relatively low cost, which is advantageous for production logistics and the final price of the product. An alternative to this material would be the use of Neoprene ® analogues.

During the approach to the trauma victim, according to all protocols (AMERICAN COLLEGE OF SURGEONS, 2018) (Level 3 guideline on the treatment of patients with severe/multiple injuries, 2018); (Fire Department of the State of Rio de Janeiro, 2018), block movement is necessary to use the long removal board. At this point, above the board with the open straps, the temporary femoral traction immobilizer (TFTI) should be placed so that, when the patient is resting, the most cranial portion of the board is at the level of the lumbosacral region. Because it is designed with a low profile, the TFTI tends not to cause discomfort to the patient when lying on the back of the device.

The straps are placed intuitively by the rescue professional and should be done before adjusting the straps of the removal board on the patient. The Velcro® or similar material straps on plate 1 fit into the components base plate (1a), intermediate plate (1b) and upper plate (1c). The pelvic strap (3) emerges laterally and has as anatomical landmarks, on the lateral portion, the upper region of the greater trochanter and the iliac crest. Its purpose is to stabilize the patient proximally for traction on the lower limbs. The internal straps (4) have a "Y" shaped profile when installed. They start from the medial aspect of the thighs towards the iliac crests, always taking care to keep them away from the genital region. They should be attached after the rotation of the fractured lower limb has been corrected, which is their purpose. The external straps (5) have a side-to-side path, starting from the lateral aspect of the thigh and being attached from the contralateral iliac crest. It is important to note that they do not form a point of ischemia in the proximal part of the lower limb, as they pass at a different level from the internal strap (3) and the posterior portion of the thigh is not involved. When adjusted to the patient, the external straps (5) form an "X", which is attached to the internal strap (4) and the pelvic strap (3).

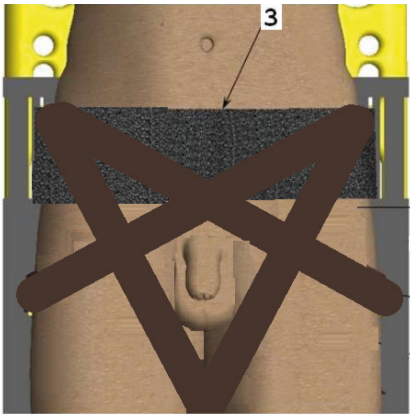

Figure 5: ITTF assembled with adjusted proximal strips. Highlight the independence of the device in relation to the removal board.

Source: the author

On the extension plate (2), in the portion close to the feet, there is support for the posterior portion of the ankles and feet, with each fixed base (9) in the shape of the letter "U", with foam that supports and protects the posterior region of the feet and ankles. Once the straps are in place, the neurovascular assessment of the lower limbs is performed. After this, traction can be performed in the caudal direction using the lateral supports (2b), always monitoring the distal pulses and the patient's discomfort due to the pain stimulus. Once the extension plate has been extended, it is fixed in position by the locking pin (6) in the holes (2a). (FIGURE 6)

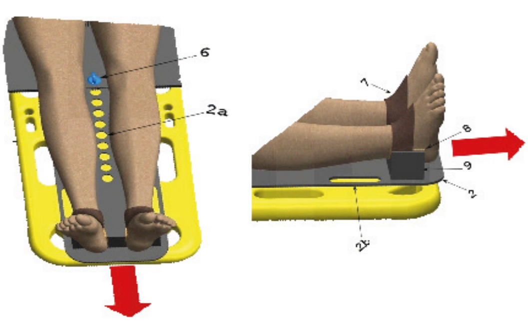

Figure 6: ITTF assembled with adjusted distal straps and direction for traction. Highlight for the ability to perform expansive ankle support for the feet. Source: the author

DISCUSSION

This stabilization method associated with traction has contraindications for musculoskeletal injuries in the knee with damage to the extensor mechanism, joint instability in the knee or ankle of the limb to be tractioned (18).

This device is contraindicated for pediatric patients due to size limitations; for victims of multiple trauma with high scores in the Injury Severity Score - ISS or Trauma Score and Injury Severity Score - TRISS criteria, due to severe, critical or life-threatening injuries due to the urgency required for care, with the orthopedic approach being secondary in the process of maintaining life and controlling damage. Finally, deformities in the pelvic ring due to LC-III injuries of the Young and Burgess classification (lateral compression with ipsilateral and contralateral open-book ligament/sacroiliac injury) because they are unstable and the pelvic belt may be able to further alter the instability. It is important to emphasize that the purpose of this immobilizer is not to stabilize the pelvic ring in fractures of this type. In addition, distal femoral fractures with large deviations in the anteroposterior direction are complex reduction fractures and, therefore, the device may not be sufficient to perform it under maintained traction. In these cases, we recommend the use of a cushion for support in the popliteal region, always monitoring the neurovascular status of the affected lower limb. The Thomas device (Figure 2a) differs from the developed device in that it does not support the lower limbs bilaterally and does not exert traction independently of external devices. The Hare method (Figure 7a), widely used in rescue services in the United States (DEYULIS; HINSON, 2023), consists of two traction poles placed parallel to the fractured limb, as in the Thomas model, and Velcro ® or similar straps providing stabilization and distributing the external traction force. The differences in the proposed model are: the number and arrangement of the Velcro straps and the non-use of traction poles near the fractured limb.

This allows for constant neurological and vascular monitoring, as well as reduced contact between possible wound areas and immobilization material. In addition, the fact that the proposed device acts as a continuous support from the posterior pelvic region allows for better distribution of traction forces.

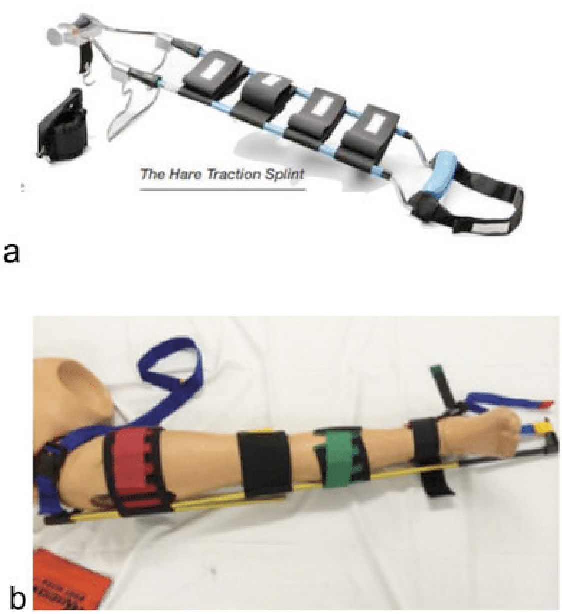

Figure 7: a) Lower limb traction and immobilization device Hare model (Source: Traction: principles and application - RCN guidance); b) Kendrick Traction Device (KTD) model (Source: https://clinical.stjohnwa.com.au/clinical-skills/trauma/traction-splints/kendrick-traction-splint)

Another notable difference is that the aforementioned traction immobilization methods are effective mainly in diaphyseal fractures of the femur. The temporary femur immobilization device also proposes stabilization in the proximal portion. The Kendrick Traction Device (KTD) model (Figure 7 b) is a lighter and more foldable prototype of the principle of immobilization and traction for lower limbs. However, its placement is time-consuming and requires training due to the assembly of straps and the lateral traction bar. In addition, it is not radiolucent like the proposed one.

A recent model that managed to combine the basic principles of Thomas, Hare and KTD was patented in 2015 under the name Specific Immobilization Device (DIE) (Matullo KS et al 2016) (Figure 8a). It differs from the proposed model for the same reasons as the original devices.

Patented in 2017, the Bishop Traction Splint Device (BTSD) (Bishop JM, 2017) (8b) differs from the proposed device in that it is unilateral and indicated for femoral fractures from the diaphysis.

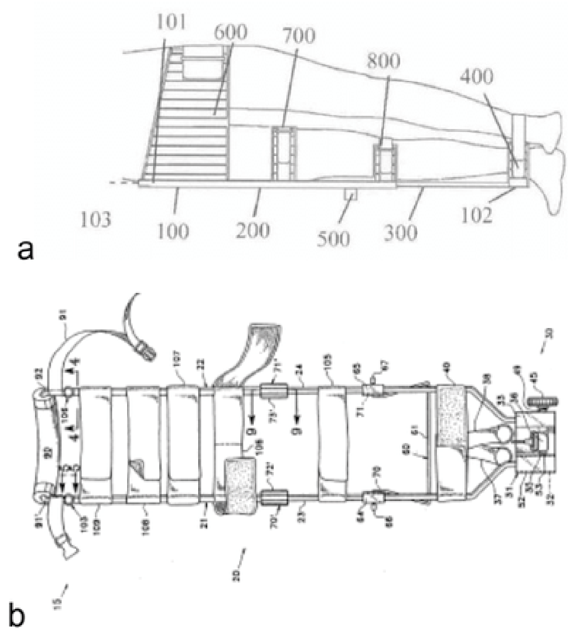

Figure 8: a) lower limb traction and immobilization device model DIE (Source: Spanish Patent and Trademark Office - Publication number: 2 619 419; b) – lower limb traction and immobilization device model BTSD (Source: Traction: principles and application - RCN guidance.

CONCLUSION

This device aims to fill the commercial gap in lower limb immobilizers for pre-hospital treatment of proximal femur fractures with associated traction.

The characteristics of this patented device are poorly supported by the immobilizers with proximal femur traction available on the market. In addition to this potential, it also stabilizes the fracture site and provides comfort to the patient, as well as safety in handling the victim, from the trauma scene to initial care in the hospital unit, without delaying the time to emergency care.

The Temporary Immobilizer with Traction for the Femur – ITTF does not alter the patient's mobilization pattern in a "block" at the trauma scene, as it is attached between the patient and the removal board, favoring the recovery of the anatomy lost in the lower limb fracture, evolving with neurovascular safety and less pain.

The ITTF emerges as an economically viable option due to the material used in its manufacture and with potential for commercial acceptance because it encompasses fractures of the proximal portion of the femur.

Victims may benefit from initial care and removal with the temporary immobilizer with femoral traction until they are evaluated radiographically, as it is radiolucent, and the orthopedic approach defined in the intra-hospital environment.

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