Issued by (Name/Signature) Katarina Ortfelt	Date
Katarina Ortfelt	**2025-10-20**
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Niclas Brissman	**2025-10-20**

LITERATURE SEARCH REPORT

Product: Qvicktrak System

Scope of the literature search: This literature search has been conducted according to [3] MEDDEV. 2.7.1 Rev.4, SOP Clinical evaluation.

Data retrieval

The search of data of safety and performance of QvikTrak system is done by evaluating data in terms of its suitability for establishing the safety and performance of the device.

Data from equivalent and similar devices was used if the device has similar intended use and the technical and biological characteristics are similar to product name.

The clinical evaluation is based on verification of the claim that the product is designed for support and traction to fractures in the leg, hip fracture at the femoral neck, femur fracture and lower leg fracture during the pre-hospital care and patient transport.

Based on the data generated from the literature the purpose is to find proofs that QvikTrak is comparable with similar, existing products on the market, a safe product, fulfilling the essential requirements and all risks identified have been properly mitigated.

CRITERIA FOR APPRAISING DATA

The appraisal has been conducted using the following method:

A) The title of the article shall indicate that the article fulfil at least one of the following criteria:
   1. The article contains scientific analysis based on data from equivalent and similar devices was used to support the safety and performance of the traction if the devices have the same intended use and the technical and biological characteristics are similar
   2. The article includes the search term in the title

B) The age of the articles covers from 2015-2025

C) The article shall content data from equivalent and similar devices and will provide a valuable contribution

D) The content of the article shall provide meaningful contribution to the literature evaluation

Literature search

Search period: 2015 - 2025

Name of person(s) undertaking the literature search: *Katarina Ortfelt,* Evaluator

Data from equivalent and similar products was used to support the safety and performance of Qvicktrak, if the products have the same intended use and the technical and biological characteristics are similar.

Literature source to identify data:

- Scientific data bases: bibliographic (PUBMED)

Justifications are included for choice of sources and describe any supplemental strategies (e.g. checking bibliography of articles retrieved, hand searching of literature) used to enhance the sensitivity of the search.

Key words

List key words such as “traction splint”, “femur”, “fracture”, “traction force”

The evaluation assessed the quality of the data sets and the extent to which the studies related to the specific characteristics and features of Qvicktrak. The collected data was appraised according to suitability (Table 1) and according to data contributions (Table 2).

All data sets collected were graded according to Table 1 and 2. As a general guide, the more level 1 grade, the greater the weight of evidence provided by the particular data set in comparison to other data sets. In Table 1 and 2 also the grades needed for a data set to be used to support the clinical evaluation of AGHT is included. Data sets that don’t receive these grades are not specific enough to concern AGHT.

Table 1. Suitability Criteria

Suitability Criteria	Description	Grading System	Grades needed to be a part of the evaluation
Appropriate device	Was the data generated from the device in question?	D1 Equivalent device D2 Similar device D3 Other device	D1, D2 or D3
Appropriate device application	Is the intended use the same?	A1 Same use A2 Minor deviation A3 Major deviation	A1, A2 or A3
Appropriate patient group	Was the data generated from a patient group that is representative of the intended treatment population?	P1 Applicable P2 Limited P3 Different population	P1,P2 or P3
Acceptable report/data collation	Does the retrieved data contain sufficient information	R1 High quality R2 Minor deficiencies	R1 or R2

	to enable a rational and objective assessment?	R3 Insufficient information	

Table 2. Data contribution criteria

Data Contribution Criteria	Description	Grading System	Grades needed to be a part of the evaluation
Data source type	Was the design of the study appropriate?	T1 Yes T2 No	T1 and T2
Outcome measures	Do the outcome measures reported reflect the intended usage of the device?	M1 Yes M2 No	M1
Follow up	Is the follow-up time long enough to assess whether long term treatment causes complications?	F1 Yes F2 No	F1
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1 Yes S2 No	S1
Clinical significance	Was the treatment effect observed clinically significant?	C1 Yes C2 No	C1

Results of Data sets meeting the criteria

Table 1&2 summarizes all data sets found that met the grades needed for a data set to be used for evaluation of the safety and/or performance concerning Qvicktrak.

Table 3. Data found to support or reject the safety and/or performance evaluation of Fel! Hittar inte referenskälla.

#	Title	Supports claim	Safety or Performance (S/P)	Number of level 1 grades	Summary of key results concerning Safety and/or Performance
1	See articles below:	Clinical evidence supports the claims of Qvicktrak system intended use.	S&P	D3, A1, P1, R1, T1, M1, F2, S1, C1	The literature supports the indiction in the treatment for traction of injured leg, hip
2	See articles below:	Clinical evidence support reducing the pain and bleeding which is the intention with Qvicktrak system	S&P	D2, A1, P1, R3, T1, M1, F1, S1, C1	The article evaluates if correction can be achieved by alight weight, low cost, easy to assemble, promotes immediate movement of

					the affected limb after assembly
3	See articles below:	Clinical evidence is comparable to Qvicktrak system	S&P	D1, A1, P1, R3, T1, M1, F2, S1, C1	This articles is an usability review of an useful technique for managing proximal femur fractures
4	See articles below:	Clinical evidence supporting encounting a femoral fracture as well as when the time to definitive treatment is long.	S&P	D1, A2, P1, R1, T1, M1, F1, S1, C1	The article is a a systematic review r the effeofts of TSs on pain, while five reported that the use of a TS was appropriate.
6	See articles below:	The purpose of this study was to determine the differences between the four commercially available traction devices sold to the U.S. Government	S&P	D1, A1, P1, R2, T1, M1, F1, S2, C1	The article assessing the efficiency and safety of different traction devices on the US market
7	See articles below:	Clinical evidence support that Qvicktrak system has been shown to significantly improve the pain intensity depending of simple and traction splints	S&P	D1, A1, P1, R1, T1, M1, F2, S1, C1	The article is a comparison of the pain intensity resuction using simple and traction splints
8	See articles below:	A review search looking at the the effects of skin traction advantages and disadvantages in adult patients with proximal femur fractures	S&P	D3, A2, P1, R1, T1, M1, F1, S2, C1	The article is a literature review using The search was done in the databases PubMed, CINAHL, Cochrane, Embase, DOAJ, ClinicalTrials.gov and OpenDissertation. where details of skin traction characteristics such as pain reduction, and skin damages were analyzed
9	See articles below:	The article evaluates the frequency of concomitant injuries that can	S&P	D1, A1, P1, R1, T1, M1, F1, S2, C1	The article concludes that routine use of skin traction does not appear

		complicate and/or contraindicate the use of traction splints (TSs) for femur fracture immobilization (FFI) in a population of multisystem trauma patients.			recommended, but more consistent evidence is necessary to make clinic decisions. The possible advantage is pain reduction between 24 and 60 h.
10	See articles below:	Study Objectives Traction splinting has been the prehospital treatment of midshaft femur fracture as early as the battlefield of the First World War. This study is the assessment of these injuries and the utilization of a traction splint (TS) in blunt.	S&P	D1, A1, P1, R1, T1, M1, F1, S2, C1	Statistically significant differences were found in the utilization of a TS and IV analgesia administration in the setting of blunt trauma when compared to penetrating trauma.
11	See articles below:	These alternative modalities of analgesia are an area for further research to determine if there is a more superior method of analgesia for femur fractures than what is currently being performed by paramedics.	S&P	D1, A1, P1, R3, T2, M2, F1, S1, C1	Our review topic of interest was primarily pain management and success rate of interventions provided to patients in the prehospital setting who have suffered a NOF or femur shaftfracture by non-physicians exclusively. Studies investigated a variety of interventions including traction splints, intravenous (IV) analgesia and alternative analgesic options

12	See articles below:	Clinical evidence support the conclusion that the traction lower LOS and mortality	S&P	D1, A1, P1, R3, T2, M2, F1, S1, C1	This study aimed to evaluate the benefit of prehospital TS (PTS) application. Hospital length of stay (LOS) was found to be significant (P = 0.05) between the patients who received a hospital TS (3.10 ± 1.709) and NTS (5.42 ± 5.144).
13	See articles below:	The clinical evidence support partly the Qvicktrak system; the article do not support urgent prehospital leg traction splinting which may result in delayed evacuation to definitive care.	S&P	D1, A1, P1, R1, T1, M1, F1, S1, C1	The article sought to understand the association between FSF and shock, and identify risk factors for shock among casualties with FSF.
14	See articles below:	Clinical evidence support skelectal traction as a treatment and correlates to the Qvicktrak system	S&P	D1, A1, P1, R1, T1, M1, F1, S2, C1	The articles conclude that traction still has some role in current practice as temporary treatment, pre, intra, and postoperative periods in orthopedics and trauma
15	See articles below:	Clinical evidence support the intended use of traction splint which correlates to the Qvick trak system	S&P	D1, A1, P1, R1, T1, M1, F1, S2, C1	.The article concludes that Traction splint is a useful emergency tool to align the femur fracture better, increase arterialblood flow, decrease pain and spasm, and reduce the risk of further injury from fractured bonefragments.
16	See articles below:	The clinical evidence correlates with Qvick trak system	S&P	D1, A1, P1, R1, T1, M1, F1, S2, C1	The article is a step by step guide in improvised femoral traction splint
17	See articles below:	The clinical evidence corrlates to Qvicktrak system	S&P	D1, A1, P1, R1, T1, M1, F1, S2, C1	The article is a Retrospective study of all adult patients with femoral shaft fractures

18	See articles below:	This is a comparison between QVicktrak and CT6/Kendrick TD/Slishman so the clinical evidence correlates	S&P	D1, A1, P1, R1, T1, M1, F1, S1, C1	The article is a Comparison Qviktrak and CT6/Kendrick TD/Slishman

PUBLICATIONS

1: A Novel Traction Frame for Femur Fracture Management in Developing Countries: Technique and Outcomes

David M Levy [1], Molly C Meadows, Dennis J Gates

Abstract

Objective:

Fractures of the femur have long been a major cause of morbidity and mortality in developing countries and are most frequently caused by road traffic accidents. Intramedullary nail fixation has become the gold standard of care for diaphyseal fractures of the femur. However, modern techniques require proper implants, access to imaging, and accessible operating room facilities, all of which have limited availability in the developing world. We describe a new technique for assembly of a polyvinyl chloride traction frame for treatment of femur fractures in resource-poor settings. Our report includes a retrospective review of patients treated with polyvinyl chloride traction frames in the Dominican Republic and Haiti.

Materials and methods: This study is a review of patients treated with polyvinyl chloride traction frames in the Dominican Republic and Haiti.

Results:

Conclusion:

2: Application of PVC pipes as an adjustable bilateral traction device in lower limb fractures

Hongshuo Sun, Peng Li, Gangqiang Du, Jianhao Jiang, Kaikai Song, Hongzhi Liu, Xinjun Zhang, Long Jia, Kai Zhang, Shuye Yang, Zhigang Wang

Abstract

Objective:

To introduce a new type of simple adjustable bilateral bidirectional polyvinyl chloride (PVC) tube traction device and discuss the value of using this device before surgery in patients with lower limb fractures. In this work, we evaluated a new type of bilateral traction device with PVC tubes, it is suitable for patients with lower leg fractures before operation temporary treatment, especially patients with lower limb fractures who are in intensive care and neurosurgery units MRI examination is required while receiving treatment. This device is lightweight, inexpensive and easy to assemble. Its greatest advantage is that the affected limb can be moved immediately after installation, so the limb is no longer limited to the traction bed. It is also convenient for nursing and improves the comfort of patients. In addition, the device can be used with titanium steel needle for MRI inspection under traction.

Materials and methods:

To introduce the manufacturing process of an adjustable bilateral traction device made of PVC pipes. From August 2018 to November 2019, the data of 36 patients with lower limb fractures who were treated with this traction device were retrospectively analysed. The treatment outcomes were analysed, including length of both lower limbs, fracture reduction, lower limb mobility, visual analogue scale (VAS) score, incidence of complications, and patient satisfaction.

Results:

All patients were able to move the affected limb immediately after using the device. The patient's pain was significantly reduced, they were able to turn over freely during bed rest, and the length of the affected limb was restored to that of the healthy limb. Thirty-four (94.5%) patients were satisfied with the reduction of the fracture end, 2 (5.5%) patients with tibiofibular fractures showed angular displacement of the fractured end and satisfactory reduction after the position of the bone traction needle was adjusted; 7 (19.5%) patients developed deep vein thrombosis of the affected lower limb during traction; there was no decubitus or vascular nerve injury, and the overall complication rate was 25% (9/36). All the patients and their families were satisfied with the results of this treatment.

Conclusion:

The aim of this study is to introduce a new type of traction device. It is advantageous in that it is light weight, low cost, easy to assemble, promotes immediate movement of the affected limb after assembly, improves patient comfort and can be used with a titanium steel needle for MRI examination under traction. In the clinical setting, it has been shown to be suitable for the temporary treatment of patients with lower leg fractures prior to surgery, particularly patients who, for various reasons, require nonsurgical treatment in the short term.

3: A Skeletal Traction Technique for Proximal Femur Fracture Management in an Austere Environment

David Lidwell, Colin A Meghoo

Abstract

Objective:

Skeletal traction is a useful technique for managing proximal femur fractures in austere environments where fracture stabilization for this injury is difficult. We present a technique and a construct appropriate for field use that facilitates patient evacuation, and we provide guidelines for the use of this technique by an advanced medical provider managing these injuries. The objectives of this article are to enable to reader to (1) recognize the role of skeletal traction in managing proximal femur fractures in an austere environment, (2) identify the key steps in placing transfemoral skeletal traction pins, and (3) identify options and requirements for building a traction construct in resource-limited environments.

Materials and methods:

A plain radiograph was used to identify the nature and extent of this patient's bony injury, as well as aiding in excluding associated pelvic or acetabular injuries (Figure 1). Without this capability, the medical provider must rely on the suspected mechanism and associated physical examination findings to suggest the specific injury. In those circumstances where a fracture is strongly suspected but where the precise proximal extent of the injury to the proximal femur is unknown, skeletal traction is quite useful.

Results:

The principles of initial fracture management in an austere setting include fracture stabilization, pain control, prevention of infection, and prevention of further injury. Stabilization of femur fractures in an austere environment where advanced medical care is available is facilitated by an arsenal of techniques ranging from splinting devices to external fixation. However, these standard strategies are often inadequate for peritrochanteric femur fractures. Hare traction splints or similar devices are bulky and often unavailable, and their application confers risk of significant skin breakdown, especially with prolonged evacuation. These traction devices are contraindicated for proximal femur fractures if concomitant ipsilateral knee or tibial injury is present. External fixation is of limited value for proximal fractures, mostly because of the difficulty of placing pins proximal to the fracture. The potentially morbid option of hip-spanning pin placement requires sufficient equipment and clinical experience, as well as an uninjured ipsilateral iliac crest and wing, to be successful.

Conclusion:

Skeletal traction is useful in the management of proximal femur fractures in an austere operating environment. The technique is readily learnable and, coupled with some adaptive ingenuity, is essential for the advanced medical provider with limited resources caring for patients with these complex injuries.

4: Traction Splinting for midshaft femoral fractures in the pre-hospital and Emergency Department environment-A systematic review

Sarah P J Philipsen [1], Arie A Vergunst [2], Edward C T H Tan [3]

Abstract

Objective:

Pain and hemorrhage are common in midshaft femoral fractures. Traction splints (TSs) can reduce pain and control hemorrhage, but evidence of their effectiveness in femoral fractures is still lacking. Through a systematic review, we aimed to analyze and discuss the potential role of TSs in the prehospital and emergency department (ED) setting.

Materials and methods:

The Embase, CINAHL, Cochrane, and PubMed databases were searched up to January 2022. All studies on femoral fractures in the prehospital or ED setting that compared TSs with immobilization or no intervention were included. Articles not written in English, German, or Dutch were excluded. Two authors screened all articles, assessed their quality, and included them if both agreed on their inclusion. The risk of bias was assessed using the modified Methodological Index for Non-Randomized Studies (MINORS). The primary outcome measures were pain and hemorrhage control, while the secondary outcome measures were survivability, morbidity, and complications.

Results:

A total of 1,248 articles matched the search strategy, 24 articles were assessed for eligibility based on their abstracts, resulting in 20 articles being included in the synthesis. Ten articles reviewed the effects of TSs on pain, while five reported that the use of a TS was appropriate. All five articles that reviewed blood loss found benefits from the use of a TS. One study found significantly fewer pulmonary complications in patients who were splinted earlier at the scene of injury (level III). No difference was found in complications or mortality between prehospital patients receiving a TS or no TS (level III). None of the studies noted that TSs were a necessity in the ED setting; however, some argued that a TS is a necessary and useful prehospital tool in rural or military areas.

Conclusion:

TS use is associated with a decreased necessity for blood transfusions and fewer pulmonary complications. No favorable effects were found in terms of pain relief. We recommend the use of TSs in situations where one is likely to encounter a femoral fracture as well as when the time to definitive treatment is long. Further well-designed studies are required to validate these recommendations.

6: Evaluation of commercially available traction splints for battlefield use

Nicholas M Studer, Seth M Grubb, Gregory T Horn, Paul D Danielson

Abstract

Objective:

The purpose of this study was to determine the differences between the four commercially available traction devices sold to the U.S. Government.

Materials and methods:

After standardized instruction, subjects were timed and evaluated in the application of each of the four listed splints. Participant confidence and preferences were assessed by using Likert-scaled surveys. Free response remarks were collected before and after timed application.

Results:

Subjects had significantly different application times on the four devices tested (analysis of variance [ANOVA], p<.01). Application time for the STS was faster than that for both the CT-6 (t-test, p<.0028) and the RS (p<.0001). Subjects also rated the STS highest in all post-testing subjective survey categories and reported significantly higher confidence that the STS would best treat a femoral fracture (p<.00229).

Conclusion:

The STS had the best objective performance during testing and the highest subjective evaluation by participants. Along with its ability to be used in the setting of associated lower extremity amputation or trauma, this splint is the most suitable for battlefield use of the three devices tested.

7: A comparison between the effects of simple and traction splints on pain intensity in patients with femur fractures

Alireza Irajpour[1], Nariman Sadeghi Kaji, Fatemeh Nazari, Reza Azizkhani, Akbar Hassan Zadeh

Abstract

Objective:

Fractures of femur are among the most important causes of mortality in musculoskeletal injuries. Owning to lack of adequate research to compare various techniques of fracture stabilization, there has not yet been an agreement over a protocol to utilize a specific type of splint for femoral fracture immobilization. This study was thus conducted to compare the effects of simple and traction splints on pain intensityimmediately after and at the 1(st), 6(th), and 12(th)h after splinting among patients with femur fracture in the centers affiliated to Isfahan University of Medical Sciences (Isfahan, Iran).

Materials and methods:

This quasi-experimental study was performed on 32 patients with femur fractures. Prehospital emergency ambulances were divided into two groups of simple and traction splints using a table of random numbers. Continuous convenient sampling was employed in each group to use either a simple or a traction splint for the patients with femur fractures. Pain intensity of the patients was then measured by a visual analogue scale (VAS) immediately, 1 h, 6 h, and 12 h after splinting. The effects of the two techniques were finally compared.

Results:

After splinting, pain intensity decreased significantly in both groups (P = 0.0001 in both groups). The reductions were significantly more in the traction splint group at the 1(st), 6(th)(P = 0.0001), and 12(th)h after splinting (P = 0.02) compared with the simple splint group. There was no significant difference in pain intensity immediately after splintingbetween the two groups (P = 0.441).

Conclusion:

The significant difference in pain reduction between the simple and traction splint groups at the 1(st), 6(th), and 12(th)h after splinting emphasizes the superiority of traction splints.

8: The use of skin traction in the adult patients with proximal femur fracture. What are the effects, advantages and disadvantages? A scoping review

Melania Miedico[1], Fabrizio Quattrini[2], Salvatore Emanuele Attardo[3], Margherita Marchioni[4], Maria Chiara Bassi[5], Enrico Lucenti[1], Leopoldo Sarli[4], Massimo Guasconi[6]

Abstract

Objective:

Hip surgery is normally the chosen therapy for proximal femur fractures. Surgery within 24-48 h after hip fracture is recommended, but surgery may not always be performed promptly. Consequently, skin-traction is applied to reduce complications. The purpose of this review is to assess both advantages and disadvantages of skin traction.

Materials and methods:

A scoping review was conducted. The research question was: which are the effects of skin traction, its advantages and disadvantages in adult patients with proximal femur fractures hospitalised in orthopaedic wards? The search was done in the databases PubMed, CINAHL, Cochrane, Embase, DOAJ, ClinicalTrials.gov and OpenDissertation.

Results:

9 records were included, skin traction effects were summarised in 7 categories: pain, pressure sores, comfort and relaxation, thromboembolism, damage from adhesive, complications and quality of care. The possible advantage is pain reduction between 24 and 60 h, the possible disadvantage is skin damage.

Conclusion:

The routine use of skin traction does not appear recommended, but more consistent evidence is necessary to make clinic decisions. Future RCTs could focus on the effects of skin traction 24-60 h after hospitalisation and before surgery.

9: Femur fracture immobilization with traction splints in multisystem trauma patients

Stephen P Wood [1], Mark Vrahas, Suzanne K Wedel

Abstract

Objective:

To evaluate the frequency of concomitant injuries that can complicate and/or contraindicate the use of traction splints (TSs) for femur fracture immobilization (FFI) in a population of multisystem trauma patients.

Materials and methods:

This was a descriptive, prospective study utilizing a data collection tool to identify patients with multisystem trauma for which a TS was in place for FFI. Patient care records and follow-up diagnoses were reviewed to identify patients with positive femur fracture(s) who concurrently had injuries that can complicate and/or contraindicate TS use. Injuries considered to complicate or contraindicate traction splint use include 1) pelvic injury, 2) patellar fracture or ligamentous knee injury, and 3) tibia/fibula fracture.

Results:

Forty patients were identified as having a TS in place with an underlying diagnosis of multisystem trauma. All 40 had follow-up diagnosis information available, 39 of which were positive for femur fracture on the side of the extremity on which the splint was placed, or bilaterally. The incidence of complicating and/or contraindicating injuries was 38%.

Conclusion:

Traction splints are commonly used in the prehospital and transport setting for immobilization of femur fractures. There are limited data available on the benefit of traction splint use for femur fracture in the prehospital or transport environment. This study identified that concomitant injuries that complicate and/or contraindicate traction splint use are common.

10: A Descriptive Analysis of Traction Splint Utilization and IV Analgesia by Emergency Medical Services

Joshua Nackenson [1], Amado A Baez [2], Jonathan P Meizoso [3]

Abstract

Objective:

Study Objectives Traction splinting has been the prehospital treatment of midshaft femur fracture as early as the battlefield of the First World War (1914-1918). This study is the assessment of these injuries and the utilization of a traction splint (TS) in blunt and penetrating trauma, as well as intravenous (IV) analgesia utilization by Emergency Medical Services (EMS) in Miami, Florida (USA).

Materials and methods:

This is a retrospective study of patients who sustained a midshaft femur fracture in the absence of multiple other severe injuries or severe physiologic derangement, as defined by an injury severity score (ISS) <20 and a triage revised trauma score (T-RTS)≥10, who presented to an urban, Level 1 trauma center between September 2008 and September 2013. The EMS patient care reports were assessed for physical exam findings and treatment modality. Data were analyzed descriptively and statistical differences were assessed using odds ratios and Z-score with significance set at P≤.05.

Results:

There were 170 patients studied in the cohort. The most common physical exam finding was a deformity +/- shortening and rotation in 136 patients (80.0%), followed by gunshot wound (GSW) in 22 patients (13.0%), pain or tenderness in four patients (2.4%), and no findings consistent with femur fracture in three patients (1.7%). The population was dichotomized between trauma type: blunt versus penetrating. Of 134 blunt trauma patients, 50 (37.0%) were immobilized in traction, and of the 36 penetrating trauma victims, one (2.7%) was immobilized in traction. Statistically significant differences were found in the application of a TS in blunt trauma when compared to penetrating trauma (OR=20.83; 95% CI, 2.77-156.8; P <.001). Intravenous analgesia was administered to treat pain in only 35 (22.0%) of the patients who had obtainable IV access. Of these patients, victims of blunt trauma were more likely to receive IV analgesia (OR=6.23; 95% CI, 1.42-27.41; P=.0067).

Conclusion:

Although signs of femur fracture are recognized in the majority of cases of midshaft femur fracture, only 30% of patients were immobilized using a TS. Statistically significant differences were found in the utilization of a TS and IV analgesia administration in the setting of blunt trauma when compared to penetrating trauma. Nackenson J , Baez AA , Meizoso JP . A descriptive analysis of traction splint utilization and IV analgesia by Emergency Medical Services.Prehosp Disaster Med. 2017;32(6):631-635.

11: Review article: Paramedic pain management of femur fractures in the prehospital setting: A systematic review

Samantha Davis [1 2], Alexander Olaussen [1 2 3 4], Kelly-Ann Bowles [1], Brendan Shannon [1 2]

Abstract

Objective:

Femur shaft and neck of femur (NOF) fractures are often undertreated in the prehospital setting. These injuries can present unique clinical and logistical concerns in the prehospital setting. This systematic review aimed to investigate paramedic prehospital pain management of patients who had suffered NOF or femur fractures, and to investigate which interventions are effective. A systematic review was conducted in line with Preferred Reporting Item for Systematic Reviews and Meta-Analyses guidelines. Four databases were searched from inception date 23 March 2020. Articles were independently reviewed by two authors and conflicts resolved by a third author, followed by a hand search of the included reference lists. References were included if they addressed paramedic interventions for NOF or femur shaft fractures. Outcomes of interest were the effectiveness and complications of different modalities administered by paramedics. The search yielded 6868 articles, of which 19 met the final inclusion criteria. Studies investigated a variety of interventions including traction splints, intravenous (IV) analgesia and alternative analgesic options. Traction splinting and IV analgesia were consistently reported as underutilised. Alternative analgesics such as auricular acupressure, transcutaneous electrical nerve stimulation (TENS) and fascia iliaca compartment block were found to be effective techniques that could be safely and competently employed by paramedics, reducing pain for patients with limited adverse events. NOF and femur shaft fractures are an undertreated injury in the prehospital setting. Traction splinting and IV analgesia remain the traditional methodologies of treatment for these injuries; however, there are alternatives such as TENS, auricular acupressure and fascia iliaca compartment block that appear to be emerging as safe and effective options for the prehospital setting.

Materials and methods:

Results:

Conclusion:

This review presents several approaches to the management of NOF and femur shaft fractures in the prehospital setting by paramedics.Traction splints and analgesia are often underutilised, and it is difficult to gain an accurate understanding of the efficacy of these interventions as studies did not consistently report on the reduction of pain scores as a primary outcome. Auricular acupressure and TENS provided a safe and non-invasive form of analgesia

based on reported patient pain scores pre- and postintervention, with no adverse events associated with either intervention. FICB appears to be a safe and effective intervention to assist in treating patients with NOF and femur shaft fractures, and has been implemented appropriately by paramedics in the prehospital setting. These alternative modalities of analgesia are an area for further research to determine if there is a more superior method of analgesia for femur fractures than what is currently being performed by paramedics.

12: Prehospital Traction Splint Use in Midthigh Trauma Patients

Danielle Campagne [1], Kathleen Cagle [1], Jannet Castaneda [1], Lori Weichenthal [1], Megann Young [1], Peter Anastopoulos [1], Susanne Spano [1]

Abstract

Objective:

This study aimed to evaluate the benefit of prehospital TS (PTS) application, using data from the trauma registry at a large Level 1 trauma center.

Traction splint (TS) use during emergency medical system transport has been theorized to relieve pain, limit continued injury from loose bone fragments, and decrease potential bleeding space in the injured thigh.

Materials and methods:

A retrospective review of patients from the NTRACS© and Trauma One© registry at an American College of Surgeons-verified Level 1 trauma center was conducted. All patients treated between the years 2001 and 2011 who were assigned a diagnosis International Classification of Diseases-9 code of 821.01 (closed fracture of shaft and femur) and 821.11 (open fracture of shaft and femur) (femur fracture [FF]) were included. All categorical variables between the first groups were compared using Pearson's Chi-square and Fisher's exact test analysis. Comparisons were made using unpaired *t*-tests and Mann-Whitney test or Kruskal-Wallis one-way ANOVA, followed by Dunn's *post hoc* pairwise comparisons.

Results:

Patients with a TS and those without indicated that the patients with no traction split (NTS) had sustained injuries beyond a FF (14.43 ± 9.740 vs. 18.59 ± 12.993, $P < 0.001$). The three groups of TS placement (PTS, hospital, and NTS) only used patients with Injury Severity Score < 9 ($n = 218$). Hospital length of stay (LOS) was found to be significant ($P = 0.05$) between the patients who received a hospital TS (3.10 ± 1.709) and NTS (5.42 ± 5.144).

Conclusion:

PTS can lower LOS and mortality. Further research is needed to confirm these findings.

13: Femur fractures and hemorrhagic shock: Implications for point of injury treatment

Ilan Y Mitchnik [1], Tomer Talmy [2], Irina Radomislensky [3], Yigal Chechik [4], Amir Shlaifer [5], Ofer Almog [2], Sami Gendler [6]

Abstract

Objective:

Femur shaft fractures (FSF) are perceived as potentially life-threatening injuries due to significant blood loss. However, these injuries are rarely the sole cause of hemorrhagic shock. Clinical practice guidelines for the prehospital management of FSF are inconsistent, especially concerning the use and timing of traction splinting which is postulated to reduce bleeding. We sought to understand the association between FSF and shock, and identify risk factors for shock among casualties with FSF.

Materials and methods:

This is a retrospective analysis of trauma casualties treated by Israeli Defense Forces (IDF) medical teams between the years 2000-2020 and suffering from isolated FSF. Prehospital data from the IDF-Medical Corps Trauma Registry was merged with hospitalization data from the Israeli National Trauma Registry. Isolated FSF was analyzed by excluding casualties with an Injury Severity Score ≥ 16 and an Abbreviated Injury Scale ≥ 3 in other anatomical regions. Shock was defined as systolic blood pressure ≤ 90 mmHg and/or heart rate ≥ 130 beats per minute. A case series review was performed for casualties in shock with isolated FSF injuries. Multivariable logistic regression was performed to assess for injury characteristics associated with shock.

Results:

During the study period, we identified 213 patients with FSF (4.9%) of which 129 were isolated injuries. Overall, 9.9% and 26.3% of casualties had concurrent thoracic and abdominal injuries, respectively. Most FSF were due to motor vehicle accidents (60.1%) and shock was present in 17.1%. In isolated FSF patients, gunshot and explosive injury mechanisms were prevalent (65.0%) with severe shock being present in 8.5%. Open fractures were present in 72.7% of isolated FSF patients in shock. Open FSF injuries were characterized by prehospital bleeding which was difficult to control. In a multivariable logistic regression model, severe concomitant injuries were associated with increased odds of shock.

Conclusion:

Shock rarely presents when FSF is the primary injury. Such casualties predominantly suffer from open FSF which may present as difficult to control thigh bleeding. Our findings do not support urgent prehospital leg traction splinting which may result in delayed evacuation to definitive care. Casualties with shock and FSF should be investigated for other sources of bleeding. Leg traction splinting should be reserved for suspected FSF injuries with shock or persistent thigh bleeding.

14. A Review on Traction in Orthopedics

Adarsh GS*, Preeti V Kulkarni, Venkatrao H Kulkarni, Venkatesh Biradar

Abstract

Objective:

Traction in orthopedic and trauma has been an age-long designed to provide a pulling force to achieve the desired purpose.We aim to write this article to describe indications, applications of various form of traction, and their relevant complications. In areas with limited resources for advanced treatment options, travtion is still used to fill its traditional roles some roles in orthopedics and trauma care. Several methods for placing skeletal traction have been described, and it is critical for orthopedic surgeons not only to be proficient in their application but also to understand the appropriate indications for use.

Materials and methods:

Skeletal traction is a treatment method for broken bones. It is a system where a combination of pulleys, pins, and weights are used to promote the healing of fractured bones. These are usually in the lower body. In skeletal traction, a pin is placed inside your bone.
Identify and demarcate the superficial landmarks around the proximal tibia. Make note of the medial and lateral knee joint lines and the four poles of the patella. The tibial tubercle and the fibular head should also be identified.
Identify the proper placement of the tibial traction pin3. This is generally approximately 2 fingerbreadths distal to the tibial tubercle and 2 fingerbreadths posterior and lateral on the tibia. Mark this trajectory on the lateral as well as the medial side where the pin will exit.

Conclusion:

Traction still has some role in current practice particularly in resource-challenged regions as well as in the developed world especially as temporary treatment, pre, intra, and postoperative periods in orthopedics and trauma. We hope this provides an aid for the practitioner when the need arises, to guide them in application, planning and decision-making processes when traction is considered.

15: EMS Traction Splint

Donald D. Davis [1], Jacob G. Ginglen [2], Yong Hwan Kwon [3], Chadi I. Kahwaji [4]

Abstract

Objective:

The femur is the longest and strongest bone of the body, and it carries the weight of the entire body. It is the heaviest tubular bone of the body that requires high-energy force to fracture, for example, as from motor vehicle accidents. Fracture of the femur carries high-risk complications like hemorrhage, fat embolism, and infection. Inappropriate management of femur fracture can also cause prolonged morbidity with shortening, misalignment, and deep venous thrombosis (DVT). The annual incidence of midshaft femur fracture is approximately 10 per 100,000 person-years. The incidence of femoral diaphyseal fractures follows a bimodal distribution that peaks in young adults and the elderly, secondary to high-energy mechanisms in the young and low-energy falls in the elderly with decreased bone density. Emergency medical service (EMS) personnel should immobilize the femur to prevent further injury during transport. Traction splints are recommended on all mid-shaft femur fractures to establish patient comfort and better fracture alignment. Traction splints have utility in the management of both closed and open fractures of the femoral diaphysis. They are designed to provide temporary stabilization at the scene for transport to the hospital for definitive treatment/management. Traction splints are a temporary form of immobilization, as prolonged use of traction splints can cause pressure sores.

The diaphysis of the femur has a normal anatomic alignment that is 5 to 7 degrees from the physiologic axis of the femur, which can be drawn from the center of the femoral head to the center of the knee. The normal femur exhibits an anterior bow, providing flexibility to withstand large amounts of axial force.

The determination of displacement seen in femur fractures is by the pull of the muscles proximal and distal to the fracture. Fractures of the diaphysis typically will result in external rotation of the proximal segment due to the pull of the external rotators and abductors such as the gluteus medius, and internal rotation of the pull of the adductor complex.

While injuries to surrounding nerves are rare in diaphyseal femur fractures, the femur does have a robust blood supply, which can lead to large amounts of blood loss. The large compartments of the thigh can hold up to 3 liters of hemorrhaged blood. A patient with a femur fracture can be expected to lose about 1 TO 1.5 liters of blood or up to 30% of the normal body's blood volume. Therefore, medical personnel must keep a close eye on the hemodynamic status of patients with a suspected femur fracture.

Materials and methods:

Clinical diagnosis is usually obvious from mechanism, pain, swelling, and deformity/shorteningof the thigh. Extreme pain may mask these secondary injuries. Since most of the femur fractureoccurs with high energy trauma, pelvic ring, hip, groin, perineum, and buttock evaluations arecrucial. Up to 40% of the femur fractures are associated with an ipsilateral knee injury.

The clinician should asses distal pulses (popliteal, dorsalis pedis, posterior tibialis) with capillaryrefills on the ipsilateral toenails. If there is a concern for malperfusion of the extremity, an ankle-brachial index (ABI) can help to evaluate for blood supply. A decreased ABI compared to thecontralateral extremity is an indication for a CT angiogram to further assess for vascular injury. Vascular injury resulting in malperfusion of the extremity is a surgical emergency.

Neurologic injury with isolated femoral diaphysis fracture is rare, but a careful motor andsensory assessments are important. A standard neurovascular exam of the extremity distal to afemur fracture should include a sharp and light subjective sensation of the sural, saphenous,superficial peroneal, deep peroneal, and tibial nerves. Examiners should assess for dorsiflexionand plantarflexion of the ankle and great toe. In a presumed femur fracture, assessment of themotor function of knee flexion and extension will be limited, but a brief ligamentousexamination is appropriate. One should not miss signs of gross knee instability or kneedislocation, which carry a very high association with an acute neurovascular injury that

Conclusion:

Traction splint is a useful emergency tool to align the femur fracture better, increase arterialblood flow, decrease pain and spasm, and reduce the risk of further injury from fractured bonefragments.

If the patient is not stable, do not waste time trying to apply traction splint at the scene. Splint theinjured leg against the uninjured leg to expedite the transport.

Frequently re-assess neurovascular function of the extremity after the application of splint andduring transport.

16: A guide to an improvised femoral traction splint in a resource-limited setting

S Swanepoel[1,2], B Bonner[1], B Salence[1], K Evans[3,4], S Maqungo[2,5], N Kauta[1,2]

Abstract

Objective:

A femoral traction splint is a mechanical device that uses traction to align and provide stability to femoral fractures. The use of this device has many benefits however there is still limited availability in low- and middle-income countries. This article provides the reader with a step by step guide to improvise a femoral traction splint built from recyclable materials readily available in most hospitals. The authors' concept will give patients access to a potentially life-saving device in a resource-limited setting.

Materials and methods:

Apply skin traction to the affected leg and slide the traction splint underneath the thigh ensuring the proximal axillary bar is placed against the ischial tuberosity. Secure the splint at the level of the groin with the sling material from the hitch knot. This will prevent proximal migration of the splint when traction is applied. Depress the spring loaded buttons and adjust the telescopic shaft to its shortest position. Apply modest traction to the skin traction rope. Make an overhand knot where the rope of the skin traction meets the most distal end of the crutch shaft. Feed the excess rope with the knot into the shaft and replace the crutch tip/foot securely

Results:

This improvised femoral traction splint is advantageous in low- and middle-income countries as it is a suitable alternative to unavailable traditional traction splints. It is cost effective, reusable and easy to build from recyclable materials readily available in most hospitals. The adjustable padded slings improve the efficacy of the traction splint by supporting the thigh and leg, thereby improving fracture alignment, patient comfort and can be discarded after use. In the authors' opinion, the absence of any part of the traction device in the groin prevents potential pressure sores in that area and additional padding aims to improve patient comfort at the ischial tuberosity. The aluminum components of the crutch are lightweight which allows for easy and quick transfer of the patient. Metal artifacts from traditional femoral traction splints prevent adequate radiographic examination of the hip and proximal femur potentially leading to missed injuries such as minimally displaced neck of femur fractures [4]. The radio-lucent nature of the proximal axillary bar results in improved radiographic exposure of the hip (Fig. 10). This improvised femoral traction splint is currently being used exclusively in the authors' district hospital in the acute management of femur shaft fractures due to the lack of availability of commercial splints. Doctors have shown willingness to participate in the application of the device after dispersion of the instructional video. At present 8 midshaft femur fractures in 8 patients have temporarily been stabilized using this femoral traction splint. No major complications were reported. Two patients reported minor discomfort at the ischial tuberosity which was rectified by placing additional padding on the proximal axillary bar. We present our personal experience using the improvised femoral traction splint and acknowledge that further studies are required to provide evidence of the efficacy and safety of the device. Commercially available splints need to meet regulatory standards and should be preferentially used if available.

Conclusion:

This step by step guide will help the reader improvise a traction splint that will give patients access to a potentially life-saving device in a resource-limited setting.

17: Femoral shaft fractures and the prehospital use of traction splints

Emeli Månsson1, Anders Rüter1, Tore Vikström1

Abstract

Objective:

Traction splints are generally accepted as standard prehospital treatment of femoral shaft fractures. The effects of different splints are not
suffi ciently studied and the use of traction splints is not evidence-based. The aim of study was to determine the incidence and epidemiology of femoral shaft
fractures and the prehospital use of traction splints in these fractures and to determine the force of traction exerted by traction splints over time.

Materials and methods:

a) Retrospective study of all adult patients with femoral shaft fractures treated at a university hospital during a 5-year period.
b) Study of traction force exerted by traction splints on ten healthy volunteers.

Results:

Femoral shaft fractures were caused by low energy trauma in 77% of the cases.
There were no signifi cant differences in age, gender, and mechanism of injury or on scene time between patients treated with tractions splints and patients not
treated with traction splints. In the experimental study the initial force of traction decreased by 58% during the fi rst 30 min, with the fastest rate of decline
within the first five minutes.

Conclusion:

Low energy trauma may today be the most common cause of femoral shaft fractures. Traction splints were in this study probably not used
on all patients were this was indicated. The force of traction exerted by the traction splint decrease considerably after application. Future studies need to
investigate the clinical signifi cance of this.

18: Comparison Qviktrak and CT6/Kendrick TD/Slishman

JS

Abstract

Objective:

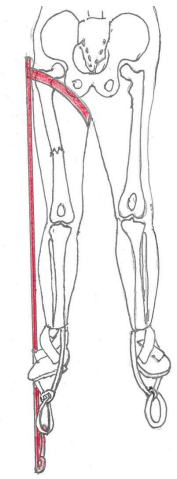
Comparison between the Qvicktrak system and CT6/Kendrick TD/Slishman.

Results:

CT6, Kendrick, Slishman is placed on the outside of the leg and has a counterweight in a band around the top of the femur. Fractures located in this part (below the groin) of the femur and in the hip joint, are subjected to pressure and pulled towards the outside of the leg where the pull rod is located.

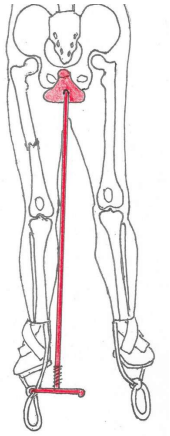
Qviktrak is placed between the legs and has a counterweight for the pull in support against both ischial tuberosity without pressure over the upper end of the femur or the hip joint. The placement between the legs means that it can be used for bilateral femoral fractures.

The majority, 80% of femur fractures, are located in the upper, proximal 1/3 of the femur, including the femoral neck.



CT6/Kendrick/Slishman abutment in band above groin

- makes pain relief more difficult for fractures in the upper 1/3 and in the hip joint
- can hinder blood flow from the leg with increased bleeding as a result
    - uncomfortable abutment and risk of continued bleeding limits time of use
    - protrudes past the foot about 25 cm CT6
    - Slishman pushes the foot into varus (rotation inward)



Qviktrak system has

- comfortable support without pressure over the groin
- traction straps with rubber link even out changes in muscle tension
- Qviktrak can handle bilateral femoral fractures
- Comfortable support and Achilles tendon-friendly traction straps allow treatment for several hours
- protrusion beyond the foot < 8 cm

Conclusion:

The Qviktrak system is comparable and even better for handling of a femoral fracture.

9. Document History

Version	Change	Issued by
01	First issue	Katarina Ortfelt