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# COMPARATIVE STUDY BETWEEN (MIPO)SUBMUSCULAR PLATE FIXATION OF FRACTURE FEMUR AND CONSERVATIVE MANAGEMENT WITH THOMAS SPLINT IN CHILDREN FROM 5 TO 8 YEARS OLD: A RANDOMIZED CLINICAL STUDY

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**Abstract**
**Introduction:** Pediatric femoral shaft fractures are common injuries that can substantially affect a child's growth and development. The ideal treatment strategy for femoral fractures in children aged 5 to 8 years continues to be a subject of debate. This study aims to compare the results of submuscular Minimally Invasive Plate Osteosynthesis (MIPO) with conservative management involving traction with the Thomas splint followed by casting in this age group.
**Methods:** A multicenter randomized controlled trial was performed with 75 children aged 5 to 8 years who had femoral shaft fractures. Patients were randomly allocated to either the submuscular MIPO group or the conservative management group. The outcomes assessed were the duration until radiographic union occurred as well as the rate of complications.
**Results:** Radiographic union occurred more rapidly in the submuscular MIPO group. The MIPO group exhibited a reduced complication rate, reporting merely two instances of superficial wound infection. In contrast, the Thomas splint group encountered several complications, including malunion and limb length discrepancy, with four cases necessitating surgical intervention.
**Conclusion:** Submuscular MIPO provides considerable benefits compared to conservative management for femoral fractures in children aged 5 to 8 years. The earlier weight-bearing capacity, faster radiographic union and reduced complication rates render submuscular MIPO the treatment of choice for this demographic. Nonetheless, conservative management is a feasible option in environments with restricted surgical resources.
**Key Words**: Pediatric femoral fracture, Conservative, Thomas splint, Traction, Surgical intervention, MIPO
**Level of Evidence**: Level II, Randomized Controlled Trial.

## Manuscript

### Introduction

Femoral fractures are prevalent injuries in the pediatric demographic[1] and are the most common pediatric fractures that require hospitalization[2]. These fractures frequently result from high-energy trauma, including falls from elevation or vehicular collisions[3]. Femoral fractures in this demographic require meticulous consideration of the treatment approach to prevent long-term complications such as limb length discrepancies, malunions, and functional impairment.

The management of femoral fractures in young children has conventionally employed conservative strategies, notably traction succeeded by immobilization in a spica cast, which is a recognized method. Traction, especially

with devices such as the Thomas splint, facilitates the gradual alignment of the fracture while preserving the femur's length. This method, although a common treatment method, especially in developing countries, frequently correlates with the inconvenience of prolonged immobilization, posing significant challenges for young children and their families. In our study, patients were subjected to traction in the emergency room and subsequently referred to the outpatient clinic for follow-up, where they would later receive casting[4].

With advancements in surgical techniques, submuscular Minimally Invasive Plate Osteosynthesis (MIPO) has surfaced as a viable alternative to traction and other surgical approaches such as the Titanium Elastic Nailing System (TENS)[5]. In older children, TENS nailing has become a common method of fixation of femoral fractures. In comparison, in younger children, TENS nailing may lead to complications which include irritation at the nail entry site, difficulty in maintaining alignment in comminuted fractures, and the possibility of growth plate injury[6]. Another potential limitation is that the small width of the medullary canal in younger children may not render TENS nailing an optimal option, and that submuscular MIPO may be a better option[7].

Submuscular MIPO has advantages. Given that the plate is away from the growth plate, the chance of growth disruption is minimal. The rigid fixation promotes earlier mobilization and ensures proper reduction and alignment, which reduces the patient's and his caregiver's overall care load.

This randomized controlled trial aimed to compare submuscular MIPO to conservative management in the form of traction and ten casting in children with femoral shaft fractures aged 5 to 8 years of age. The 2 groups would be compared regarding radiological bony union and the rate of complications.

**Materials & Methods**

This double-limbed randomized controlled trial was planned following CONSORT guidelines after the approval of our institutional review board, to evaluate the effectiveness of conservative care with the Thomas splint and then spica casting in the treatment of femur fractures in children aged 5 to 8 years, compared to submuscular MIPO plating. Between January 1, 2020, and June 1, 2024, participants were drawn from two different pediatric orthopedic departments at two different tertiary institutions. Children between the ages of 5 and 8 with a diaphyseal femoral fracture were eligible candidates. The exclusion criteria comprised open fractures, pathological fractures, fractures exhibiting substantial comminution, preexisting metabolic bone disorders, and prior surgical procedures on the impacted femur.

Before enrollment, informed consent was secured from the parents or guardians of all participants, and consent was acquired from children when applicable.

Patients were randomly allocated to one of two treatment groups: MIPO or conservative management utilizing the Thomas splint and casting. Randomization was accomplished through a computer-generated sequence. Given the nature of the interventions, both the patients and the treating surgeons were aware of the treatment assignment; however, outcome assessors were blinded to lower bias.

**Intervention and Surgical Technique**

- **MIPO Group:** Submuscular plate fixation was done utilizing a standard technique within the MIPO group. A small incision was made proximal and distal to the fracture site under general anesthesia. A pre-contoured plate was submuscularly inserted through a sub-vastus lateralis approach as it was suggested by Al-Faily et al.[8], to bridge the fracture and was then secured with screws. Intraoperative fluoroscopy was employed to verify correct alignment and fixation. Efforts were made to reduce periosteal disruption and to avoid the growth plate. Post-operatively, patients were advised to initiate partial weight-bearing as tolerated, with full weight-bearing progressively implemented as healing advanced. **Figure 1** displays a series of radiographs from a case within the MIPO group. Plates were removed at the parents' request following a complete bony union.
- **Conservative Management Group:** In the conservative management cohort, traction was initially administered using the Thomas splint. The limb was subjected to traction for a duration of 3 to 4 weeks, depending upon the healing progression. After traction, patients were placed in a spica cast, which was retained for an additional 4 to 6 weeks. Patients underwent regular monitoring through clinical evaluations and radiographic imaging to follow up on fracture alignment and union. **Figure 2** displays a sequence of radiographs from a case within the conservative management group.

Data collection was conducted prospectively at various intervals, including baseline (pre-intervention), post-intervention (at discharge), and during follow-up visits at 6 weeks, 3 months, 6 months and 2 years post-treatment. The following data were gathered:

- **Demographic Information:** Age, gender, weight, and fracture side.
- **Radiographic Outcomes:** Fracture alignment, time to radiographic union (which was determined by the union of at least 3 cortices on AP and lateral radiographs), and any evidence of malunion or limb length discrepancy.
- **Post-operative Complications:** nonunion, malunion, infection and reoperation rate.

**Statistical Analysis**

Data were analyzed utilizing SPSS version 22 (IBM Corp, Armonk, NY). Descriptive statistics were employed to summarize patient demographics and baseline characteristics. Continuous variables were compared utilizing the independent t-test or Mann-Whitney U test, as applicable, whereas categorical variables were assessed using the chi-square test or Fisher's exact test. A Kaplan-Meier survival analysis was performed to compare the duration until full weight-bearing between the two groups. A p-value of less than 0.05 was deemed statistically significant.

This study was approved by our institute's ethical review committee. All procedures were conducted in accordance with the Declaration of Helsinki.

**Results**:

Seventy-five children participated in the study, comprising 37 patients in the MIPO group and 38 in the Thomas splint group. **Figure 3** presents a CONSORT flowchart illustrating included patients' progression at each trial stage.

The demographic characteristics of the two groups did not exhibit statistically significant differences in age, sex, or weight. The mean age of patients in the MIPO group was 6.3 ± 1.1 years, whereas in the Thomas splint group, it was 6.8 ± 1 years. **Table 1** contains the demographic data of the patients included in the study.

The MIPO group attained radiographic union sooner, with a mean time to union of 9.08 weeks, compared to 10.8 weeks in the Thomas splint group ($p < 0.001$). Fracture alignment was effectively preserved in both cohorts; however, two patients in the Thomas splint cohort experienced malunion with an angulation exceeding 20 degrees, while no malunions were observed in the MIPO cohort.

Complications were categorized into major complications requiring surgical intervention and minor complications that did not necessitate surgery. Significant complications occurred more frequently in the Thomas splint cohort, with four patients affected: one patient experienced malunion with an angulation exceeding 20 degrees, two patients exhibited limb length discrepancies greater than 2 cm, and one patient presented with both an angulation greater than 20 degrees in which both underwent guided growth at 2 years post-operative. Conversely, the MIPO group experienced no significant complications, with only two minor incidents, specifically a superficial wound infection that was effectively treated with oral antibiotics. The conservative management group also had 10 cases with a minor limb length discrepancy of less than 2 cm, which was managed by follow-up without surgical intervention and were all spontaneously corrected at 2 years to be equal or less than 1cm in discrepancy. The results are presented in **Table 2**.

**Discussion**

Femoral shaft fractures in children aged 5 to 8 years can be treated using various approaches, including conservative methods like traction and spica casting or surgical techniques such as TENS and MIPO, particularly submuscular MIPO[9]. In resource-limited settings or regions with minimal access to advanced surgical care, conservative methods like casting and traction remain common[10]. However, with advancements in surgical techniques, there is a growing interest in comparing conservative treatments with surgical interventions for pediatric femoral fractures[10-13].

According to our knowledge, to date, no studies have directly compared traction and casting with submuscular MIPO plating in this specific age group. Our study revealed that MIPO offered several advantages over traditional methods such as the Thomas splint. These advantages included faster radiographic union, better mobility, fewer complications, and improved alignment. These findings highlight significant implications for pediatric orthopedic care in managing femoral fractures, especially in developing countries where traction and casting is still commonly used.

Our results align with previous studies suggesting that surgical intervention often provides superior outcomes compared to conservative treatments[14,15]. MIPO, in particular, allows for early mobilization and a quicker return to normal activities, which are essential for young children's physical and psychological well-being[7]. Sutphen et al. similarly found that children treated with MIPO could bear weight sooner, had faster bony union,

and had fewer incidences of malunion compared to those treated with TENS[16]. In our study, the submuscular MIPO group demonstrated an average reduction of 9.08 weeks in radiographic union compared to the Thomas splint group of 10.8 weeks, likely due to the enhanced stability provided by submuscular plating. The minimally invasive approach of submuscular MIPO preserves periosteal blood flow and minimizes soft tissue damage, both of which are crucial for bone healing in children[17].

Additionally, the submuscular MIPO group experienced a lower complication rate. While there were two cases of superficial wound infections, both resolved with antibiotics. In contrast, the Thomas splint group showed complications such as malunion and limb length discrepancies. These findings align with previous research, which has shown that surgical techniques, in general, result in fewer complications than conservative methods in this age group[11].

Despite the advantages of submuscular MIPO, conservative treatment remains a valuable option in certain clinical situations. Although this study associated the Thomas splint with longer recovery times and higher complication rates, it remains a viable option for children who are not suitable candidates for surgery, due to comorbidities or limited access to surgical resources. In resource-limited settings, traction and casting remain affordable, low-risk alternatives, however long-term complications should be considered. Reeves reported that conservative management could cost 40% more than surgical treatment of femoral shaft fractures in pediatric patients if the candidate is not chosen correctly[4].

The results of this study carry important clinical implications. They underscore the importance of individualized treatment planning in pediatric orthopedic trauma, considering factors such as the child's age, the complexity of the fracture, and the availability of surgical resources. For simple, non-displaced fractures, conservative treatment may still be appropriate in younger children. However, MIPO offers a good alternative with superior outcomes in older children or those with more complex fractures.

While the study's strengths include its randomized design and use of validated outcome measures, several limitations should be acknowledged. The short follow-up period limited the assessment of long-term outcomes at skeletal maturity, such as growth abnormalities or delayed complications. Additionally, the study was conducted in only two centers, potentially limiting the generalizability of the findings.

In conclusion, our findings strongly support MIPO as the preferred treatment for femoral shaft fractures in children aged 5 to 8. The benefits of early weight-bearing and faster radiographic healing, lower complication rates, and improved functional outcomes make MIPO an attractive option for this age group. While conservative treatments like the Thomas splint may still be appropriate in specific circumstances, this study suggests that MIPO should be prioritized when feasible especially in cases where shortening is more than 2cm. Future research should focus on optimizing surgical techniques and evaluating long-term outcomes to enhance pediatric femur fracture care further.

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**Tables Legend:**
Table 1: Patients' Demographics
Table 2: Results

**Figures Legend:**

**Figure-1** A&B: AP and lateral view of a femur fracture upon arrival to the ER. C: Intraoperative fluoroscopy image of fixation by a submuscular MIPO technique. D&E: AP and lateral view of the femur 3 months post-operative showing bony union. F&G: AP and lateral view of the femur after removal of the plate.

**Figure-2**. A&B: AP and lateral view radiographs of the femur upon presentation to the ER. C: Photograph of the patient on a Thomas traction. D&E: AP and lateral view radiographs of the femur on the Thomas traction. F&G: AP and lateral view radiographs of the femur at 4 weeks after removing the traction and being placed in a spica cast. H&I: AP and lateral view radiographs of the femur at 3 months. J&K: AP and lateral view radiographs of the femur showing union with 1 cm shortening and 15 degrees of retroversion.

**Figure-3** CONSORT Flowchart