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a prospective one-year follow-up study of 49 patients

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Authors: Peter Larsen PT, PhD Uffe Laessoe PT, PhD Sten
Rasmussen MD, PhD Thomas Graven-Nielsen DMSc
Christian Berre Eriksen MD Rasmus Elsoe MD, PhD



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Asymmetry in gait pattern following tibial shaft fractures – a prospective one-year follow-up study of 49 patients

Peter Larsen, PT, PhD¹, Uffe Laessoe, PT, PhD^{3,4}, Sten Rasmussen, MD, PhD^{2,5}, Thomas Graven-Nielsen, DMSc³, Christian Berre Eriksen, MD², Rasmus Elsoe, MD, PhD²

¹ Department of Occupational Therapy and Physiotherapy, Aalborg University Hospital, Denmark.

² Department of Orthopaedic Surgery, Aalborg University Hospital, Denmark.

³ Center for Neuroplasticity and Pain (CNAP), SMI, Department of Health Science and Technology, Faculty of Medicine, Aalborg University, Denmark.

⁴ Physiotherapy Department, University College North Denmark, UCN, Denmark

⁵ Department of Clinical Medicine, Faculty of Medicine, Aalborg University, Aalborg, Denmark

Running title: Tibial Shaft Fracture - Gait Asymmetry

Peter Larsen: peter.larsen@rn.dk; Uffe Laessoe: ufl@ucn.dk; Sten Rasmussen: sten.rasmussen@rn.dk; Thomas Graven-Nielsen: tgn@hst.aau.dk; Christian Berre Eriksen: cbe@rn.dk; Rasmus Elsoe: rae@rn.dk

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Corresponding author:

Peter Larsen

Department of Occupational Therapy and Physiotherapy,
Aalborg University Hospital, Aalborg, Denmark

18-22 Hobrovej.

DK-9000 Aalborg.

E-mail: peter.larsen@rn.dk

+45 99 32 31 05

+45 40 68 27 61 (mobile)

+45 99 32 31 09 (fax)

Highlights

- Intramedullary nailing of tibial fractures and 1-year development in gait function
- Gait asymmetry is common after the first 6 months post-operatively
- Gait asymmetry becomes normalized between 6 and 12 months post-operatively
- Weak associations between gait asymmetry and patient-reported HRQOL were observed
- Regaining pre-injured gait function after a tibial fracture is a prolonged process

ABSTRACT

Introduction: Despite the high number of studies evaluating the outcomes following tibial shaft fractures, the literature lacks studies including objective assessment of patients' recovery regarding gait pattern. The purpose of the present study was to evaluate whether gait patterns at 6 and 12 months post-operatively following intramedullary nailing of a tibial shaft fracture are different compared with a healthy reference population.

Patients and Methods: The study design was a prospective cohort study. The primary outcome measurement was the gait patterns at 6 and 12 months post-operatively measured with a 6-meter-long pressure-sensitive mat. The mat registers footprints and present gait speed, cadence as well as temporal and spatial parameters of the gait cycle. Gait patterns were compared to a healthy reference population.

Results: 49 patients were included with a mean age of 43.1 years (18 to 79 years). Forty-three patients completed the 12-month follow-up (88%). Gait speed and cadence were significantly increased between the 6- and 12-month follow-up ($P < 0.001$). At 6-month follow-up, patients showed considerable asymmetry in the injured leg compared with the non-injured leg: single-support time 12.8% shorter, swing-time 12.8% longer, step-length 11.9% shorter, and rotation of the foot increased by 32.3%. At the 12-month follow-up, gait asymmetry become almost normalized compared to a healthy reference group.

Conclusion: In patients treated by intramedullary nailing following a tibial shaft fracture, gait

asymmetry accompanied with slower speed and cadence are common during the first 6 months and become normalized compared with a healthy reference population between 6 and 12 months post-operatively.

Keywords: Tibial shaft fracture; intramedullary nailing; gait; function

INTRODUCTION

Fractures of the tibial shaft are recently reported with an incidence of 16.9/100,000/year [1], making it a common injury. The standard treatment is intramedullary nailing due to low rates of complications and high rates of union [2].

Patient-reported outcomes and function following a shaft fracture of the tibia have been reported in several studies [2–6]. Most studies have reported on fracture union, knee pain, joint stiffness, degenerative joint disease, rotational malalignment and limitations in activity of daily living and health-related quality of life (HRQOL) [2–6]. Despite the high number of studies evaluating the outcomes following tibial shaft fractures, the literature lacks studies including objective assessment of patient's recovery regarding functional ability and gait pattern. Gait analysis is important in the evaluation of functional deficit following tibial shaft fractures [6–8]. The LEAP study group [9] have reported significant gait abnormalities and decreased walking speed following severe injuries of the lower extremity and that patients' satisfaction was highly correlated to physical function.

The recovery of gait function and underlying gait variables following fractures of the tibial shaft are poorly understood. Macri et al. [8] evaluated the gait pattern in a group of patients with tibial shaft fractures and reported normal gait function in only 48% of patients at 6-month follow-

up. Improvement in gait function was associated with the absence of pain at weight-bearing, reduced tenderness at the fracture site, a higher degree of radiographic union and improved functional status. However, studies evaluating specific gait variables (pace, rhythm, variability, injured/non-injured asymmetry, cadence and walking speed) have not been reported previously. Increased knowledge on specific gait characteristics following shaft fractures of the tibia may contribute to improving rehabilitation programmes and patient information during recovery.

The purpose of the present study was to evaluate whether gait patterns at 6 and 12 months post-operatively following intramedullary nailing of a tibial shaft fracture are different compared with a healthy reference population. The explorative aim was to report the association between gait patterns and patient-reported HRQOL.

The hypothesis was that patients treated by intramedullary nailing following a tibial shaft fracture would show gait asymmetry at 6 and 12 months post-operatively compared with a healthy reference population.

PATIENTS AND METHODS

Study design

The study design was a prospective cohort study including all patients treated with intramedullary nailing following a tibial shaft fracture, between September 2012 and June 2014 at Aalborg University Hospital, Denmark. Patients with multi-trauma, bilateral fractures and patients with pathological fractures were excluded. Patients who were unable to participate due to mental disabilities were also excluded.

Basic characteristics regarding age, gender, body mass index (BMI), trauma mechanism, type of trauma and fracture classification were obtained at the time of admission to hospital. All

participants gave written informed consent. Complications were reported throughout the study. All patients were examined at the outpatient clinic at 6 and 12 months post-operatively.

The primary outcome measurement was the gait patterns at 6 and 12 months post-operatively. The Danish Data Protection Agency (J. nr. 2008-58-0028) and the local ethics committee (J.nr: N-201-200-11) approved the study, which was performed according to the principles of the Helsinki declaration. The reporting of the study complies with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement [10].

Gait assessment

Walking ability and gait asymmetries were measured while walking on a pressure-sensitive mat (GAITRite System®) [11]. The mat registers footprints and present gait speed, cadence as well as temporal and spatial parameters of the gait cycle. The method is thoroughly described and validated in a number of studies also including orthopaedic injuries [11–13].

The patients were asked to walk on the (6-metre-long) pressure-sensitive mat. The test was performed twice (12-metre test). The values from each trial were averaged. The patients walk with a self-selected walking speed from a starting position standing approximately 2 metres outside the measuring area, continuing 2 metres past the pressure-sensitive mat.

The outcome of the GAITRite system consisted of 21 different gait variables. The mean temporal (step-time, stance time, single- and double-support time, swing-time, cadence and speed) and spatial values (step length, foot angle) were calculated during the 12- metre test.

Selection of gait variables for outcome analysis

Gait speed and cadence represented the general characteristics of the gait pattern. Gait characteristics for the injured and the non-injured leg were evaluated with respect to: single-

support, step-length and foot rotational characteristics. The asymmetry between the injured and the non-injured leg was reported as percentage asymmetry ($100 \times \ln(\text{injured/non-injured})$) [14].

Furthermore, the variability of the gait cycles was reported as the coefficient of variance (CV) of stance-time ($100 \times \text{SD/mean}$). Gait patterns from the outcome analysis were compared to a healthy reference population [15].

Radiological measurements

Fracture classification was performed according to the AO classification [16] and was conducted on preoperatively obtained X-rays. Post-operatively, X-rays of the fractured lower leg were obtained and used to evaluate the bone healing and alignment. The radiological assessments were made on AP and side X-rays.

The evaluation of bone union was defined as: *i*) visible callus formation on at least three of four sides, no visible fracture line and no pain from fracture at weight-bearing and following clinical examination (defined as: union); *ii*) visible callus formation on at least 1 of 4 sides, with a visible fracture line (defined as: partial union); and *iii*) visible fracture lines and no visible callus formation (defined as: no union). The evaluation of union was performed in agreement with other studies' evaluation of union after tibial fractures [17].

Patient-reported HRQOL

Eq5D-5L is a standardized and validated instrument to assess health outcome[18]. It consists of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and a self-rated health scale on a 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine'. An Eq5D-5L index at 1.0 indicated full

health, and 0 denoted death. Eq5D reference data from a general population-based sample in Denmark is available[19].

The authors have previously reported the one-year development in patient-reported HRQOL in patients treated with intramedullary nailing after tibial shaft fractures and found generally lower HRQOL scores compared to an established reference group [X]. The present study used the same study population and Eq5D-5L scores to evaluate the association between HRQOL and asymmetry in patients' gait patterns.

Statistics

The assumption of normal distribution variables was checked visually by QQ-plots. Continuous data were expressed with mean and standard deviation (SD). Categorical data were expressed as frequencies. Paired *t*-test was considered to test for the difference between the 6- and 12-month follow-up. Asymmetry between injured and non-injured leg is expressed as % asymmetry ($100 \times \text{Ln}(\text{injured}/\text{non-injured})$) [14]. At 6 and 12 months post-operatively the Pearson's-test was used to analyse the correlation between Eq5D-5L and % asymmetry between the injured and non-injured leg. A P-value of < 0.05 was considered significant. The statistical analysis was performed by SPSS V.22 and STATA V.13.

RESULTS

A total of 50 patients were treated for a tibial shaft fracture with intramedullary nailing during the study period. One patient was initially excluded due to a pathological fracture. Thus, the study population consisted of 49 patients, 17 females and 32 males. The mean age at the time of the fracture was 43.1 years, ranging from 18 to 79 years. The baseline characteristics of all patients are presented in Table 1.

Throughout the study period, five patients were lost to follow-up. One patient was excluded before the 6-month follow-up due to a tibial fracture of the opposite lower leg, and two patients refused to enter the study. One patient died and one patient was diagnosed with a mental disability between the 6- and the 12-month follow-up, leaving 45 patients at the 6-month follow-up and 43 patients at the 12-month follow-up.

Radiological outcomes

All fractures united during the 12-month study period (N=43, completed the final radiological examination). At the 6-month follow-up, 36 patients presented with union and 10 with partial union.

Twelve months after surgery, two patients were out of alignment, representing a varus deformity of 7° and 9° respectively. No patients presented with flexion, extension or valgus deformity $>5^\circ$.

Gait outcomes

The general characteristics of gait patterns (gait speed and cadence) are presented in Table 2, showing a significant increase in gait speed and cadence between the 6- and 12-month follow-up.

Compared to an established reference population [15] the study group showed a significant difference in gait speed at 6 months for men, revealed by the non-overlapping 95% confidence intervals. At the 12-month follow-up, no significant difference was observed due to none overlapping 95% confidence intervals (Table 3).

The primary analysis of gait asymmetry is presented in Table 4. Patients presented with a shorter single-support phase of the injured leg compared to the non-injured leg, representing an asymmetry of 12.8% at 6-month follow-up, decreasing to 3.8% at the 12-month follow-up ($P<0.001$). Analysis of swing-time showed a longer swing-time of the injured leg, representing an

asymmetry of 12.8% at 6-month follow-up, decreasing to 4.6% at the 12-month follow-up ($P<0.001$). Moreover, patients had a shorter step-length of the injured leg compared with the non-injured leg, representing an asymmetry of 11.9% at 6 months, decreasing to 5.1% at 12-month follow-up ($P<0.001$). The functional rotation of the foot showed an asymmetry of 32.3% between the injured and non-injured leg at 6 months, decreasing to 2.6% at the 12-month follow-up ($P=0.02$). The evaluation of variability in the stance-phase showed an asymmetry in the coefficient of variation (CV) between the injured leg and non-injured leg, representing 20.3% at 6-month follow-up, decreasing to 15.1% at the 12-month follow-up ($P=0.05$). The two patients out of alignment did not show any major difference compared to the study population at 6- and 12-month follow-up.

Correlations between patient-reported HRQOL, speed and gait asymmetry

The relationship between gait (%) asymmetry of: single-support, step-length, rotational-foot and patient-reported HRQOL (Eq5D-5L) at 6- and 12- month follow-up showed weak and non-significant associations between asymmetry in gait pattern and patient-reported HRQOL (Pearson's test: single-support: 6 months: $R= 0.04$, $P = 0.78$ and 12 months: $R= 0.18$, $P = 0.28$; step-length: 6 months: $R= 0.09$, $P = 0.54$ and 12 months: $R= 0.39$, $P = 0.01$; functional-rotation: 6 months: $R= 0.21$, $P = 0.24$ and 12 months: $R= 0.09$, $P = 0.60$). Likewise, the relationship between gait speed and patient-reported HRQOL (Eq5D-5L) at 6- and 12-month follow-up showed weak and non-significant associations between gait speed and patient-reported HRQOL. (Pearson's test: 6 months: $R= 0.05$, $P = 0.74$ and 12 months: $R= 0.08$, $P = 0.61$).

DISCUSSION

Fractures of the tibial shaft are a common fracture of the long bones [20]. Several studies have

examined the functional outcomes in patients' post-injury [2–6,21]. However, the literature is limited in studies evaluating the functional outcome regarding the development in gait function post-injury. A single study by Macri et al. [8] evaluated the gait pattern following tibial shaft fractures and reported normal gait function in only 48% of patients at 6-month follow-up. Asymmetry in gait pattern has commonly been reported with associations to patients' function and HRQOL in other patient groups[13,22,23].

In the 12-month observation period, the present study showed that gait asymmetry is common during the first 6 months and becomes almost normalized between 6 and 12 months post-operatively. Moreover, weak associations between gait asymmetry and patient-reported HRQOL were observed.

Overall, the gait of healthy individuals is considered almost symmetrical [24]. At the 6 month follow-up the study group showed considerable asymmetry. Patterson et al.[24] reported the degree of asymmetry from an established reference group of healthy individuals and showed an asymmetry in step-length of 3.0% and swing-time of 2.4%. At the 12-month follow-up step-length and swing-time asymmetry represented 4.1% and 2.2%, respectively, showing a substantial decrease in gait asymmetry between the 6- and 12-month follow-up. Between the 6- and 12-month follow-up, gait asymmetry become almost normalized. Knee and ankle pain, joint stiffness, degenerative joint disease, rotational malalignment, complications due to soft tissue injury and muscle weakness are commonly reported following a tibial shaft fracture [2,4,6,25,26] and may affect development in gait asymmetry.

Asymmetry in gait pattern has been reported with associations to patients' function and QOL [13,22,23]. However, the literature lacks studies that evaluate the association between asymmetry in gait pattern and patient-reported HRQOL following a tibial shaft fracture. The present study showed weak correlations between measurements of gait asymmetry and patient-

reported HRQOL. This might partly be a result of generally high levels of HRQOL at both 6 and 12 months, which may in turn be partly due to high scores with low variance in both HRQOL and gait asymmetry scores. Injury-specific questionnaires, such as KOOS or WOMAC scores, may be more sensitive in capturing reduction in knee-related HRQOL resulting in increased variance.

Walking speed has been reported as an important predictor of functional performance and patient-reported HRQOL[27,28]. Patients from the present study showed a significant increase in gait speed and cadence between the 6- and 12-month follow-up. At 12-month follow-up no significant differences in gait speed between the study group and a healthy reference population were observed. Moreover, increased gait speed was not related to an increase in patient-reported HRQOL. The difference between the present study and studies reporting on associations between gait speed and HRQOL may be due to a difference in the level of comorbidity between the patient groups. In general, patients with tibial shaft fractures are young and have a low level of comorbidity, compared to patients with multiple sclerosis and elderly people with osteoporosis, in which a strong association between gait speed and QOL is commonly reported [27,28]. Furthermore, the lack of difference in gait speed between the study group and a healthy reference group may be an important factor in the observed weak correlation between gait speed and HRQOL.

Rotational malalignment is reported as a common complication following intramedullary nailing [29]. The present study evaluated the development in functional rotation during walking at both 6 and 12 months and showed an asymmetry between the injured and non-injured leg of respectively 44.6% and 15.9%, with an increased external rotation of the injured leg. To the best of the authors' knowledge, the present study is the first to report on the development in functional rotation during walking following intramedullary nailing of tibial shaft fractures. Unexpected was the substantial decrease in rotational asymmetry between the 6- and 12-month follow-up, indicating

that functional rotational malalignment following intramedullary nailing may be explained by factors other than only post-operative malalignment of the tibial shaft. The importance of rotational malalignments on HRQOL and function after intramedullary nailing of tibial shaft fractures lacks evidence. The present study found a weak association between patient-reported HRQOL and functional rotational asymmetry during walking.

Findings from the present study indicate that regaining pre-injured gait function following a shaft fracture of the tibia is a prolonged process and significant improvement in gait function from 6 to 12 months may be expected. Such information is important in advising patients and planning rehabilitation in patients treated with intramedullary nailing following a tibial shaft fracture.

The main limitations of this study are the observational design, implying that no conclusions regarding causality can be drawn. However, this prospective study provided novel findings regarding the development in gait pattern following a tibial shaft fracture. The strength of this study is the use of a standardized gait measurement including objective measurements of different gait patterns. Finally, a strength of the study is the inclusion of associations between HRQOL and gait asymmetry, which is novel.

CONCLUSION

Compared to a healthy reference population, gait asymmetry is common after the first 6 months and becomes normalized between 6 and 12 months post-operatively in patients treated by intramedullary nailing following a shaft fracture of the tibia.

Conflicts of interest statement: None

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- [X] Blinded ref.

Table 1: Baseline characteristics of the study group

Age at time of fracture, mean (range)			43.1(18-79)
Gender, male/female			32/17
Height, mean (SD)			176.0 (11.2)
Weight, mean (SD)			77.7 (14.6)
BMI, mean (SD)			25.1 (3.7)
Smoker, yes/No			18/31
High/low-energy trauma			12/37
Fracture classification AO-42-			
A			30
B			14
C			5
Open/closed fracture			6/43
Fibula fracture, no/yes			5/44
Additional treatment besides intramedullary nailing			
Initial screw fixation of posterior aspect of the distal tibia			14
Metatarsfracture treated with Kirschner-wire			2
Complications			
Compartment syndrome			1
Broken screws			2

Table 2: General characteristics of gait pattern

	6 months		12 months		<i>p</i> value
	mean	SD	mean	SD	
Speed (cm/s)	107.3	29.9	136.1	23.9	<0.0001*
Cadence (step/min)	106.0	16.4	118.6	10.8	<0.0001*

* significant difference between 6 and 12 months

Table 3: Gait speed compared to a reference population

	6 months		12 months	
	mean	95% CI	mean	95% CI
Study group speed men (cm/s)	112.1	101.1-123.0*	140.1	132.8-147.3
Reference group men, mean, (95% CI)	131.6 (123.5-139.7)			
Study group speed women (cm/s)	98.6	82.9-114.4	129.7	114.1-145.4
Reference group women, mean, (95% CI)	110.5 (105.2-115.8)			

Reference group: Öberg et al. Basic gait parameters : Reference data for normal subjects, 10-79 years of age (26)

* significant difference to reference population due to none overlapping 95% CI

Mean age (SD): men 36.1(14.9) and women 56.2(16.6)

Table 4: Asymmetry of gait pattern

	6 months		12 months		<i>p</i> value
	mean	SD	mean	SD	
Single support injured (sec)	0.410	0.01	0.405	0.01	0.46
Single support non-injured	0.456	0.01	0.412	0.01	<0.001*
Single support asymmetry (%)	12.8%	13.3	3.8%	4.2	<0.001*
Step length injured (cm)	57.6	13.6	67.4	10.4	<0.001*
Step length non-injured	62.3	11.4	70.2	10.9	<0.001*
Step length asymmetry (%)	11.9%	12.0	5.1%	5.5	<0.001*
Swing time injured (sec)	0.455	0.06	0.411	0.03	<0.001*
Swing time non-injured	0.410	0.05	0.402	0.04	0.47
Swing time asymmetry (%)	12.8%	13.3	4.6%	7.3	<0.001*
Rotational foot injured (°)	8.9	6.3	7.5	6.1	0.02*
Rotational foot non-injured	5.7	6.4	6.4	5.1	0.16
Rotational foot asymmetry (%)	32.3%	80.5	2.6%	92	0.02*
Variance of stance time injured (CV)	3.5	2.3	2.5	1.6	0.03*
Variance of stance time non-injured	2.8	1.9	2.8	1.9	0.76
Variance of stance time asymmetry (%)	20.3%	56.7	15.1%	64.6	0.05

* significant difference between 6 and 12 months