

The Aseptic Femoral and Tibial Shaft Non-Union in Healthy Patients – An Analysis of the Health-Related Quality of Life and the Socioeconomic Outcome

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Abstract: Long bone non-unions may lead to recurrent surgical procedures and in-hospital stays. Thus, restrictions of the health-related quality of life and of socioeconomic parameters might be expected. Knowledge of the impact on several parameters of professional life is sparse. Therefore, we analyzed the outcome in patients following non-unions of the tibial and femoral shaft after fracture compared to patients with uneventful healing.

Material and Methodology: 51 patients following non-unions of the the femoral (FNU) or tibial shaft (TNU) were compared to 51 patients (groups FH and TH) with uneventful fracture healing. Physical and mental health was assessed using the Short-Form Health Survey (SF-12), Hospital Anxiety and Depression Scale (HADS) and the Impact of Event Scale (IES). We also analyzed employment status and the usage of medical aids.

Results: Scores of the SF-12 physical and psychological were lower in group TNU compared to group TH, the score of SF-12 physical but not psychological was significantly lower in group FNU compared to FH. Compared to uneventful healing, a significantly more frequent usage of medical aids was found in both non-union groups. A higher incidence of early retirement and unemployment was found in group FNU but not in group TNU.

Conclusions: There is a profound influence on the quality of life following femoral or tibial non-unions after trauma. Compared to patients with uneventful fracture healing, patients with tibial and even more so femoral non-union show worse scores of the SF-12. Medical aids are frequently used following both, femoral and tibial non-unions. Not tibial, but femoral non-unions frequently lead to severe restrictions in professional life such as early retirement and unemployment.

Keywords: Non-union, posttraumatic complications, long bone fracture.

INTRODUCTION

Femoral and tibial shaft fractures are severe injuries and challenging for both, the patient and the surgeon. In case of an uneventful healing, both entities should be healed in about 8 to 12 weeks and the patient therefore reintegrated in social life [1]. Due to improved implants and surgical techniques such as intramedullary nailing, union rates up to 90% were reported depending on fracture type and localization [2]. However, non-union rates of 2% to 12% for femoral and 16% to 80% for tibial shaft fractures depending on sub-collectives have been reported [3, 4]. The incidence of non-unions after tibial shaft fractures has been reported to be highest compared to other long bone fractures [5, 6].

Identified causes of non-unions are severe trauma, infection, bone loss, low mechanical stability of the osteosynthesis, poor nutrition of the bone or extensive osteonecrosis [7]. Further individual risk factors include smoking and systemic corticoid therapy [8, 9]. Several surgical options have been established to treat non-unions of the lower leg, such as reamed nailing, the use of compression

plates or bone grafting. Furthermore, beneficial effects of osteogenic protein-1 (OP-1) and non-operative methods such as electrical and ultrasound stimulation have been reported [10, 11]. As non-unions of the femur and the tibia result in extended surgical procedures, an increase of in-hospital days and prolonged rehabilitation procedures, restrictions in the quality of life but also socioeconomic effects such as in professional education and employment might be expected. Former studies already demonstrated the profound psychosocial effect following septic femoral and tibial non-unions. Poor outcome with regard to quality of life has been shown [12].

Up to date, knowledge of the health-related quality of life and socioeconomic outcome of patients without significant comorbidities following aseptic non-unions of the femoral or tibial shaft is sparse. Therefore, we examined the outcome in patients without significant comorbidities after aseptic femoral and tibial fracture non-unions compared to patients with uneventful fracture healing.

MATERIALS AND METHODOLOGY

The study followed the guidelines of the revised UN declaration of Helsinki in 1975 and its latest amendment of 1996 (42nd general meeting). It was approved by the local ethical committee of Hannover Medical School. Written consent was obtained by all of the study participants.

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Definitions

Non-unions of the femoral or tibial shaft were defined as radiologically confirmed unhealed shaft fractures at least 9 months following the injury and osteosynthetic treatment. Healing was confirmed clinically (painless full weight bearing) and radiologically (bridging callus on three or four cortices on radiographs) [13].

Infections were defined as deep wound infection with evidence of bacteria at the fracture site. The necessity of medical aids implied the requirement of crutches, walkers, canes or wheelchairs. Unemployed patients were not able to work in their pre-trauma job because of injury sequels or were dismissed because of sick leave times while they were generally able to work. Early retirement comprises patients who were retired due to the trauma sequels before reaching the statutory retirement age of 62 years in females and 65 years in males. Total in-hospital time as well as the amount of surgical procedures related to fracture treatment were analyzed.

Patient Recruitment

Patients from age 16 to 65 at the day of injury with surgically treated femoral or tibial shaft fractures between 2000 and 2008 were analyzed by our database. Definitive treatment consisted of intra- or extramedullary osteosynthetic treatment. Sub-analyses were performed to identify patients with non-unions of the tibial (group TNU) or the femoral shaft (group FNU). Exclusion criteria were infections, diabetes, bilateral fractures, smoking or systemic corticoid therapy. Details of the inclusion and criteria are displayed in Table 1.

Table 1. Inclusion and Exclusion Criteria of the Study Population

Inclusion Criteria	Exclusion Criteria
Age 16-65 years	Infection
Surgically treated fracture of the femoral or tibial shaft	Diabetes (type 1 and 2)
	Smoking
	Bilateral femoral or tibial fractures
	Systemic corticoid therapy
	Casting

In total, 124 patients with the diagnosis tibial non-union were screened. 73 patients of group TNU had to be excluded due to exclusion criteria. The remaining 51 patients were contacted by phone and mail and asked to join the study. Patients of the group femoral shaft non-union (FNU) were invited accordingly. We identified 48 patients with the diagnosis aseptic femoral non-union, 16 had to be excluded mostly due to exclusion criteria. The remaining 32 were contacted by mail and phone and asked to join the study. As controls, a similar number of patients with uneventful healing of surgically treated tibial or femoral shaft fractures were invited to join the study. Stratified block randomization out of a total of over 250 patients of the control group was

performed to avoid bias like place of residence, age or working hours.

Follow-Up Examination and Acquisition of Clinical Data

All included patients were assessed by an experienced trauma surgeon in the follow-up. To safely exclude all patients with co-morbidities, we asked again for chronic diseases, medication and smoking. For determination of the general outcome for each patient the 12-Item Short-Form Health Survey (SF-12), the Glasgow Outcome Scale (GOS) and the hospital anxiety and depression score (HADS-A, HADS-D) was evaluated. The SF-12 was a modified version of the Short Form-36 in German language. It implies a Physical Component Summary Scale (PCS, SF-12 physical) and a Mental Component Summary Scale (MCS, SF-12 psychological) of the SF-12 [14, 15]. The Hospital Anxiety and Depression Scale (HADS) is a self-report measure developed to identify symptoms of anxiety (HADS-A) and depression (HADS-D) in somatically ill patients. The two subscales are added separately with a total range from 0 to 21. A cut-off at 8 points is most often used in current literature [16]. To reveal the incidence of the Posttraumatic Stress Disorder Syndrome (PTSD), the Impact of Event Scale (IES) was used. The IES was developed as a symptom scale for psychological responses to stressful life events. The scale consists of the two subscales avoidance and intrusion. The IES is highly reliable and widely accepted to reveal posttraumatic stress symptoms [17]. The item pain was analyzed using a visual analogue scale, ranging from 0 (no pain) to 10 (heaviest pain).

Statistics

Statistical differences were analyzed using SPSS 16.0 software. Data is displayed as mean±SEM. To compare groups, we used the student t-, Mann-Whitney U and Chi² test. p<0.05 was considered to be statistically significant.

RESULTS

Demographic and Clinical Data

Demographic and clinical data are presented in Tables 2 and 3.

Table 2. Demographic and Clinical Data of the Study Population Following Tibial Non-Union (TNU) or Uneventful Healing After Tibial Shaft Fracture (TH). * = p<0.05

Parameter	TNU	TH	p-Value
Patients (n)	30	30	n.a.
Male	70%	60%	0.58
Age (day of injury, years)	37.6±14.9	35.5±14.7	0.34
Surgical procedures (n)	4.5±2.8*	1.6±1.3*	0.001
In-hospital time (days)	37.9±17.6*	18.1±8.4*	0.02

There were no significant differences in gender distribution. There were significantly more surgical procedures and an increased in-hospital time in both non-union groups.

Table 3. Demographic and Clinical Data of the Study Population Following Femoral Non-Union (FNU) or Uneventful Healing After Femoral Shaft Fracture (FH). *= $p \leq 0.05$

Parameter	FNU	FH	p-Value
Patients (n)	21	21	n.a.
Male	66.7%	77.3%	0.2
Age (day of injury, years)	41.5±12.9*	29.5±11.5*	0.02
Surgical procedures (n)	3.3±2.4*	1.2±0.6*	0.001
In-hospital time (days)	65.1±25.4*	21.1±9.8*	0.01

Psychosocial Outcome Following Tibial Shaft Non-Union

Results of psychosocial and rehabilitation factors are presented in Table 4.

Table 4. Psychosocial Outcome Following Tibial Shaft Non-Union. GOS: Glasgow Outcome Scale. IES: Impact of Event Scale. HADS: Hospital Anxiety and Depression Score. *= $p \leq 0.05$

Parameter	TNU	TH	p-Value
SF-12 psychological	45.4±10.9*	52.2±9.1*	0.02
SF-12 physical	43.1±10.9*	48.8±8.3*	0.03
GOS	4.1±0.6*	4.6±0.6*	0.001
IES	19.1±2.5*	12.7±2.9*	0.01
HADS-D	4.1±4.1	2.8±4.1	0.3
HADS-A	6.2±3.7	4.8±4.4	0.8
Medical aids (%)	55*	23.3*	0.04
Unemployment (%)	6.8	3.3	0.7
Early retirement (%)	10.3	6.6	0.3
Pain (visual analogue scale)	2.0±2.1	2.6±2.1	0.3
Psychological counseling (%)	20.7	16.6	0.8

There were significant psychological impairments as measured by the SF-12 psychological, GOS and IES. No differences were found for anxiety or depression syndromes. Psychological counseling as well as intensity of pain was comparable between the groups. A frequent use of medical aids like crutches or wheelchairs was evident, profound physical restrictions were found by analyzing the SF-12 physical. Concerning the status of reintegration, no influence was evident.

Psychosocial Outcome Following Femoral Shaft Non-Union

In group FNU, there were no significant psychological restrictions as measured by the SF-12 psychological, IES, GOS, HADS-A or HADS-D (Table 5).

Psychological counseling as well as the intensity of pain was comparable in both groups. There were significant lower scores of the SF-12 physical in group FNU compared to

group FH indicating considerably restrictions of the physical activity. With regard to social reintegration and rehabilitation status, there were significantly more patients using medical aids in group FNU compared to FH, furthermore a significantly increased early retirement and unemployment was evident in group FNU.

Table 5. Psychosocial Outcome Following Femoral Shaft Non-Union. GOS: Glasgow Outcome Scale. IES: IMPACT of Event Scale. HADS: Hospital Anxiety and Depression Score. *= $p \leq 0.05$

Parameter	FNU	FH	p-Value
SF-12 psychological	49.4±14.0	52.3±9.3	0.5
SF-12 physical	33.9±10.9*	43.9±11.1*	0.01
GOS	4.5±0.5	4.6±0.6	0.5
IES	16.5±11.1	18.3±8.4	0.7
HADS-D	5.9±4.7	3.6±3.9	0.4
HADS-A	5.7±4.8	3.9±2.2	0.5
Medical aids (%)	71.4*	21.7*	0.003
Unemployment (%)	23.8*	4.3*	0.03
Early retirement (%)	33.3*	13.1*	0.01
Pain (visual analogue scale)	3.6±2.8*	2.6±2.5*	0.08
Psychological counseling (%)	33	13	0.3

DISCUSSION

In the present study, we analyzed the health-related quality of life and several parameters of the socioeconomic outcome of patients without significant comorbidities following aseptic non-unions of the femoral or tibial shaft as compared to patients with uneventful healing.

The SF-12 physical was decreased in both non-union groups; furthermore, the need for medical aids like crutches and wheelchairs seems to be present in patients following non-unions. Early retirement and unemployment was frequently observed following femoral shaft non-union, this was not evident in the corresponding group of the tibia. The use of psychological support was comparable in both groups meanwhile the SF-12 psychological was decreased in group TNU only.

It is widely known that patients with posttraumatic physical restrictions require effective coping strategies, strong social support and psychologic integrity to deal with the treatment outcomes [18, 19]. Several authors assume that severely injured patients as well as those with repeated in-hospital stays and consecutive surgical procedures are at greater risk of posttraumatic stress disorder syndrome (PTSD) [20, 21]. However, the injury severity in multiple trauma patients has no profound effect on the symptoms of PTSD [22]. In our report, possible anxiety and depression syndromes were evaluated using the HADS. According to the most commonly used cut-off values in literature [16], there was no evidence for the presence of either anxiety or depression symptoms in our study population. However, we found evidence for profound psychological impairments in group TNU. There were remarkable differences concerning

the SF-12 psychological and the IES indicating the presence of PTSD symptoms in these patients. Although patients with femoral shaft fractures were more severely injured, there were no alterations concerning these scores of SF-12 psychological or IES in the femoral non-union group. This is in line with current literature. Quale *et al.* performed a study to evaluate the correlation of injury severity and the risk for posttraumatic stress syndromes. There was no correlation between overall injury severity or stress syndromes, however, the most evident risk factors for the development of stress syndromes were anxiety and negative attitudes toward emotional expression [22]. Moreover, a superior social reintegration, forced rehabilitation and organization of the whole social surrounding following major injury might be evident. A study by Georgiadis *et al.* described the clinical course following tibial fractures with severe soft tissue loss compared to lower knee amputation. He observed not only a comparable rate of non-unions between his groups, but also did the patients with limb salvage consider themselves severely disabled [23]. These results display the focus of the patients to one major injury, meanwhile patients with multiple injuries obviously show comparable or even better psychosocial long-term outcomes. However, to best of our knowledge, this is the first report analyzing possible alterations in the course with regard to the SF-12 and IES scores.

As a limitation to our study, the number of patients is not as high as in some other studies dealing with non-unions, ranging from 10 up to 124 patients. However, these studies particularly do not only focus on patients with non-unions of the shaft but also on those with periarticular non-unions. In addition, there is frequently no differentiation between septic and aseptic non-unions [6, 10, 24]. In the study presented here, we excluded all patients with laboratory evidence for bacteria in both, at the wound and at the (former) fracture site as these are one of the main risks for non-unions [25]. In most of the published studies, patients with personal risk factors are included, too. Medications like corticoids, smoking habits and comorbidities such as diabetes were either not identified or not excluded. In former studies, several authors showed an increased risk of non-unions of the lower leg in smokers [9, 26]. Diabetes still remains to be a challenging situation in surgical patients. Not only prolonged wound healing and increased risk of infections but also decreased bone mineral density and abnormal bone formation are described [27, 28]. The adverse effect of corticosteroids on bone healing is widely known. Several studies showed the deleterious effect not only in bone formation but also in bone healing [8]. Thus, we feel safe to use our data for further conclusion.

In our study, we were able to demonstrate decreased values for the SF-12 physical in both, the femoral and the tibial non-union group, indicating profound restrictions in patients with healed non-unions of the femoral and tibial shaft. A study by Zlowodzki *et al.* investigated the clinical and psychosocial outcome of 23 patients one year after surgically treated non-unions of the lower limb. Signs of healing were achieved in 90% of the patients. Using the SF-36, they found an improvement of some of the physical sub-scores compared to the pretreatment status, social functioning was successfully improved after one year. However, general health and pain was comparable as to the

pretreatment status. As the investigators included several types of non-unions such as femoral and tibial, aseptic and septic, subtrochanteric, shaft and supracondylar, the results display an interesting overall result of surgically treated non-unions [29].

A study by McKee *et al.* revealed changes during and following ilizarov treatment of the lower limb. In line with our results, the investigators did not find a significant improvement of the physical function. Furthermore, the role-physical, as part of the SF-36, was not significantly improved. Nonetheless, an improvement of the general health as compared to preoperative status was evident [30].

The intensity of pain, measured by the visual analogue scale, was not different between the patients of group TNU or FNU compared to their respective control groups. Habernek *et al.* examined restrictions following tibial fractures. In that study, over 30% of the patients reported pain, mainly at the former fracture site and anterior knee pain. Levaifre and colleagues investigated the long-term outcome following intramedullary stabilized fractures of the tibia. In their report, the investigators did not find differences compared to the normal population concerning the SF-36. However, at a 14 years follow-up, over 73% of the patients reported pain in the injured lower leg [31]. Outcome following non-unions of the femoral shaft was one of the endpoints in the study of Chiang *et al.* After consolidation of the non-union, the investigators found significantly improved values concerning all sub-scores of the SF-36, including the intensity of pain [32]. Compared to our results, we suggest that healed non-unions do neither essentially lead to increased risk of pain nor seems the intensity to be different compared to patients with uneventful healing.

In our study, we found significantly more patients using medical aids like crutches or wheelchairs in groups TNU and FNU compared to their respective control groups. This indicates the need for a systematic investigation of the complete postclinical course of patients with non-unions towards weight bearing, physiotherapy and mental support. To the best of our knowledge, this is the first report dealing with this special topic in aseptic tibial and femoral shaft non-unions.

In addition, we found a significantly increased percentage of patients with femoral non-union who retired early or were unemployed. Concerning the return to work following trauma, our results are in line with the published rates for patients following major trauma [33]. We therefore conclude that patients following femoral non-union have the same chance to return to work as those severely injured but rehabilitated despite their prolonged or repetitive in-hospital stays and the need for medical aids.

CONCLUSION

In our study population of healthy patients following femoral or tibial shaft non-unions, we found profound differences with regard to several psychosocial outcome parameters when compared to patients with uneventful healing. Early retirement and unemployment are frequent in patients following femoral non-unions reflecting the outstanding economical role of this disease. Medical aids are frequently used following both, femoral and tibial non-unions.

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