

Reamputation in patients with diabetic-related minor amputations who underwent physical therapy during their hospitalization. A single-facility retrospective cohort study

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Research

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Abstract

Background: Diabetic foot lesions are a major cause of non-traumatic lower limb amputations; they can interfere with daily life, reduce physical function and lower a patient's quality of life. Physical therapy is necessary to prevent such social disadvantage. Patients at high risk of reamputation may require physical therapy to prevent reamputation. The purpose of this study was to elucidate the factors that influence re-amputation in patients with minor amputations who were treated with physical therapy during their hospitalization.

Methods: This was a retrospective cohort study of 245 consecutive hospitalized patients who presented to our Wound Care Center between January 2015 and February 2018 and received physical therapy after a minor amputation. Participants were identified from admission records (to surgical and physical therapy units) stored in the electronic medical records. We examined reamputations that occurred in the ipsilateral lower extremity during the 1-year post-discharge outpatient period. The maximum follow-up period was 1 year. We used Cox proportional hazards analysis to examine factors affecting the risk of reamputation.

Results: Of the 129 patients enrolled, 42 patients (32.5%) underwent reamputations during an average observation period of 6.2 months (range, 2.1 to 10.9 months). The factors associated with reamputation were a requirement for hemodialysis, ankle dorsiflexion angle, and ambulation Functional Independence Measure score.

Conclusions: We identified a requirement for hemodialysis, ankle dorsiflexion angle, and functional independence measure (FIM) ambulation as the factors associated with reamputation in patients with diabetes who had undergone minor amputation. In the future, developing a physical therapy program that focuses on these factors could help reduce reamputations.

Background

In a survey of lower limb amputations in Japan, the amputation rate in the 1960s was 1.6/100,000 patients, and 70% of the amputations were caused by trauma; however, in the 2000s, the amputation rate was reported to be 5.8/100,000 patients, and the cause was peripheral circulatory disturbance in 66.2% cases [1]. A prognostic study of amputee patients reported that the mean age of patients with foot amputations was 72.4 years and that the reamputation rate was 18.2% [2].

A report examining the time to reamputation concluded that after minor amputations, 49.1% of patients underwent ipsilateral reamputation within 3 years after the initial surgery, and 78.9% of these patients underwent reamputation within the first 6 months [3]. These reports indicate that amputees are older and have a higher short-term reamputation rate.

After minor amputation, a patients' quality of life is reduced, with limitations on their daily activities [4]. In addition, metabolic functions and microcirculatory systems are often impaired [5, 6], and postoperative

rest can cause a disuse syndrome, such as lower limb muscle atrophy and reduced physical endurance, leading to a decreased walking ability, and limitation in social life. Physical therapy interventions are needed to prevent such social disadvantage [7]. With the decline in walking ability, nursing care may be required for daily life, which may increase social security costs.

In addition, the unloading and maintenance of ankle function plays an important role in preventing ulcers that may be a precursor to amputation [8, 9]. Previous studies have shown that the risk factors for reamputation in mildly amputated cases are age [10], wound depth [11], history of peripheral arterial disease [12], and wound infection [13].

However, the impact of physical therapy and reamputation on patients with a previous history reamputation has not been elucidated. Therefore, the present study aimed to elucidate the factors affecting reamputation in patients with a history of minor amputations who received physical therapy during their hospitalization.

Methods

Study Design and Participants

This single-centre retrospective cohort study was conducted in the Wound Care Center of Oita Oka Hospital, community medical support hospital with a multidisciplinary foot care team.

A total of 245 consecutive inpatients, who presented to our Wound Care Center between January 2015 and February 2018 and who received physical therapy after revascularization and a minor amputation were included. Participants were identified using information from the admission records (to surgical and physical therapy units) stored electronically. We examined reamputations in the ipsilateral lower extremity during the 1-year post-discharge outpatient care period. The maximum follow-up period was set at 1 year.

In this study, diabetic foot was defined as a plantar ulcer associated with neuropathy and peripheral artery disease in patients with diabetes [14]. The amputation region was defined as a minor amputation of the toes, rays, and metatarsal bones. Amputation below and above the knee was defined as major amputation [15]. We excluded patients with the following. (1) infection after minor amputation, (2) major amputation (below and above the knee), (3) death following discharge due to systemic complications, (4) use of a wheelchair for mobility before admission, (5) severe progression of dementia, (6) missing data, and (7) patients who did not visit the hospital for regular outpatient visits (1, 3, 6, or 12 months) after discharge. The reason for excluding patients with postoperative infections was that if an obvious wound infection appeared postoperatively, the rehearsal intervention was discontinued in view of the spread of infection. We excluded physical therapy, since we expected it to be ongoing, and thus we did not assess its association with reamputation.

The date of death within 1 year after the minor amputation was confirmed based on the medical information from the cooperating medical institutions. Finally, 129 patients were enrolled in this study

(Fig. 1).

Data collection and definition

We collected basic data on all patients by reviewing electronic medical records and structured interviews that were conducted when they were admitted for the first amputation.

Measurement items included participants' basic and medical information, physical function, and the presence or absence of a reamputation.

Basic information included age, sex, body mass index (BMI), hospitalization days, physical therapy duration, average length of daily physical therapy in minutes, non-weight-bearing duration, comorbidities (hypertension, hyperlipidemia, heart disease, cerebrovascular disease, chronic kidney disease, and chronic obstructive pulmonary disease), and the requirement (or no requirement) for hemodialysis.

The medical information included laboratory parameters including serum albumin, serum hemoglobin, blood glucose, C-reactive protein, white blood cell counts, and estimated glomerular filtration rate [16].

For data collection, we divided the patients into four groups as follows: The estimated eGFR (1) ≥ 60 mL/min/1.73 m², (2) 45–59.9 mL/min/1.73 m², (3) 30–44.9 mL/min/1.73 m², and (4) <30 mL/min/1.73 m². Lower limb blood flow data (skin perfusion pressure and ankle-brachial pressure index), wound ischemia foot infection (WIFI) classification system [17], amputation region (toe, ray, and transmetatarsal) [15], foot deformity (Charcot's joint [18], hallux valgus [19], hammertoe [20], and claw [21]). Deformity was determined by a specialist based on x-ray and clinical indicators. X-rays were taken periodically before surgery and at 1, 3, 6, and 12 months postoperatively. Physical function was determined by knee extension strength [22], range of motion in the ankle joint [23], presence or absence of plantar sensory disorder [24], and ambulation status was evaluated using the movement parameter of the FIM score [25]. The measurement methods and definitions of the study items are shown in Table 1.

Study main outcome

In this study, all patients with minor amputations were followed with data from electronic medical records for 1 year after surgery or until death. The endpoint was the presence or absence of reamputation within 1 year after surgery. Reamputation was defined as an amputation that occurred on the same side of the limb as the initial amputation. To detect the presence or absence of reamputation, the operative information in the electronic medical record was checked; in addition, the date of amputation and the site of surgery were identified. Our Wound Care Center is the only facility of its kind in the prefecture; therefore, post-discharge outpatient follow-up is basically limited to our facility. As a rule, outpatient visits to the hospital are conducted at intervals of 1, 3, 6, and 12 months after discharge.

Physical Therapy Program

Physical therapy was given to improve physical function and walking ability. The 1st postoperative day started with strength training and range-of-motion exercises of the hip and knee joints, which were performed according to the level of pain experienced by the patient. Additionally, walking practice started after wound healing. The physiotherapy session and physical function measurements were performed by two experienced staff (physiotherapists).

Statistical analysis

A Mann-Whitney's U-test, t-test, and χ^2 test were used to compare background factors and indices of physical functioning between the two groups with reamputation histories versus groups with no reamputation histories, depending on the data characteristics. Multivariate Cox regression analysis was also performed after adjusting for confounding by inputting sex [2], age [10], serum albumin levels [26], and knee extensor muscle strength [27] as covariates with reference to items that were significant in univariate analysis and previous studies to identify factors associated with reamputation. To account for multicollinearity in this process, variables that were considered clinically important were left in the model if the absolute value of the correlation coefficients between the independent variables was greater than 0.7. In addition, incomplete data sets (missing data) were excluded from the multivariate Cox regression analysis for case-pair-wise deletions.

The incidence of the presence or absence of reamputation was calculated using Kaplan-Meier curves for the extracted factors. Differences between groups were estimated using the log-rank test. All analyses were performed using R version 3.2.5 (R Foundation for Statistics Computing, Vienna, Austria). The significance level was set to $P < 0.05$.

Result

Of the 129 patients enrolled, 42 patients (32.5%) underwent reamputations during an average observation period of 6.2 months (range, 2.1 to 10.9 months). The demographic and medical information of the patients is shown in Table 2. The reamputation group exhibited significantly higher rates of hemodialysis and FIM ambulation compared to rates observed with the non-reamputation group. Lower rates of lower ankle dorsiflexion were observed in the non-reamputation group compared to that seen in the reamputation group. Univariate Cox regression analysis showed that hemodialysis, ankle dorsiflexion angle, and FIM ambulation were potential risk factors for reamputation. Subsequently, multivariate Cox regression analysis adjusted for age, gender, serum albumin level, and knee extension muscle strength as covariates showed that hemodialysis (HR 2.20, 95% CI 1.12-4.34), ankle dorsiflexion angle (HR 5.82, 95% CI 2.93-11.58), and FIM ambulation (HR 3.85, 95% CI 2.00-7.39) were identified as significant risk factors for reamputation (Table 3). The Kaplan-Meier curves in Figures 2, 3, and 4 show the cumulative incidence of reamputation after minor amputation. The survival analysis using Kaplan-Meier log-rank test showed that the requirement for hemodialysis (Fig.2), ankle dorsiflexion angle (Fig.3), and FIM ambulation score (Fig.4) were significantly associated with survival ($P < 0.05$).

Discussion

The present study examined factors that influence reamputation within 1 year of discharge in patients who had undergone minor amputations. We revealed that the requirement for hemodialysis, ankle dorsiflexion angle, and FIM ambulation were associated with reamputation in this patient population significantly ($P < 0.05$). The reamputation rate was 32.5% within 1 year of discharge, similar to previous findings [28].

Regarding the relationship between hemodialysis and reamputation, it has been reported that hemodialysis caused periodic fluid fluctuations and worsened microcirculation, thereby promoting blood circulation disorders [29]. Miyajima et al. reported that hemodialysis was also an independent risk factor of major limb amputation [30]. Okamoto et al. reported that approximately 40% of 140 patients who had undergone hemodialysis had peripheral arterial disease [31]. These findings were similar to ours. We therefore determined that patients who had undergone hemodialysis may have undergone reamputation due to peripheral arterial disease.

Next, regarding the association between ankle dorsiflexion angle and reamputation, Fernando reported that the incidence of ulcers in patients with diabetes, who had limited joint range of motion, was as high as 65%, compared to 5% in those with an unrestricted range of motion [32]. Lavery et al. reported that minor amputations are a risk factor for ulcer recurrence [33]. In the present study, the recurrence of ulceration after a minor amputation may have led to reamputation.

Furthermore, Eduardo et al. reported that patients with diabetes who had minor amputations had an average ankle dorsiflexion angle of 9.6° . The mean dorsiflexion angle in the reamputation group in this study was 2.6° , which was very low compared to that reported in previous studies.

In this study, all patients received foot range of motion training early after surgery, and the physical therapy duration was similar for both groups. It has been suggested that regular screening for preoperative range of motion limitations and postoperative ROM practice time should be expanded, since interventions after surgery may not improve foot mobility sufficiently.

Secondly, with regard to the association between FIM ambulation and reamputation, the reamputation group had a higher FIM ambulation score. The reamputation group had a median FIM ambulation score of 6 and were able to ambulate independently to 50 m with the use of walking aids. Therefore, post-discharge mobility is assessed mainly by walking distance, which may increase following reamputation compared to that observed for the non-reamputation group.

In addition, a study reported that an increase in cumulative plantar tissue stress associated with the extent of walking distance resulted in wound formation [35]. Therefore, this report suggests that walking with a limited ankle range of motion may lead to an increase in cumulative plantar tissue stress. Finally, this paper demonstrated how recurrence prevention is possible with the progress being made in limb salvage treatment. This finding suggests that physical therapy after minor amputations should

incorporate programs that include activities that maintain ankle mobility. There is also a need to teach adequate off-road walking if there is a high risk of revision surgery.

There are several limitations to this study. First, our results were obtained from a single institution. Similar findings derived from other facilities are needed to validate ours for generalizability. Second, the definition of reamputation was limited to the original hospital only. Thirdly, it was not possible to evaluate the foot pressure. Further, patients who did not receive physical therapy were excluded. In addition, we did not investigate the living conditions and self-management status of patients after discharge from the hospital.

Moreover, the results may not be generalizable to all hospitalized patients with minor amputations; thus, further longitudinal studies with larger samples in a multiple hospital setting are required to investigate the reamputation rates in hospitalized patients with minor amputations.

Conclusions

To conclude, the requirement for hemodialysis, ankle dorsiflexion angle, and FIM ambulation were the factors associated with reamputation in patients with diabetes who had undergone minor amputations. The data obtained from this study will be valuable in aiding future rehabilitation programs aimed at preventing reamputation. Further studies with larger samples are needed to confirm our results.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki (as revised in Brazil in 2013), and approval was obtained from the Ethical Committee of the Oita Oka Hospital (approval number: B0018). In place of informed consent from every participant, consent was sought by publishing details of the study on the homepage of the research institute website, as well as on-site posting in the facility.

Consent for publication

Not applicable.

Availability of data and materials

Competing interests:

The authors declare that they have no competing interests.

Funding:

None

Authors' contributions

SI and TH were involved in study conception and design, data collection, data analysis and interpretation, and drafting the manuscript. KS, MF, and MO were involved in data interpretation and contributed to drafting the manuscript. All authors have read and approved the final manuscript.

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Abbreviations

BMI: body mass index

eGFR: estimated glomerular filtration rate

FIM: Functional Independence Measure

HR: hazard ratio

WIFI: wound ischemia foot infection

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Tables

Due to technical limitations, tables 1-3 are only available as downloads in the supplemental files section.

Figures

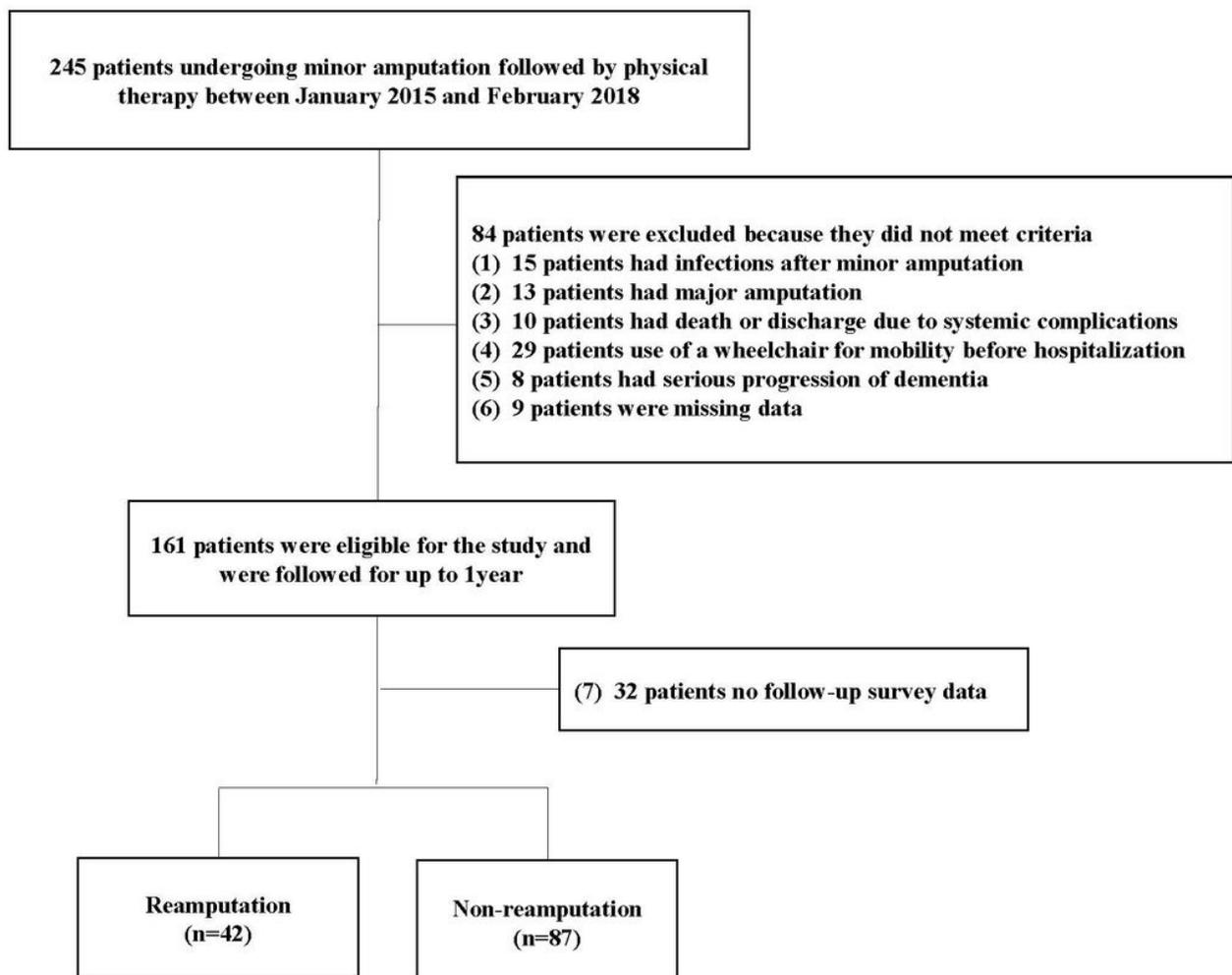


Figure 1

Flowchart of patient selection

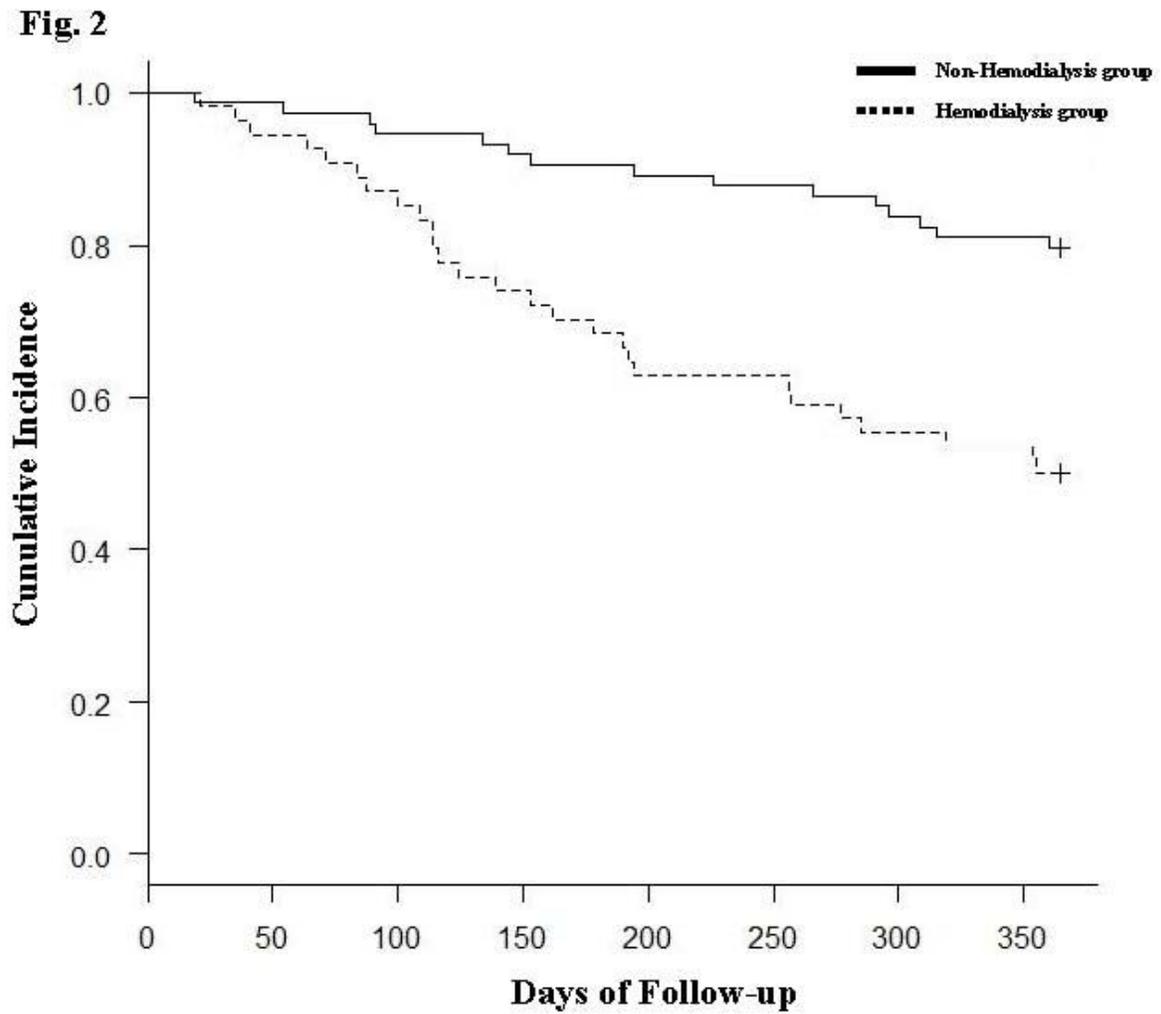


Figure 2

Kaplan-Meier curves of survival versus reamputation: presence or absence of hemodialysis.

Fig. 3

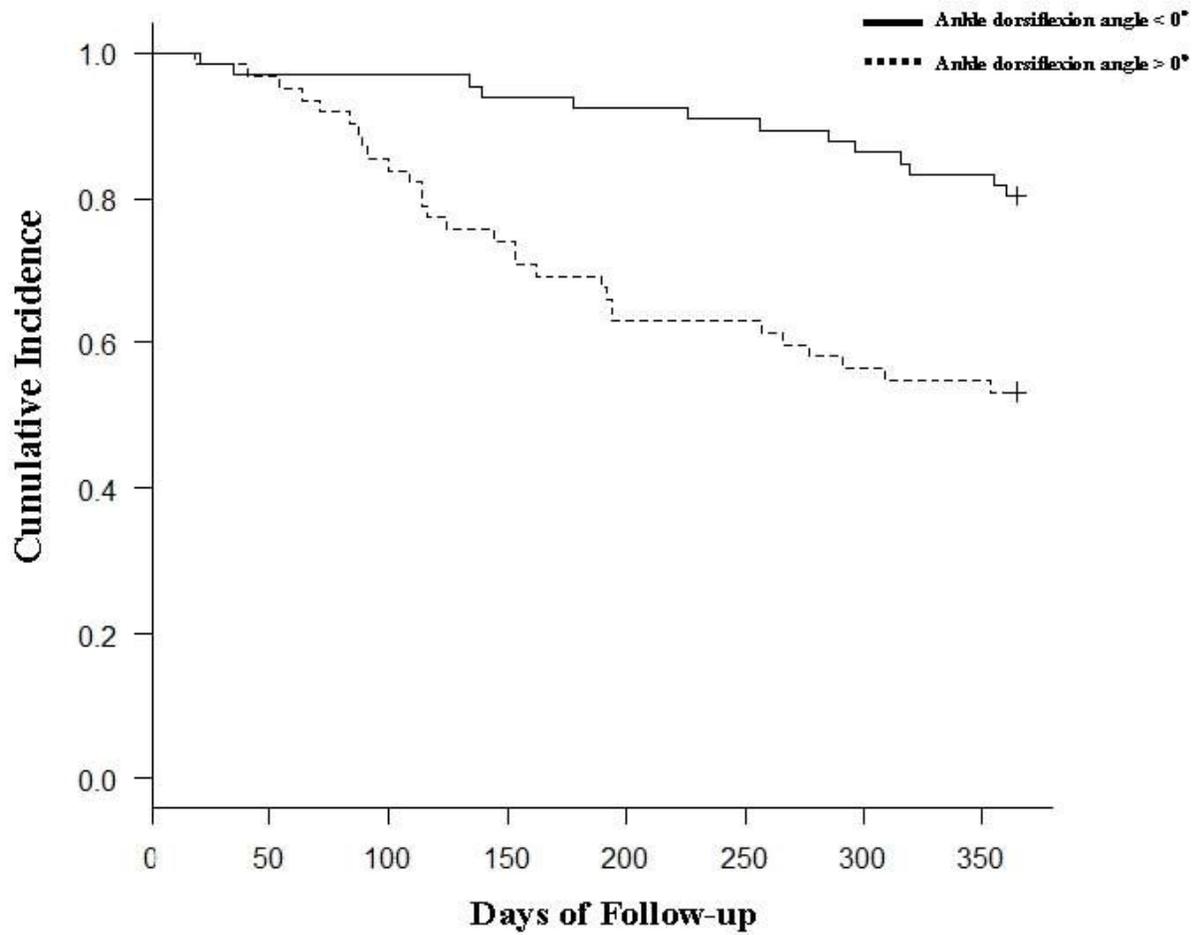


Figure 3

Kaplan–Meier curves of survival versus reamputation: presence or absence of ankle dorsiflexion limitation.

Fig. 4

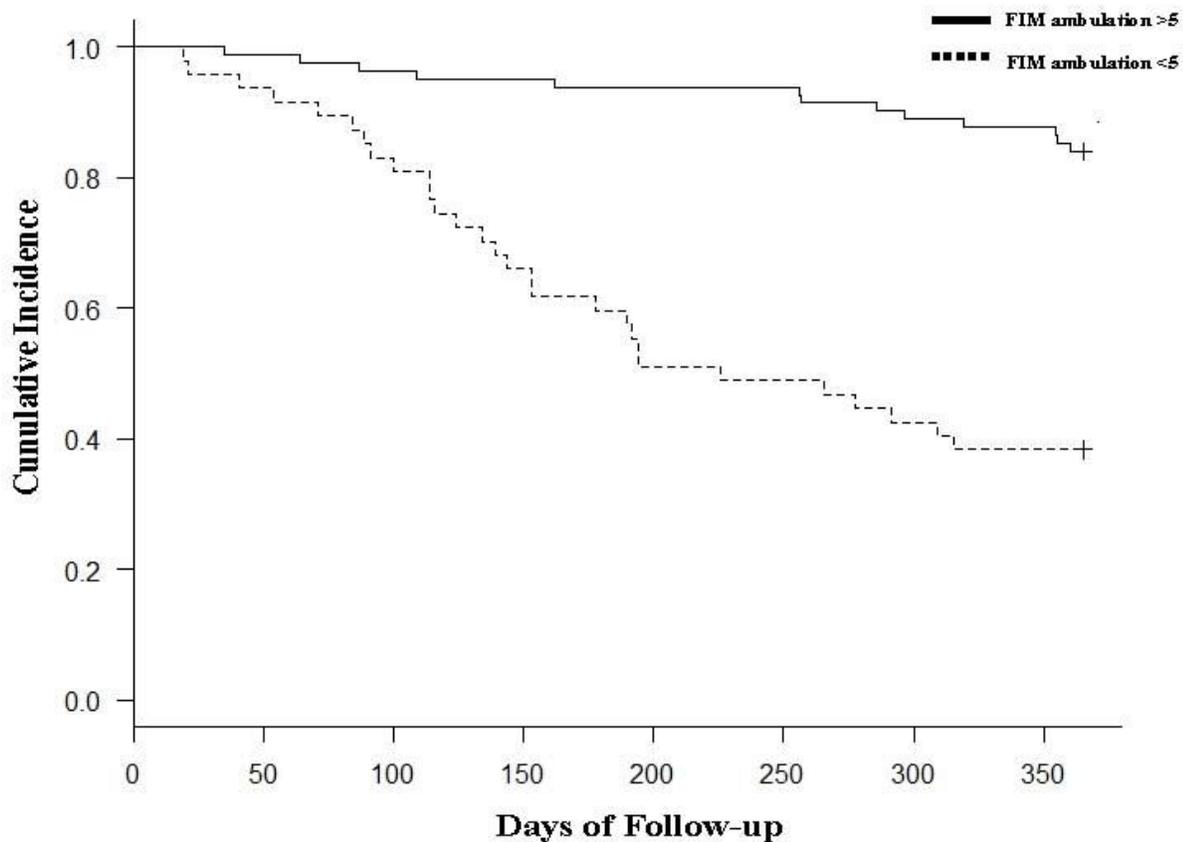


Figure 4

Kaplan–Meier curves of survival versus reamputation: ambulation group and non-ambulation group.

Supplementary Files

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