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Fractures of the lateral malleolus AO-44B1 – An evaluation study of treatment after the implementation of a structured treatment algorithm at Sahlgrenska University Hospital

Degree Project in Medicine

Hampus Brezicka

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Supervisor: David Wennergren, MD, PhD
Co-supervisor: Emilia Möller Rydberg, MD

Department of Orthopaedics, Sahlgrenska University Hospital
Mölndal, Sweden

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Abstract

Introduction

The lateral malleolar fracture classified as AO-44B1 (B1-fracture) is still difficult to assess regarding ankle-fracture stability and deciding subsequent correct treatment and follow-up procedure. With a structured treatment algorithm for ankle fractures (PM) being introduced at Sahlgrenska University Hospital/Mölndal (SU/M) in September 2017, the ambition has been to sharpen diagnostics and simplify assessment of ankle fractures, including B1-fractures.

Aim

The aim of this report was to study the adherence to PM-guidelines when it comes to the management of B1-fractures at SU/M and furthermore elucidate if the PM has had an effect over time. Further aim has been to study the PM´s effect on selected parts of Patient Reported Outcome Measures (PROMs) relevant to ankle function and in relation to B1-fracture treatment.

Methods

Two independent patient groups with B1-fractures were studied, one group having been treated before the introduction of the PM, and the other after. Data was extracted from the Swedish Fracture Register (SFR) with additional review of medical records and radiographs. Descriptive and statistical analyzing was conducted.

Results

Non-surgically treated patients with B1-fractures had significantly increased (pre-PM: 70%; post-PM: 90%) since the introduction of the PM ($p < 0.001$) and received more degree of full weight bearing advice following treatment ($p < 0.001$). Surgically treated patients had a significant decrease in inpatient care days (pre-PM: median 2; post-PM: median 0) ($p <$

0.001), immobilization time (pre-PM: median 45 days; post-PM: median 42 days) ($p < 0.001$) and were given less restriction on weight bearing following treatment ($p < 0.001$). Documentation of medial tenderness has descriptively increased. Analyses of selected parts of SMFA for non-surgically and surgically treated B1-fractures showed no significant decrease in dysfunction or bother from the ankle since the introduction of the PM.

Conclusion

There is a compliance to the PM, but room for improvement exists. The PM has yet to have an effect on PROMs.

Keywords

Ankle fracture, treatment algorithm, The Swedish Fracture Register, Patient Reported Outcome Measures.

Introduction

An ankle fracture involves a fracture in one or more of the malleoli in the ankle joint and can also involve soft tissue and ligament injury. The majority of ankle fractures are lateral malleolar fractures. The treatment of ankle fractures depends on the stability of the ankle joint. Stable fractures are treated non-surgically through immobilization below the knee. Unstable fractures are usually treated surgically, most often with open reduction and internal fixation (ORIF) [1-3].

Anatomy of the ankle joint

The ankle joint is formed by three articulating bones; the tibia, fibula and talus. The distal parts of the tibia and fibula forms the malleoli which can be palpated on the medial and lateral side of the ankle respectively. The majority (80-90%) of once bodyweight is, through the tibia, transferred to different parts of the talus depending on the position of the foot [4]. Plantar- and

dorsiflexion is mainly permitted by the ankle joint, but in more unstable positions other mobility is also possible including some smaller movements of adduction, abduction, inversion and eversion[5, 6]. The tibiofibular syndesmosis is a complex of ligaments giving the ankle joint stability preventing the tibia and fibula from being forced apart. It is made up of three ligaments: the interosseous tibiofibular ligament, anterior tibiofibular ligament and posterior tibiofibular ligament. Being a distal continuation of the interosseous membrane, the interosseous tibiofibular ligament has fibers that fills out most of the distal space between the tibia and fibula. The anterior tibiofibular ligament is a continuation of the anterior part of the Interosseous tibiofibular ligament and runs obliquely in laterodistal direction. The posterior tibiofibular ligament runs almost horizontally between the distal posterior surface of the tibia to the lateral malleolus and is a continuation of the interosseous ligament´s posterior fibers[7, 8]. The collateral ligaments on the medial and lateral side further reinforces the stability of the ankle joint. On the lateral side three ligaments connects the lateral malleolus on the fibula with the talus and calcaneus separately. The anterior talofibular ligament, posterior talofibular ligament and calcaneofibular ligament.[9] On the medial side of the ankle the deltoid ligament is located which stretches out from the medial malleolus on the tibia in a distal direction. Studies have shown that the deltoid ligament together with the medial malleolus constitute the primary stabilizing parts of the ankle.[10-13]

The AO classification of ankle fractures

The AO classification system has been proven accurate and valid showing substantial agreement between classification of ankle fractures made in the SFR and gold standard classification.[14]

The AO classification is based on the anatomical location of the fracture specified by two

numbers. The first number corresponds to the injured bone and the second number to a specific segment of the same bone. In accordance malleolar fractures in tibia/fibula are specified as 44 where the first four refers to tibia/fibula and the second four to the malleolar section. In accordance with the Danis-Weber system there is further subgrouping of ankle fractures into type A, B and C depending on the fracture´s position in relation the syndesmosis. Fractures inferior to the syndesmosis are referred as type A, trans-syndesmotic fractures are type B and fractures located superior to the syndesmosis is type C. The AO classification further divides the A, B and C types into three subgroups individually, numbered one to three, where the numbers correlates to the number of fractured malleoli. B1-fractures, which are the fractures highlighted in the current study, corresponds to fractures of the lateral malleolus in contrast to B2-fractures that additionally also has fractures on the medial malleolus or medial ligament injury. In the B3-fracture there is also an involvement of the posterior malleolus making it a tri-malleolar fracture. For the A1-3 and B1-3 types additional subgrouping is made by decimals one to three. In accordance a fracture restricted to the lateral malleolus, passing trans-syndesmotic and excluding injury to the anterior syndesmosis will be categorized as 44-B1.1. If the anterior syndesmosis on the other hand is injured it is labeled 44-B1.2 and if the fracture is comminute it is classified as 44-B1.3 (Figure 1).[15]

The B1-fracture

The fracture of the lateral malleolus at the level of the syndesmosis (B1-fracture) is the most common ankle fracture registered in SFR representing nearly 30 % of all ankle fractures.[16] There is a challenge in evaluating B1-fractures as on the first plain radiographic image they can look stable. Yet, additional injury to the deltoid ligament is not visible on plain

radiographs. Higher grade of injury on the lateral malleolus increases the risk for simultaneous medial injury, transforming the fracture from B1 to B2 which consequently renders the fracture as unstable indicative to surgical treatment.[17]

As already mentioned, B1-fractures are divided into three subgroups (figure 1). The B1.1-fracture is regarded as stable allowing only minor displacement of fibulas distal part while the lateral ligament is intact. However, if rotation of the ligament has occurred the displacement of the distal part of fibula may be assessed as more severe than is really the case. Thus, displacement should be measured utilizing radiographic examination with frontal- and straight sideview images of the ankle. The B1.2 fracture when compared to the B2.1-fracture can be confusingly similar on radiographic examination due to the fact that that ligament-injuries are hard to visualize when performing plain radiographic imaging. However, due to that the fact that latter has an injured deltoid ligament, which consequently moves the talus in lateral direction, the B2.1 fracture displays key differences. These include medial tenderness and more displacement with the radiographic ‘’fork-view’’ revealing incongruency in the ankle joint. Thus, because of the increased distance between the medial side of the talus and the medial malleolus the B2.1-fracture is regarded as unstable when compared to the B1.1-fracture. Relevant pictograms illustrating the B1-fracture subgroups (Figure 1) with addition to the B2.1-fracture (Figure 2) derived from the latest AO-compendium released in 2018 are presented below.

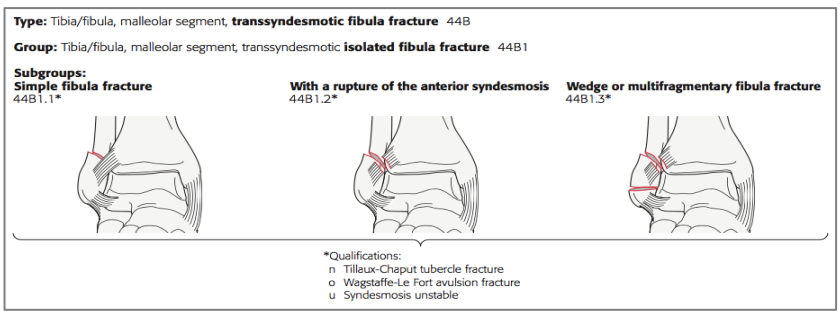

Figure 1. The AO classification of B1-fractures according to Fracture and Dislocation Classification Compendium – 2018.

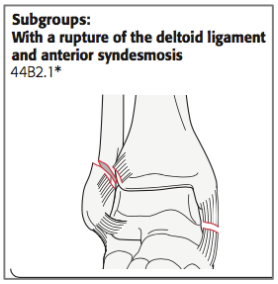

Figure 2. The AO classification of a B2.1-fracture with rupture of the deltoid ligament according to Fracture and Dislocation Classification Compendium – 2018.

Acute injury to the ankle often occur when an axial load is passed through to a pronated- or supinated foot giving cause to a rotational force [18]. As with most B1-fractures the body rotates externally in relation to the supinated foot causing damage to the distal part of fibula and lateral syndesmosis which is referred to as supination external rotation injury (SER). If a higher level of force is applied the deltoid ligament might break as well. In the case of pronation the external force will cause damage to the medial malleolus and deltoid ligament first.[19]

Diagnostics & treatment

When it comes to acute injury of the ankle the first thing to be addressed at the accident & emergency department (A&E) is the prospect of a fracture or not. Since fractures should be radiographic examined the Ottawa ankle rules is a proven accurate method to distinguish fractures from ankle sprains subsequently reducing unnecessary radiographic examination. The method includes three questions that addresses if there is tenderness posterior to the lateral- or medial malleolus and/or 6 cm above and if no weight bearing on the injured foot as well as if no walking more than four steps is possible. If any of the conditions are met indication of fracture exists and radiographic examination should be performed. [20]

When it comes to diagnosing ankle fractures both radiographic imaging as well as the combination of clinical examination and knowledge of injury mechanism is of key importance to be able to pinpoint fracture type. For B1-fractures it is crucial to determine the stability of the ankle joint as this decide the appropriate treatment method. Apparent malalignment of the foot or incongruency in the ankle joint space are strong indicators of instability. Signs of deltoid ligament injury with medial side tenderness, swelling and ecchymosis must be considered as well. As already mentioned, unstable ankle fractures with displacement (> 2 mm) are beneficiary to surgical intervention through ORIF reducing the risk of non-union, malunion and loss of reduction [2, 17]. With this said, the risk of acute complications including infection and peroneal nerve damage are increased as well [21]. Risk factors for short term complications following surgical intervention include smoking, high age and comorbidity [22, 23], highlighting the importance of individual assessment. Additionally, late side effects following surgical intervention can also arise due to troubles with the internal fixation material requiring reoperation. Stable fractures on the other hand have the chance of better outcome if treated non-surgically with immobilization below the knee and the risk of displacement is very low [24, 25].

An evidence based guideline for treatment of stable ankle fractures have previously been implemented in the United Kingdom resulting in a significant decreased number of follow-up radiographic examinations and reduced immobilization time without adverse effect on patient safety [26]. This greatly influenced the subsequent treatment algorithm for ankle fractures introduced at SU/M in 2017.

PM-guidelines for B1-fractures

The PM stipulates treatment recommendations according to classified ankle fracture. When it

comes to the stable B1.1-fracture the recommendation is immobilization below the knee with an orthosis for 4 weeks with immediate full weight bearing allowed and further radiographic examination is unwarranted. Occurrence of remaining pain or stiffness when dismantling the orthosis at follow-up visit physiotherapy is advocated. If remaining symptoms still occur after this an additional visit to surgeon for evaluation is advised. Hence, without complications a B1.1-fracture undergoes only one radiographic examination and have only two visits to surgeon (A&E and follow-up).

Addressing the B1.2/3-fractures, which are potentially unstable, there are two treatment options according to PM-recommendations. In occurrence of instability or incongruence of the ankle joint surgical treatment is advocated. If this is not the case then immobilization below the knee with either circular plaster or orthosis is advised, allowing full weight bearing promptly. Radiographic examination of placement and congruency is followed after one week. If no signs of displacement or incongruence is evident an immobilization of six weeks is advocated. If the follow-up radiograph shows evident displacement or increasing of the tibiotalar clear space, then the non-surgical treatment should be converted to surgical intervention with ORIF.

Overall the PM recommends the immobilization time to be the doubled if the patient has comorbidity with diabetes regardless of fracture type. Furthermore, there is usually no need of inpatient care for B1-fractures regardless of intervention. Whit this said, it is advocated that each case must be evaluated individually.[27]

The Swedish Fracture Register

SFR is a national quality register that prospectively collects data on fractures regarding patient, date and cause of injury, type of fracture, given treatment and subsequent treatment

results in terms of reoperations and patient reported outcome measures (PROMs). PROMs are collected at day 0 and after one year. PROMs are recorded in SFR using Short Musculoskeletal Function Assessment questionnaires (SMFA), which is of interest in this study, and the health status questionnaire EQ-5D which is not of interest in this study.[28]

The registration of fractures in the register was initiated in 2011 with the addition of ankle fractures including lateral malleolar fractures 2012-04-01. In 2019 fracture of the lateral malleolus was the fifth most common fracture in the register. In 2018 just over 80% of the orthopedic departments in Sweden have started registration and among 70% conduct a continuous fracture registration with adequate completeness. In 2019 the number of registered fractures increased from 350 000 to 428 000 and it is projected that in 2020 the number of registrations will exceed over 500 000.[29-32]

SMFA

PROM-data at day zero is registered through a survey using the recall technique that measures function the week before the fracture. One year after injury responding patients receive an identical survey enabling possible comparisons between one-year result and pre-injury status. Since the start of the register in 2011 all patients are asked to fill in the questionnaires.[30]

SMFA is a two-part, forty-six-question, self-reported health status questionnaire that is designed to find differences in the functional status of patients with musculoskeletal disorders. Furthermore, it also evaluates how bothered they are by functional problems. Used as a functional assessment tool it can be utilized to evaluate treatment effectiveness. The two parts are made up of the dysfunction-index and the bother-index. The dysfunction-index contains thirty-four questions from SMFA assessing patient´s perceptions of their functional performance. The questions in the dysfunction-index are grouped into four categories

including daily activities, emotional status, function of the arm and hand, and mobility with each question having a five-point response format, ranging from 1 point (good function) to 5 points (poor function). The bother-index contains twelve questions assessing how much the patients are bothered by problems in wide functional areas and also uses a 5-point response format, ranging from 1 point (not at all bothered) to 5 points (extremely bothered). [33]

Overall both indexes are presented on a descending scale from 100 (maximum bad score) and 0 (best possible score).

Ponzer et al assessed that the Swedish translation of SMFA is a reliable and valid instrument showing sensitivity to changes in musculoskeletal function over time.[34]

As with many surveys PROM, including SMFA, also has problems with the responsiveness. However, Juto et al indicated that non-responders report similar function in the SMFA-surveys compared to those who had initially responded.[35]

Previous & current research

In 2015 a study of ankle fractures was conducted at SU/M using data from SFR with the aim to describe the epidemiology of all types of ankle fractures as well as to investigate how B1-fractures were treated at SU[36]. For that study data was extracted from SFR on all patients registered with an ankle fracture during two consecutive years (2012-04-01 to 2014-03-31). For all fractures registered as AO-44B1 and treated at SU/M, medical records and radiographs were studied. The study provided to the development of the PM for ankle fractures mentioned above and was implemented at the orthopedic department at SU/M in September 2017 [27]. In 2019, after the algorithm had been in use for two years, a follow up study was initiated. For the follow-up study a new set of data was extracted from SFR compromising all patients with B1-fractures registered and treated at SU from 2017-09-01 until 2019-05-31. The current

report will refer to the new dataset of ankle fractures from 2017-2019 as the ”post-PM” group and the dataset on ankle fractures from 2012-2014 as the ”pre-PM” group. First objective of the follow up study was to investigate what impact the introduction of a structured treatment algorithm has had on the assessment and treatment of lateral malleolar fractures. The second objective was to compare the post-PM group to the patients with B1-fractures included in the previous mentioned study conducted in 2015 (pre-PM group) in order to evaluate treatment results of B1-fractures since the introduction of the PM. [37]

Aim

The aim of this report was to study the adherence to PM-guidelines when it comes to the management of B1-fractures treated at SU/M since the introduction of the PM by analyzing medical records and radiographs for the post-PM period (2017-09-01 until 2019-08-31). Additionally, this report aimed to elucidate if the PM has had an effect over time in the treatment of B1-fractures at SU/M, by comparing the outcome variables between the pre-PM and post-PM groups. Furthermore, this report wanted to study if the PM has had an effect on PROMs in relation to the choice of treatment of B1-fractures by comparing the scores of selected parts of SMFAs relatable to ankle function between the pre- and post- PM groups.

Material and methods

Data collection

The 2015 study of ankle fractures at SU/M generated a final dataset of 439 patients with B1-fractures, referred to in the current report as the pre-PM group. To make comparisons a similar dataset with corresponding variables was extracted from SFR in 2019. The extracted dataset included patients with B1-fractures registered at SU between 2017-09-01 and 2019-08-31 and after exclusion consisted of 319 patients that made up the unit referred to as the

post-PM-group. For the patients in this group medical records and radiographs were reviewed which generated information on the number of radiographic examinations including ultrasounds, number of visits to surgeon, number of days immobilized, number of inpatient care days, weight bearing advice and if there comments on signs of injury to the medial side of the ankle when examined at the A&E.

Furthermore, score results from nine selected questions included in the SMFA-questionnaires were reviewed. The SMFA-data was included in the initial datasets extracted from SFR for the pre- and post-PM groups respectively and was composed of scores measuring dysfunction and bother index before injury (day 0) and as well as follow up scores one year later (year 1) measuring the same variables. The selected questions were chosen since they were thought to reflect ankle-function relevance after assessment by senior orthopedic surgeons with the other questions not being relevant to review as they showed inconsequential relevance in assessing ankle-function. The final selected SMFA-questions for this report included:

”How difficult was/is it for you to climb stairs?”,

”How difficult was/is it for you to walk?”,

”How difficult was/is it for you to do your usual physical recreational activities, such as bicycling, jogging, or walking?”

”How often did/do you walk with a limp?”

”How often did/do you avoid using your painful limb(s) or back?”

”How often did/does your leg lock or give way?”

”How much were/are you bothered by problems using your hands, arms, or legs?”

”How much were/are you bothered by problems with leisure or recreational activities?”

”How much were/are you bothered with stiffness and pain?”

The entire SMFA-questionnaire can be found in the attached appendix to this report.

In order to make comparisons in SMFA-scores between the pre-PM and the post-PM groups only patients who had answered all the selected questions, both at day zero and after one year, were included. This resulted in the inclusion of 137 patients from the pre-PM group and 39 patients from the post-PM group for the final SMFA-score analysis. With this said, for a quite substantial number of patients in the post-PM group the year 1 questionnaire had not yet been sent to them at the time this report was conducted.

Statistical methods

Post-PM group

In the first part of the results descriptive statistics including exclusions is presented for the post-PM group. Since the group includes two subgroups of fractures, B1.1 and B1.2/3, results in the post-PM group were analyzed individually for the two fracture subgroups with a further subgrouping based on non-surgical or surgical treatment. The aim of this was to evaluate each subgroup's results in relation to PM-guidelines. Production of charts and descriptive statistics was executed utilizing Microsoft Excel version 16.3.

Post-PM & pre-PM comparison

In part two of the results the given B1-fracture treatment was compared between the pre-PM and post-PM groups which applies the categorial non-surgical and surgical variables. Since the groups are independent of each other due to different individual patient-populations and the separation in time the Chi^2-test was executed utilizing SPSS version 26. Building of charts was conducted utilizing Microsoft Excel version 16.3.

Furthermore, comparisons of the numerical variables (e.g. the number of plain radiographic examinations) and the categorical variables (e.g. weight bearing advice), were done between

the pre- and post-PM groups. Observations in the respective groups are considered independent since the pre- and post-PM groups are separated in time and included different patients. Production of charts and independent parametric/non-parametric-testing were performed using Microsoft Excel version 16.3 and SPSS 26.

Selected SMFA-data analysis

Of the nine selected questions, six was selected from the dysfunction index and the other three from the bother index. Hence, one could not utilize the original index-score systems in the SMFA when comparing the scores. Therefore, two modified indexes correlating separately to the two different sets of questions mentioned above, was created. The modified indexes were created using the identical formula used by both the dysfunction- and bother-indexes, ([actual raw score – lowest possible raw score]/possible range of raw score) x 100[33]. These modified indexes, referred to as the ankle-dysfunction and ankle-bother index respectively, with a score rating (0-100) identical to the original indexes, was used to make comparisons. The modified indexes hade never been used in research before and therefore the validity of them comes into question. With this in mind, the results presented from the selected SMFA-data should be considered as a giving a very rough estimation of ankle dysfunction and bother between the groups.

The reviewed SMFA-scores from both the initial and follow-up questionnaire within both groups were not evenly distributed, showing great floor effect. Therefore, when analyzing the SMFA-data the non-parametric Wilcoxon signed-rank test was used utilizing SPSS 26.

Ethics

This report is based on data from SFR with included patients having been informed about registration in the register and their right to decline. With SFR being a swedish national

register, no mandate for written consent is required for registration. Due to this being a register study utilizing only data collected from the register and medical records, the potential risk is assessed as minimal when it comes to violation of privacy. Furthermore, the benefits of increased in-depth knowledge overweigh the potential risks. All data studied were after collection and consolidation subject to de-identification followed by analyzing and presentation of the results at group level. Permission for accessing and reviewing the medical records was approved by the head of the orthopedic department at SU. This report is included in the approval Nr. 1011-15 by the Regional Ethical Review Board in Gothenburg, Sweden.

Results – Post PM-group

Patient characteristics and Exclusions

During the post-PM period of 2017-09-01 until 2019-08-31 a total of 382 patients had been registered as having sustained a B1-fracture. 63 of the registered patients were excluded due reasons explained in Table 1.

After exclusions had been made a total of 319 patients were included in this report.

Table 1. Exclusion criteria and number of patients excluded from the post-PM group.

Reason for exclusion	N
Initially treated or follow up at other hospital	26
Not visited health care in acute phase of injury	26
Other fracture than AO-44B1	7
Missing follow up information in medical journals	2
Never visited the A&E	1
No fracture	1
Total	**63**

Among the 319 patients that were included in this report 125 (39%) were males and 194 (61%) were females. 167 (52%) patients were classified as AO-44B1.1 and were primarily treated non-surgically. Among the remaining 152 patients that were classified as AO-44B1.2/3 121 (80%) patients were treated non-surgically and the remaining 31 (20%) patients

were surgically treated. The range for age was between 16 and 99 years old with an average age at 52 years (Table 2).

Table 2. Patient characteristics in the post-PM group

Dataset	Age (Years)		Gender		Fracture type			
					AO-44B1.1		AO-44B1.2/3	
	Range	Average	Male	Female	Non surgical	Surgical	Non surgical	Surgical
post-PM (N=319)	16-99	52	125 (39%)	194 (61%)	167 (100%)	0	121 (80%)	31 (20%)

Variables in relation to PM

Descriptive statistics is presented separately for patients with B1.1 and B1.2/3-fractures in the post-PM group with subcategorization based on treatment.

Table 3. Post-PM group variables and medians in relation to PM-recommendations.

Fracture class	Primary treatment	Variables	Sum	Median	Range	Recommendation according to PM	Deviation
AO-44-B1.1 (n=167)	**Non-surgical** (*n* =167)	Number of plain radiographic examinations	335	**2**	1-4	**1**	**+1**
		Number of visits to surgeon	503	**3**	1-6	**2**	**+1**
		Days of inpatient care	83	**0**	0-16	**0**	0
		Days immobilized	6872	**42**	25-92	**28**	**+14**
AO-44-B1.2/3 (n=152)	**Non-surgical** (*n* =121)	Number of plain radiographic examinations	291	**2**	1-5	**2**	0
		Number of visits to surgeon	407	**3**	2-7	**3**	0
		Days of inpatient care	87	**0**	0-17	**0**	0
		Days immobilized	5204	**42**	25-78	**42**	0
	Surgical (*n* =31)	Number of plain radiographic examinations	81	**3**	2-5	**2**	**+1**
		Number of visits to surgeon	127	**4**	2-6	**4**	0
		Days of inpatient care	35	**0**	0-10	**Case by case**	N/A*
		Days immobilized	1317	**42**	40-48	**42**	0

Deviations from the PM-recommendations were generally seen with B1.1-fracture patients

given non-surgical treatment. This subgroup had in median one more radiographic examination and visit to surgeon than recommended by the PM. Furthermore this subgroup had a median of 14 extra days of immobilization compared to the recommendations.

Patients with B1.2/3-fracture given surgical treatment were in median given one more plain radiographic examination compared to PM-recommendations.

Patients with B1.2/3-fracture given non-surgical treatment had no deviation from the PM when looking at the variable outcome in Table 3.

Number of plain radiographic examinations

The median number of plain radiographic examinations for non-surgically treated patients regardless of fracture subgroup was 2. Surgically treated patients, which were all classified as B1.2/3-fractures, had 3 plain radiographic examinations in median number (Figure 3).

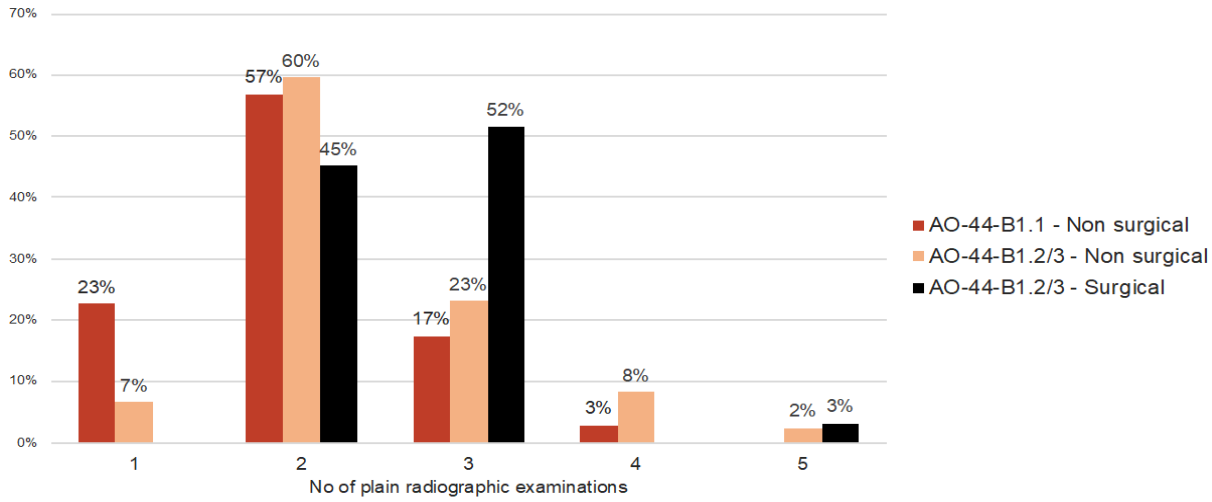

Figure 3. Number of plain radiographs examinations given to patients non-surgically and surgically treated within the post-PM group.

For almost all patients (98%) plain radiographic imaging was the imaging technique exclusively used regardless of fracture-subgroup or treatment. All patients (100%) were given plain radiograph examination as first used radiographic method. When it comes to additional

radiographic examinations computer tomographic imaging was used in four cases and Magnetic resonance imaging in one case. Ultrasound did not occur in any case.

Number of visits to surgeon

The number of visits to surgeon was quantified using patient-related information from medical journals and included: visits to the A&E, follow-up visits, stability testing and occasions of inpatient care and primary surgery. Furthermore, orthopedic consultation of patients admitted to other departments was also counted. Non-surgically treated patients visited the surgeon a median 3 times whilst surgically treated patient visited a median 4 times. Patients with with B1.2/3-fractures visited the surgeon more in comparison to B1.1-fractures. The proportion of patients with four or more visits was greater amongst those classified with a B1.2/3-fracture (Figure 4).

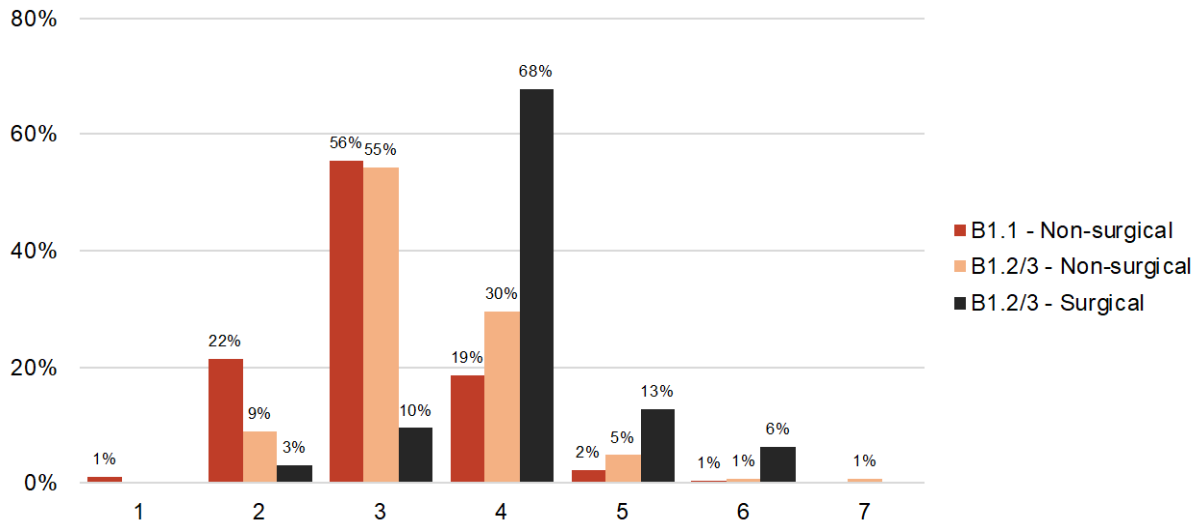

Figure 4. Number of visits to surgeon for patients treated non-surgically respective surgically wihin the post-PM groups.

Number of days immobilized

For a majority of patients in the post-PM group immobilization time were in the span 39-45 days. Non-surgically treated patients were predominantly in the lower end of the span while

surgically treated patients were more common in the higher end. A minority of patients had immobilization time of 46 or more days with a few having over 60 days (Figure 5).

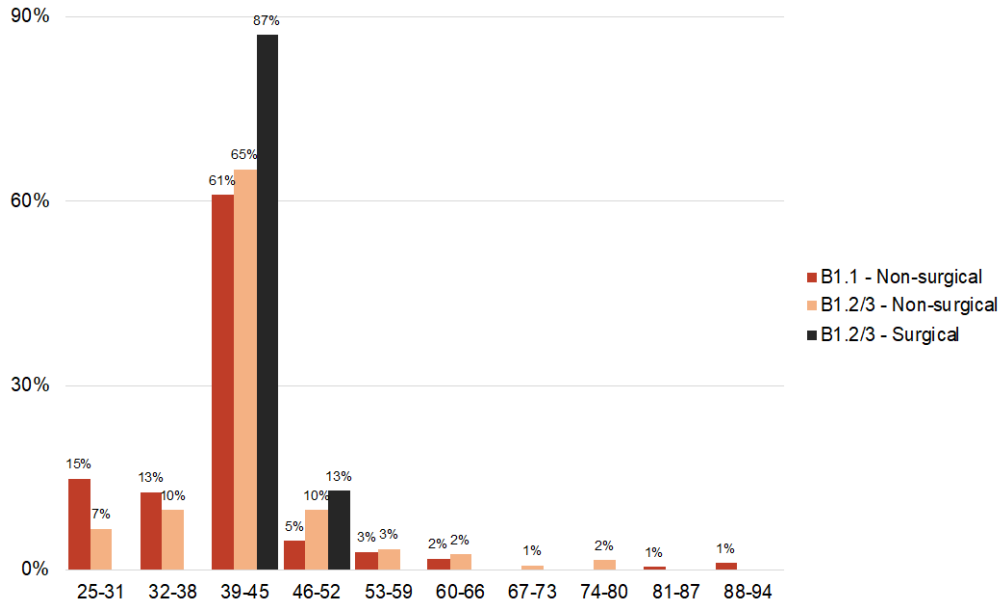

Figure 5. Number of days immobilized for patients non-surgical respective surgically treated within the post-PM-group.

Number of inpatient care days

The median number of inpatient care days was 0 for all patients regardless of fracture class or treatment (Table 4). 32 patients (10%) in the post-PM group had inpatient care and were predominantly given non-surgical treatment although 93% of all non-surgically treated patients within the group had no inpatient care (Figure 6).

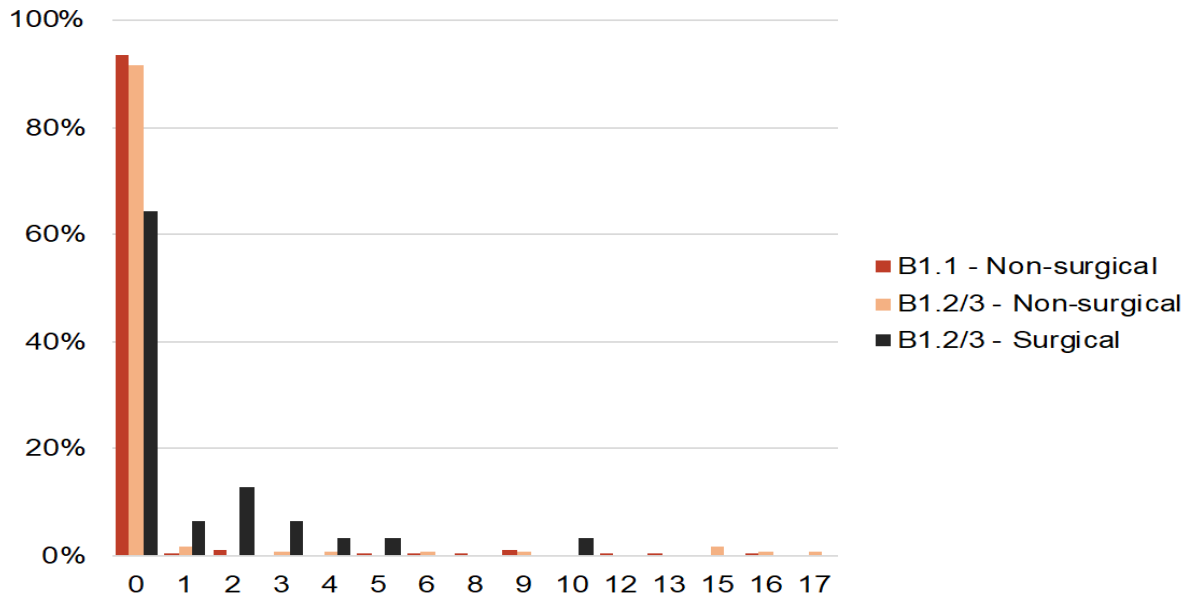

Figure 6. Number of inpatient care days for patients given surgical or non-surgical treated within the post-PM group.

Conversion of treatment

Among the fractures classified as B1.1 the vast majority (99%) were treated non-surgically. In only one B1.1-patient were treatment converted to surgical at an early stage. A detailed review of this case revealed no clear reasons as to why conversion to surgical treatment was done which suggest deviation from the PM-guidelines. The same patient later underwent reoperation due to hardware related pain. Among the patients classified as having sustained a B1.2/3-fracture (n=152) the distribution of treatment was 121 (80%) for non-surgically treated and 31 (20%) non-surgically treated. Among the non-surgically treated only 1 of 121 patients was converted to surgical treatment due to findings on radiographs. After detailed reviewing of this case it is suspected that the fracture had been misinterpreted as unstable. Among the B1.2/3-fractures treated surgically a total of 6 (19%) patients underwent surgery at a later stage. 3 patients had unplanned reoperations with extraction of internal fixation material due

to hardware related pain. 2 patients had planned follow-up surgery with extraction of internal fixation material. One patient underwent reoperation at an early stage due to displacement of the fracture.

Signs of injury to the medial side of the ankle

Table 4. Examination of the medial ankle side characteristics in the post-PM group

Fracture class	Treatment	N	Medial status commented		No. not commented	Medial Status occurence		No. of medial status occurence
			Yes	No	*n=36*	Yes	No	*n=97*
AO-44-B1.1	Non-surgical	167	87%	13%	21	27%	73%	40
AO-44-B1.2/3	Non-surgical	121	93%	7%	9	38%	62%	42
	Surgical	31	81%	9%	6	60%	40%	15

283 (89%) patients in the post-PM group had medial status commented in their medical records and of those 186 (66%) had no medial status occurrence. Surgically treated patients regardless of fracture subgroup, had a higher absence when it came to surgeons comment on the examination of the medial side of the ankle (19%) when compared to non-surgical treated (10%). Furthermore, they also had a higher proportion (48%) of suspect injury to the medial side of the ankle when compared to the non-surgically treated patients (28%) (Table 4).

Weight bearing advice

When reviewing the medical records for surgeons advice on weight bearing following treatment a great variety of linguistic variety was noted. As with the review of medial sign of injury this leaves a great room for interpretation which makes conclusions and comparisons for this variable difficult. Hence, the results presented below should be seen as a rough indicator.

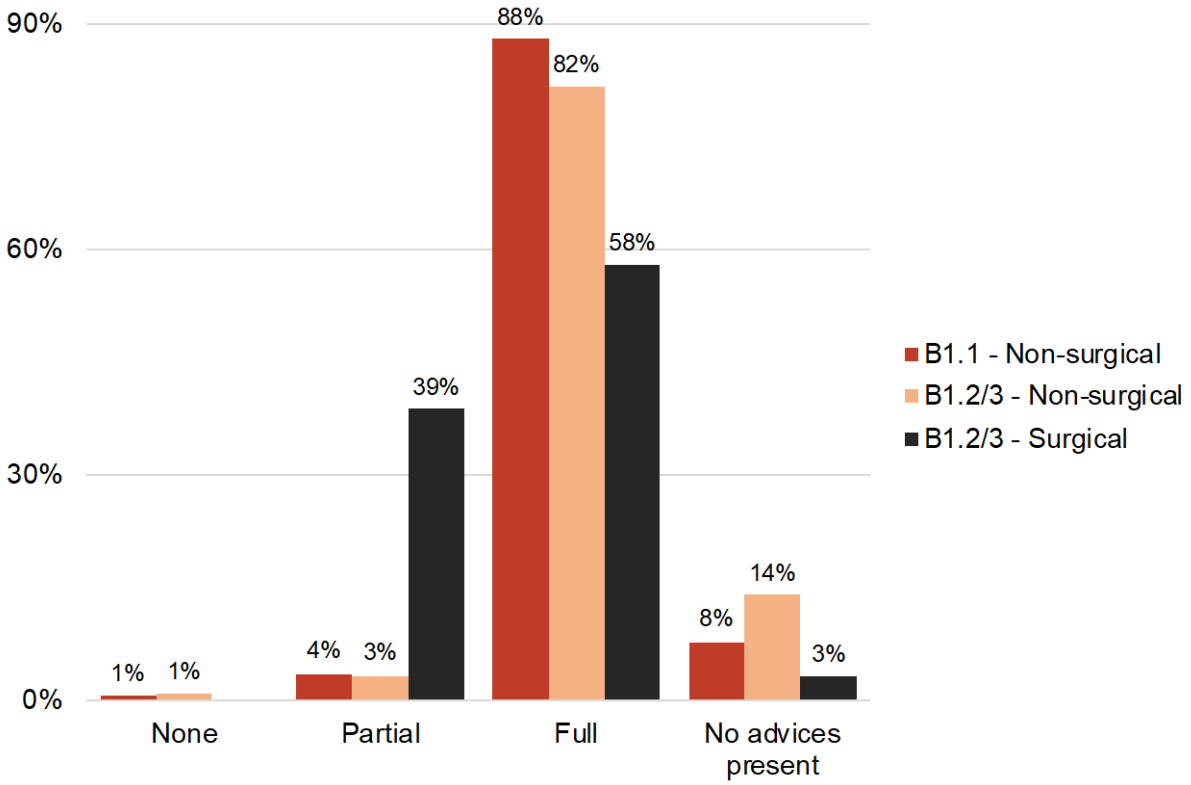

Figure 7. Surgeons advice on weight bearing following treatment in the post-PM-group.

A vast majority, 264 patients (83%), were allowed full weight bearing while 22 (7%) were allowed partial weight bearing, regardless of fracture subgroup or treatment. Furthermore 2 patients (0,6%) were allowed no weight bearing following treatment and for 31 patients (10%) no advice on weight bearing was present in the medical records. Noteworthy is that among the patients classified with B1.1-fractures 88% (n=147) had no weight bearing restriction, suggesting that the PM-recommendations here were followd. Additionaly, 39% (n=12) of the patients with B1.2/3-fractures who were surgically treated were given partial weight bearing as advice (Figure 7).

Results – pre & post-PM comparisons

Data collected before the introduction of the PM (Pre-PM-dataset) did not include subgrouping of B1-fractures. Rather they were all labeled as only B1 with subgrouping based on surgical or non-surgical treatment. Hence, to enable comparisons, the two fracture classes B1.1 and B1.2/3 from the data collected after introduction of the PM (Post-PM dataset) were merged into one group with a subgrouping based on primary treatment. In accordance, surgically treated patients from Pre-PM-data were only compared to surgically treated patients from the post PM-data. The same comparisons were made between patients given non-surgical treatment. The follow results are presented separately for each of the two treatment types.

Proportions of number of treatments

30% (n=130) of the patients in the pre-PM group had surgical treatment while 10% (n=31) of patients in the post-PM were surgically treated. The groups were quite evenly matched when it came to numbers of non-surgically treated with 309 patients in the pre-PM group versus 288 patients in the post-PM group. With this said, the post-PM group had a higher proportion (90%) of non-surgically treated patients in comparison to the pre-PM-group were 70% received non-surgical treatment (Table 5).

Table 5. B1-fractures primarily treated non-surgically and surgically respectively in the pre- and post-PM groups.

Dataset	N	N Non-surgical	N Surgical	Total	P < 0,001
Pre-PM	439	309 (70%)	130 (30%)	439	
Post-PM	319	288 (90%)	31 (10%)	319	

Significant difference in treatment was confirmed through the Chi^2-test with lesser amount of patients given surgical treatment in the post-PM group compared to the pre-PM group ($p < 0,001$).

Non-surgically treated

Significant difference for non-surgically treated patients between the groups were found on one variable when comparisons were made, with the non-surgical treated patients in the post-PM group having received more degree of full weight bearing advice following treatment when compared to the pre-PM group ($p < 0,001$). Descriptively, examination of the medial sign of the ankle was commented on more often for non-surgically treated patients in the post-PM group compared to the pre-PM group. When it came to the other variables no significant difference was found for non-surgical treated patients between the groups.

Descriptive variable comparisons

The median numbers for the outcome variables matched evenly between the groups. However, the ranges were different between the groups with the pre-PM group in general having a wider range with a higher maximum for almost each outcome variable in comparison to the post-PM group. An exception to this was the being days of inpatient care where the post-PM group both had a wider range and higher maximum compared to the pre-PM group (Table 6).

Table 6. Medians and ranges of variables for non-surgical treated patients in the pre- and post-PM groups.

Primary treatment: Non Surgical		N (pre-PM) = 309 N (post-PM) = 288	
Variable	**Dataset**	**Median**	**Range**
Number of plain radiographic examinations	pre-PM	**2**	1-7
	post-PM	**2**	1-5
Number of visits to surgeon	pre-PM	**3**	1-11
	post-PM	**3**	1-7
Days of inpatient care	pre-PM	**0**	0-15
	post-PM	**0**	0-17
Days immobilized	pre-PM	**42**	0-108
	post-PM	**42**	25-92

Number of plain radiographic examination

When it comes to radiographic examinations the pre-PM had a similar predominance of plain radiographic examination when compared to the post-PM group, being exclusively used in 97% of cases. Therefore, CTs, MRIs and ultrasounds are not accounted for in this comparison.

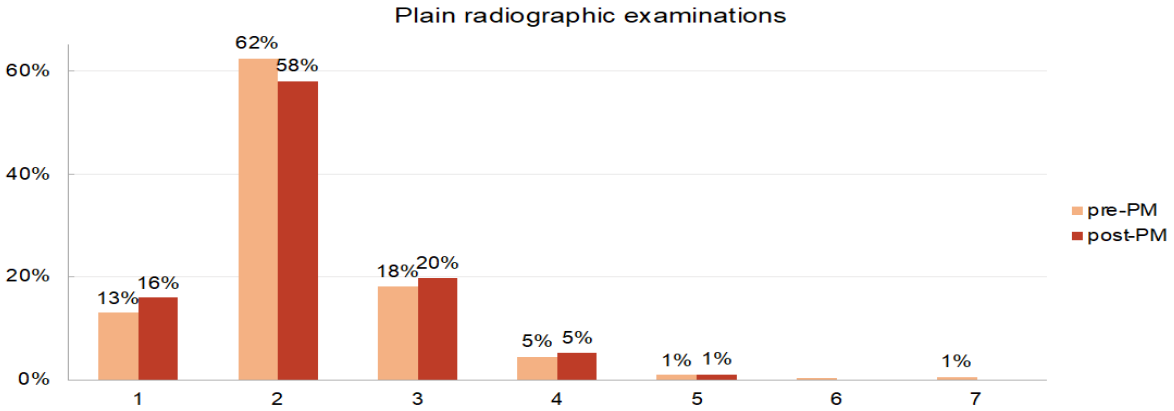

Figure 8. Number of plain radiographic examinations given to patients non-surgically treated in the pre- respectively post-PM groups.

Overall the number of plain radiographic examinations was evenly distributed for non-surgical treated patients regardless of group (Figure 8). Parametric testing with the Independent t-test showed no significant difference in the number of plain radiographic examinations given to non-surgically treated patients between the pre- and post-PM groups. (p = 0,843)

Number of visits to surgeon

Both groups had a median 3 visits to surgeon with the range in the pre-PM group being greater with highest number of visits at 11 (Table 6 and Figure 9).

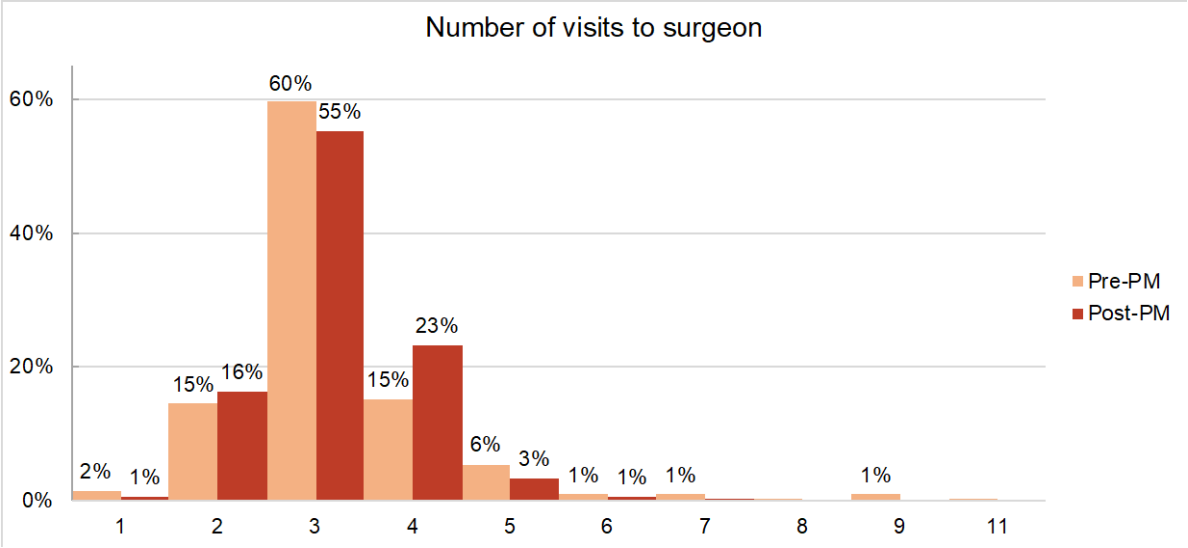

Figure 9. Number of visits to surgeon for patients treated non-surgically in the pre- and post-PM groups

Both groups showed even distribution in number of visits to surgeon. Parametric testing with the Independent t-test showed no significant difference in number of visits to surgeon for patients receiving non-surgical treatment between the groups. (p = 0,268)

Days of inpatient care

The median number days hospitalized for non-surgically treated patients was zero regardless of group with results also showing similar ranges with similar maximums of 15 to 17 inpatient care days (Table 6). The vast majority of non-surgically treated in both groups (>90%) were not hospitalized in association with their B1-fracture injury. This follows the PM-guidelines which stipulates that patients with B1-fractures who requires non-surgical treatment do not generally require hospitalization, especially if other factors than the fracture are excluded. Non-parametric testing utilizing the Mann-Whitney test showed no significant difference in number of inpatient care days for patients receiving non-surgical treatment between the groups. (p = 0,948)

Number of days immobilized

Medians for number of days immobilized were 42 regardless of group. The pre-PM showed a wider range with 0-108 days compared to the range 25-92 days in the post-PM group (table 5). The immobilization interval at 40-44 days was predominant in both groups. Worth mentioning was that larger portions in the post-PM group were immobilized in the ranges of 25-29 and 30-34 days respectively compared to the pre-PM-group (Figure 10).

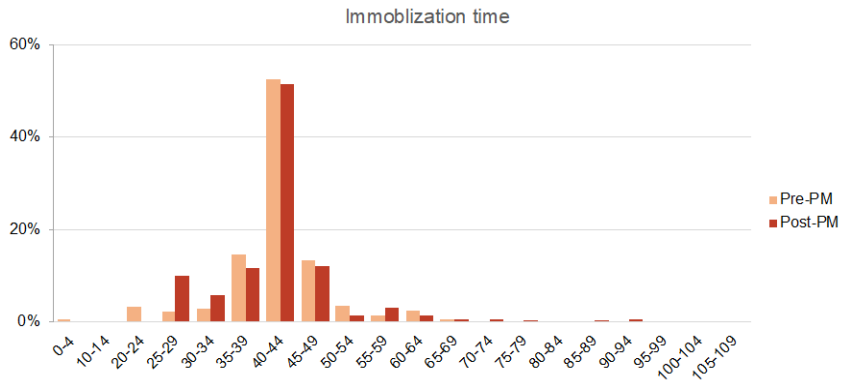

Figure 10. Number of immobilization days for patients treated non-surgically in the pre- and post-PM groups respectively.

Both groups showed even distribution in number of days immobilized. Parametric testing with the independent t-test showed no significant difference in number of days immobilized for patients treated non-surgically between the groups. (p = 0,605)

Weight bearing

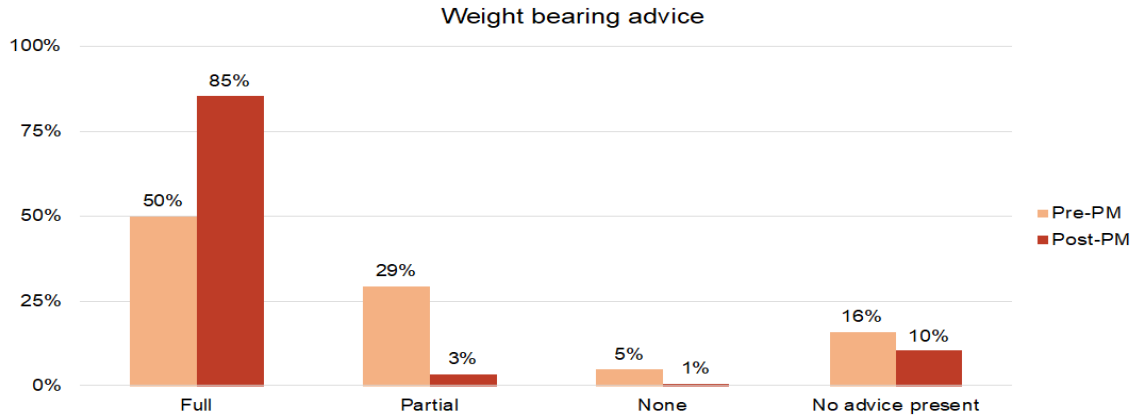

Figure 11. Weight bearing advice for patients treated non-surgically in the pre- and post-PM groups.

The non-surgical treated patients in the post-PM group were given more degree of full weight bearing following treatment when compared to the pre-PM group with Chi^2-testing confirmed statistical difference between the groups when it came to surgeons advice on weight bearing ($p < 0,001$)

Signs of injury to the medial side of the ankle

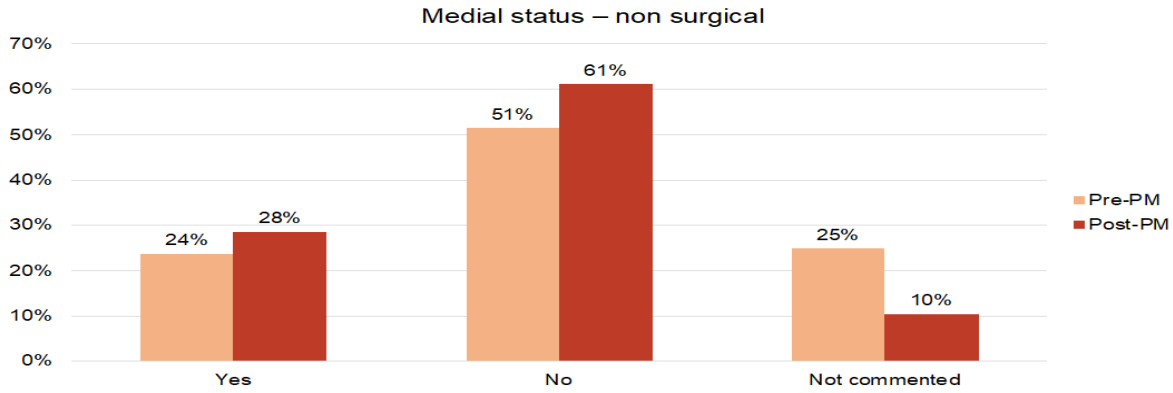

Figure 12. Signs of Injury to the medial side of the ankle occurrence including cases not commented for non-surgical treated patients in the pre and post-PM groups.

Examination of the medial side of the ankle was commented on more often in the post-PM group as compared to the pre-PM group. Nearly 25% of non-surgical patients in both groups had comments that assessed suspecting signs of injury to the medial side of the ankle (Figure 12).

Surgically treated

Significant difference was found on several variables when comparing surgically treated patients between the groups including days of inpatient care ($p < 0,001$), immobilization time ($p < 0,001$) and advice on weight bearing ($p < 0,001$). Descriptively, the post-PM group had a higher proportion of surgically treated patients where examination on the medial side of the ankle was commented on, compared to the pre-PM group.

Descriptive variable comparisons

When it came to the surgically treated patients the median numbers for the outcome variables between the groups showed deviation from each other. The pre-PM group had a higher median (+1) when it came to days of inpatient care and days immobilized compared to the post-PM group. The latter had a higher median number of plain radiographic examinations at 3 compared to a median 2 in the pre-PM group. When it came to number of visits to surgeon both groups had a median of 4 visits. The pre-PM group had a wider range with a greater maximum number in all the outcome variables compared to the post-PM group (Table 7).

Table 7. Medians and ranges of variables for surgical treated patients in the pre- and post-PM groups.

Primary treatment: Surgical			N (pre-PM) = 130 N (post-PM) = 31
Variable	Dataset	Median	Range
Number of plain radiographic examinations	pre-PM	**2**	2-9
	post-PM	**3**	2-5
Number of visits to surgeon	pre-PM	**4**	1-9
	post-PM	**4**	2-6
Days of inpatient care	pre-PM	**2**	0-35
	post-PM	**0**	0-10
Days immobilized	pre-PM	**45**	16-75
	post-PM	**42**	40-48

Number of plain radiographic examinations

The median number of plain radiographic examinations performed in the pre-PM group was 2 compared to 3 in the post-PM group (Table 7). Furthermore, the pre-PM group had a greater range with 2-9 examinations compared to 2-5 examinations in the post-PM group.

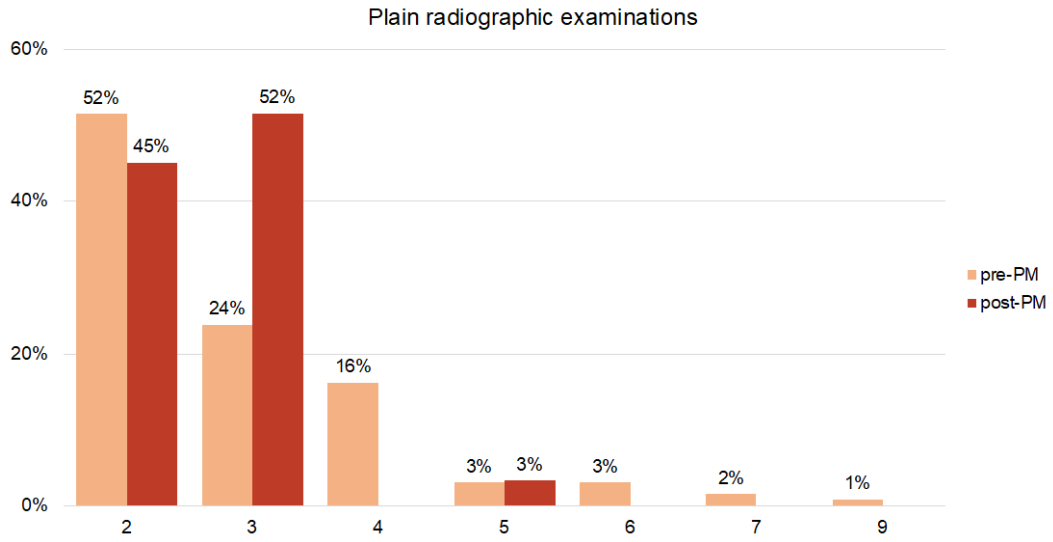

Figure 13. Number of plain radiographic examinations given to patients surgically treated in the pre- respectively post-PM group.

Due to both groups not having normal distribution when it comes to this variable, nonparametric testing with the Mann-Whitney test was conducted with no significant difference in the number of radiographic examinations between the pre- and post-PM groups. (p = 0.624)

Number of visits to surgeon

Both the groups had a median number of 4 visits to surgeon. Although, the range of visits was greater in the pre-PM group with a top figure of 9 visits compared to 6 in the post-PM group (table 7 and figure 14).

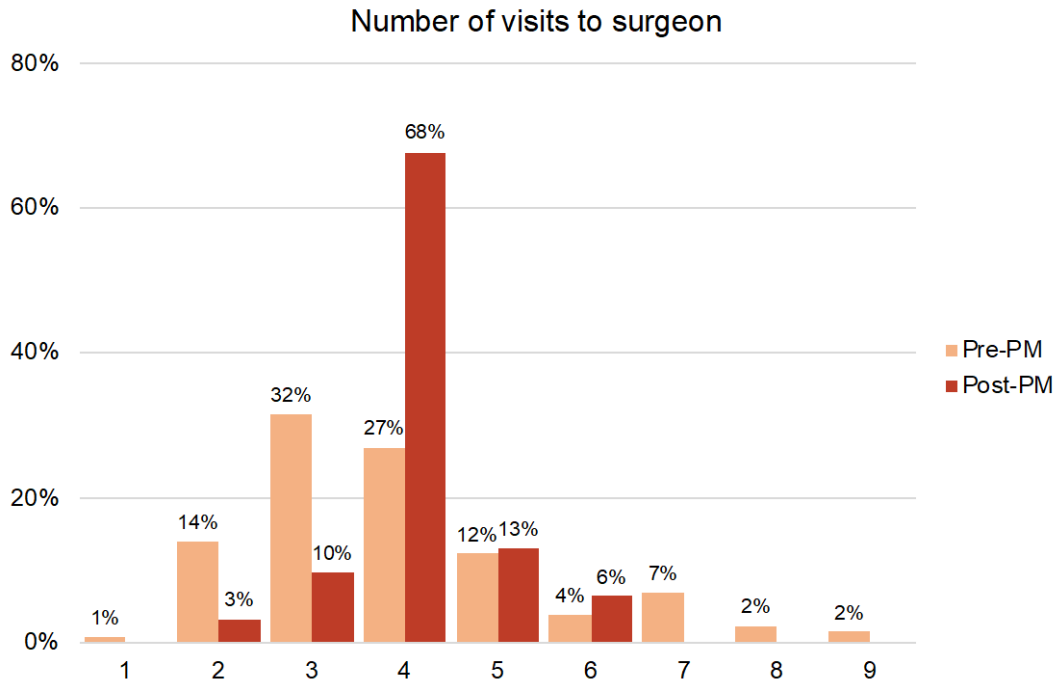

Figure 14. Number of visits to surgeon for surgically treated patients in the pre- and post-PM groups.

Though the post-PM group had a normal distribution when it came to number of visits to surgeon, the pre-PM group on the other hand did not. Hence non-parametric testing was conducted utilizing the Mann-Whitney test showing no significant difference in number of visits to surgeon between the pre- and post-PM groups. (p = 0,092)

Days of inpatient care

The median number of days hospitalized for surgical treated patients were 2 days for the pre-PM group compared to the post-PM group were surgical treated patients were hospitalized a median 0 days. Furthermore, the ranges of days hospitalized between the groups also differed with surgical treated in the pre-PM group having range of 0-35 days compared to 0-10 days in the post-PM group (table 7).

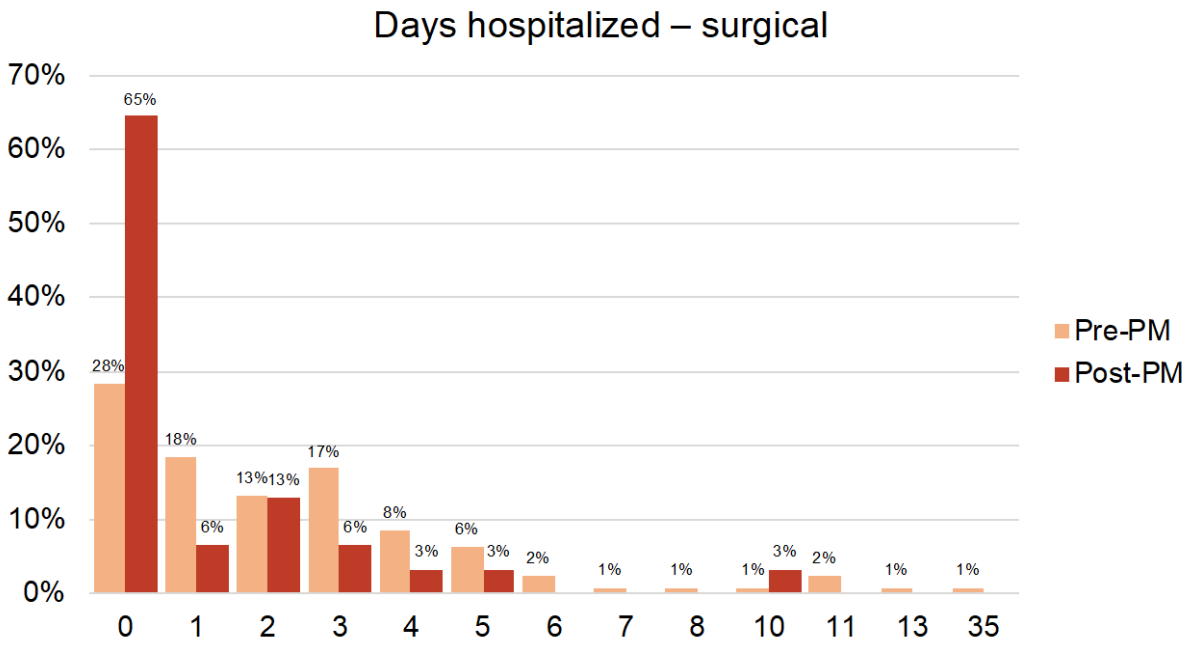

Figure 15. Number of days hospitalized for surgically treated patients in the pre- and post-PM groups.

The number of inpatient care days for surgically treated patients were not normally distributed in either group with especially the post-PM group showing a great floor effect in this regard. Non-parametric testing, utilizing the Mann-Whitney test, showed a significant difference in number inpatient care days for surgically treated patients with the post-PM group having a significant lesser amount of hospitalization days when compared to the pre-PM group. (p = 0,001)

Number of days immobilized

There was a difference in the median number of days immobilized for surgical treated patients between the groups. The pre-PM group had a median of 45 days of immobilization compared to 42 days in the post-PM group. Ranges for this variable also different with 16-75 days in the pre-PM group compared to 40-48 days in the post-PM group (Table 7)

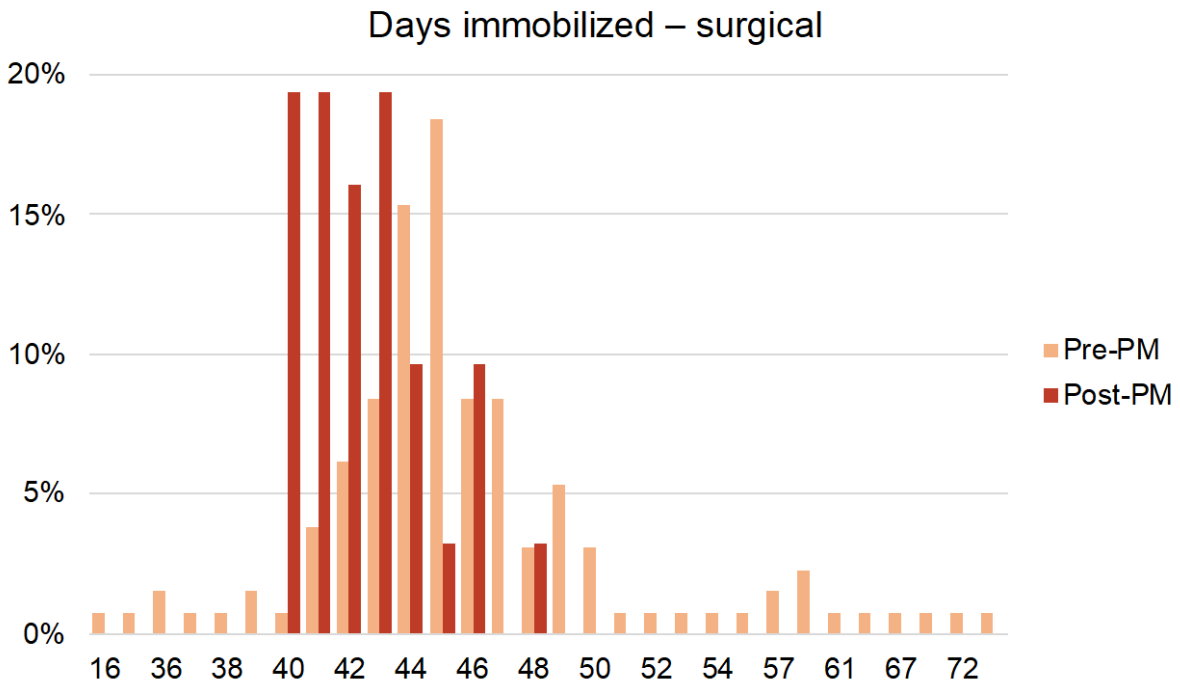

Figure 16. Number of days immobilized for surgically treated patients in the pre- and post-PM groups.

The pre-PM group showcased normal distribution when it came to number of days immobilized for surgical treated patients. In comparison the post-PM group had a left skewness and did not either showcase normal distribution (Figure 16). Non-parametric testing utilizing the Mann-Whitney test showed significant difference with surgical treated patients in the post-PM group having lesser amount of immobilization days compared to the pre-PM group. ($p < 0.001$)

Weight bearing

A higher proportion of surgically treated patients were given full weight bearing advice in the post-PM group when compared to the pre-PM group. The reverse case was true for those given partial weight bearing advice. Noteworthy is that none of the surgical treated patients in the post-PM group were advised to none weight bearing as compared to 8% of surgically treated patients in the pre-PM group. Additionally, there was no instance of no advice present regarding weight bearing in the pre-PM group (figure 17).

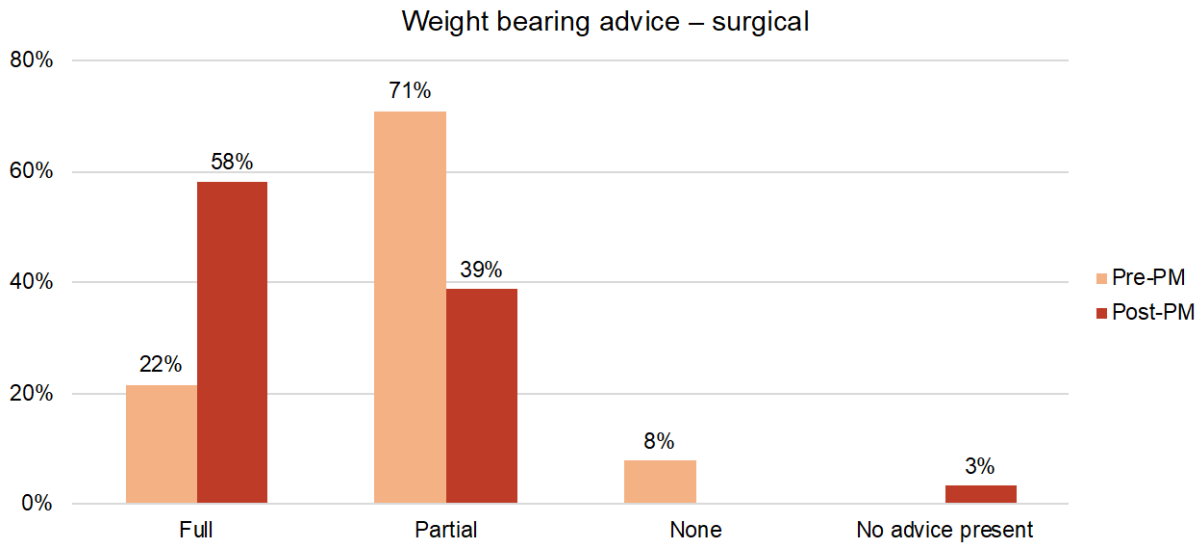

Figure 17. Weight bearing advice for surgically treated patients in the pre- and post-PM groups.

Significant difference in surgeons advice on weight bearing for surgically treated patients between the pre-PM and post-PM group was showed utilizing the Chi^2-test with a significant higher proportion of patients in the post-PM group haven been given full weight bearing advice. ($p < 0{,}001$)

Signs of injury to the medial side of the ankle

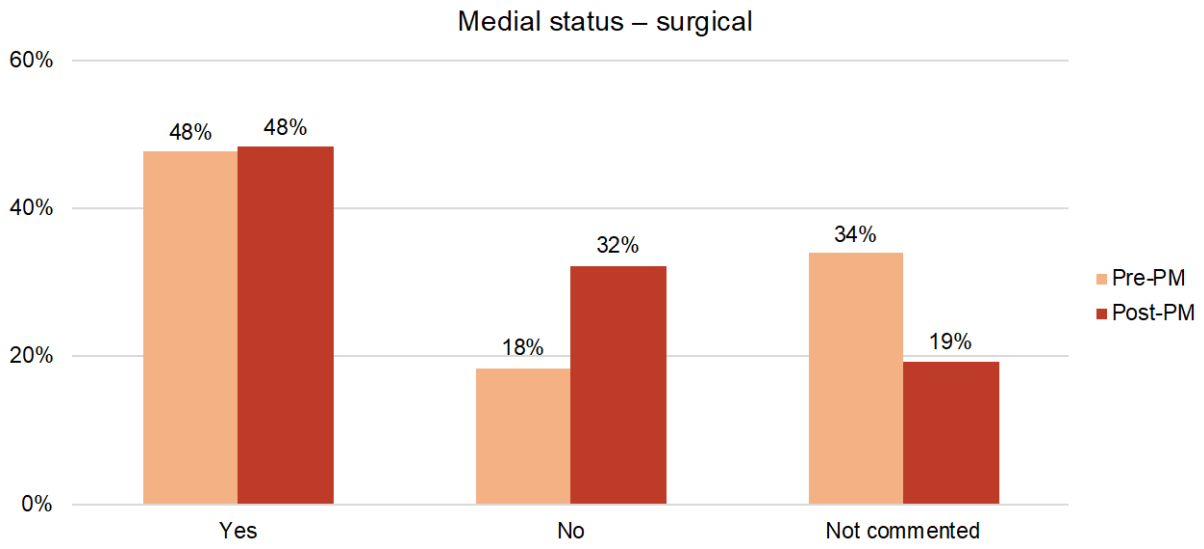

Figure 18. Signs on of injury to the medial side of ankle occurrence including cases not commented for surgical treated patients in the pre and post-PM groups.

The proportion of cases were examination of the medial side of the ankle was documented for surgical treated patients were greater in the post-PM group (81%) when compared to the pre-PM group (66%). Both groups had even proportions when it came to occurrence of suspect injury to the medial side of the ankle. The post-PM group had a higher proportion of surgically treated patients with no sign of injury to the medial side of the ankle (32%) compared the pre-PM group (18%). With this said, the groups differed in size with the pre-PM group having 130 surgically treated patients in comparison to 31 patients in the post-PM group (Figure 18).

SMFA outcome

The ankle dysfunction-index and ankle bother-index used on the nine selected SMFA-questions relating to function of the ankle were calculated for the day zero and year 1 questionnaires. A number of 137 patients from the pre-PM group, 93 non-surgically and 44

surgically treated, responded to the selected questions. The post-PM group had 39 patients, 31 non-surgically and 8 surgically treated, responding to the selected questions.

Median index scores – pre- & post-PM

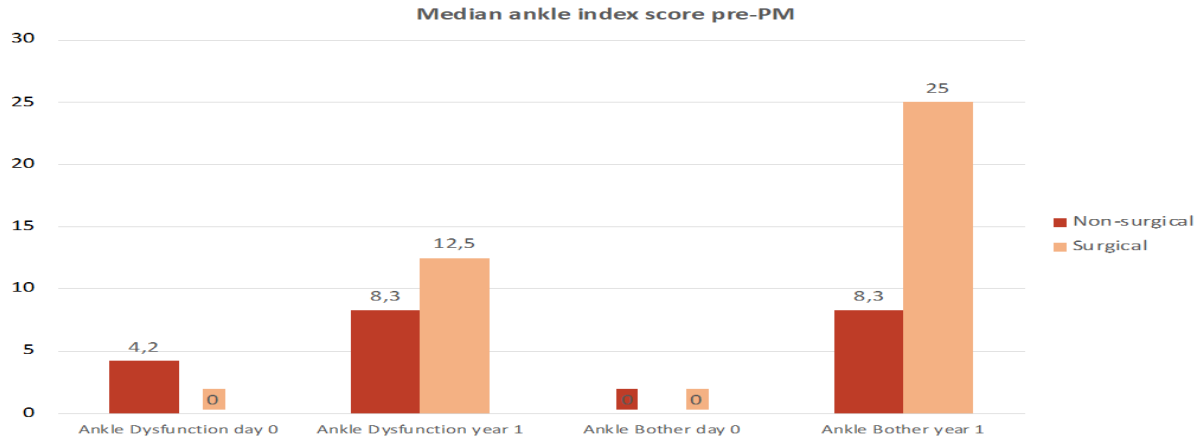

Figure 19. Median index scores for ankle dysfunction and bother between non-surgical and surgical treated in pre-PM group.

For non-surgically treated patients in the pre-PM group the median ankle-dysfunction index indicates a minimal increased dysfunction of the ankle one year after injury compared to day zero (Day zero: 4.2, Year one: 8.3). In comparison surgically treated patients showed a slightly higher increase in dysfunction of the ankle (Day zero: 0, Year one: 12.5). ($p < 0.001$)

0 patients in the pre-PM group experienced bother from the ankle before they were injured, according to the median ankle-bother index, regardless of treatment. However, both non-surgically and surgically treated patients had an increase (Day zero: 0, Year one: 8.3 and Day zero: 0, Year one: 25) in bother from the ankle at year one compared to day zero (Figure 19). ($p < 0{,}001$)

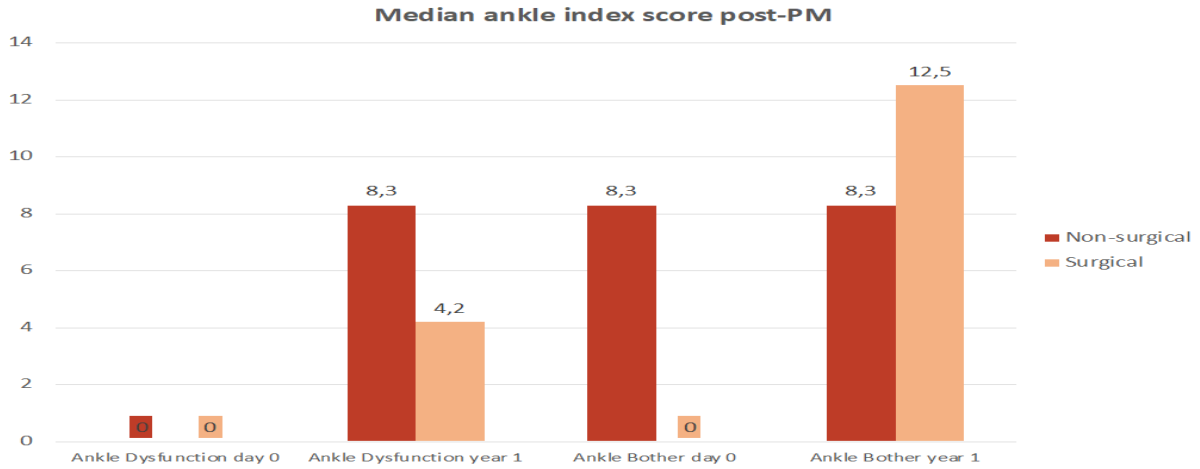

Figure 20. Median index scores for ankle dysfunction and bother between non-surgical and surgical treated in post-PM group

0 patients in the post-PM group had dysfunction from the ankle at day zero. However, they showed a minimal increase in ankle-dysfunction at year one (Day zero: 0, Year one: 4.2). The non-surgically treated had a slightly more increase in ankle-dysfunction at year one (Day zero: 0, Year one: 8.3). ($p = 0.008$)

Bother from the ankle was the same (8,3) for non surgically treated patients in the post-PM group at day zero and one year after injury. There was a slight increase in ankle bother for surgically treated patients from day zero to one year after injury (Day zero: 0, Year one: 12.5) (Figure 20). ($p = 0.033$)

Index score group comparisons

Median index score for patients classified with B1-fractures between the pre- and post-PM group are presented below.

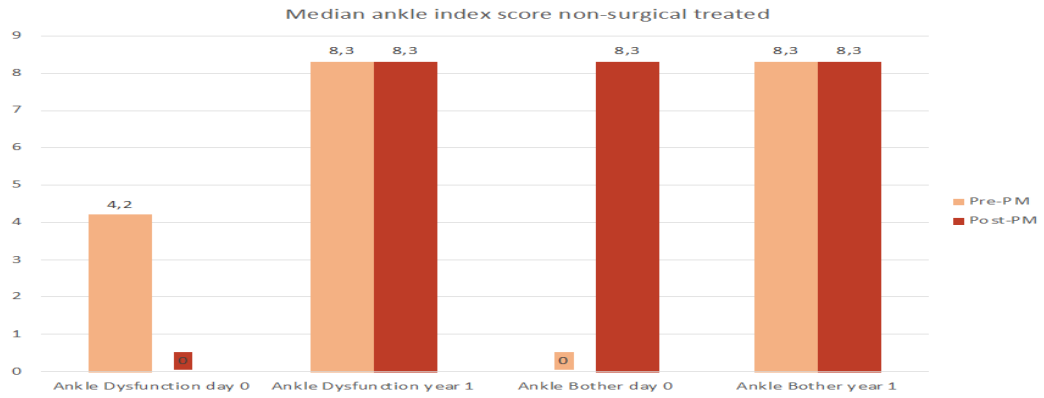

Figure 21. Median index scores for ankle dysfunction and bother between non-surgical treated in the pre- respectively post-PM groups.

There was no significant or noteworthy difference before or after the introduction of the PM when it comes to non-surgically treated patients looking at dysfunction (p = 0.756) and bother (p = 0.431) from the ankle at year one (Figure 21).

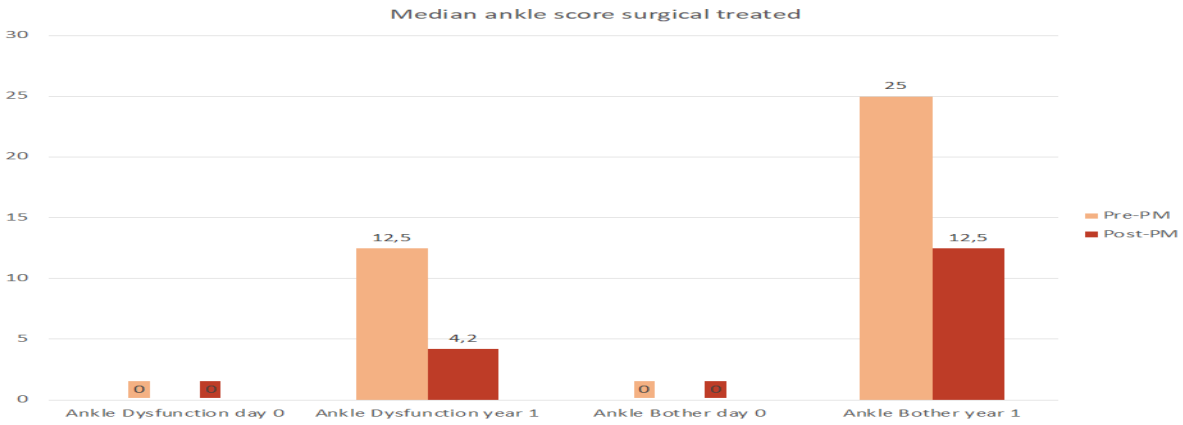

Figure 22. Median index scores for ankle dysfunction and bother between surgical treated in the pre- respectivly post-PM group

Surgically treated patients in the pre-PM group descriptively had more dysfunction of the ankle one year after injury (Year one: 12.5) compared to the post-PM group (Year one: 4.2) with no significant difference found (p = 0.400) . Additionally, surgically treated patients in the pre-PM group descriptively experienced more bother from the ankle one year after injury (Year one: 25) compared to the post-PM group (Year one: 12.5) with no significant difference (Figure 22). (p = 0.777)

Discussion

Examination on the medial side of the ankle

The examination of the medial side of the ankle is of key importance as it is commonly used to detect injury to the deltoid ligament which subsequently influence fracture-classification an choice of subsequent treatment. As suggested by Stenquist et al medial tenderness is associated with deltoid ligament injury and ankle joint instability [38]. Furthermore, the PM stipulates that a suspect B1-fracture with simultaneous injury to the medial side of the ankle automatically transforms into a B2-fracture which subsequently require surgical treatment due to ankle joint instability. With this in mind, the results in this report showed that a substantial part of the non-surgically treated patients in the post-PM group (28%) had or were suspected of having injury to the deltoid ligament, which suggests that many patients with B1-ankle fractures that receives non-surgical treatment are not only classified incorrectly, but might also be given the wrong treatment. Furthermore, information in the medical records about medial tenderness were missing in 10% of the non-surgically and 9% of the surgically treated patients respectively. Overall 11% of the patients in the post PM-group had no information regarding medial tenderness. This is troublesome when regarding its impact on decision-making already mentioned above thus warranting greater compliance in the examination and documentation of medial tenderness.

Weight bearing advice

When it comes to advice on weight bearing, this report has revealed a wide range of linguistic wording leaving lots of room for interpretation. Results here roughly indicated that a substantial majority of patients (83%) in the post-PM group were given no restrictions on weight bearing following non-surgical or surgical treatment compared to 42% in the pre-PM

group. This suggests that PM-guidelines has had an effect on this outcome variable as it was on the wholesome followed in this regard. However, with 39% of surgically treated patients in the post-PM group having received partial weight bearing advice room for improvement still exists. As concluded by Smeeing et al, active mobilization with early weight bearing results in earlier return to work when it came to patients with ankle fractures treated surgically.[39] Bearing this in mind while also considering the PM-recommendations, there is no reason not to allow full weight bearing following B1-fracture treatment, regardless of treatment choice.

Treatment

Looking at the variables related to treatment, the assessment was that compliance here was of satisfaction as the vast majority of the patients classified with B1.2/3-fracture received non-surgically treatment, with only 20% within this group having received surgically treatment. Furthermore only one of the patients classified with B1.1-fracture was operated on, being converted to surgical treatment at an early stage without an obvious reason after detailed reviewing.

Resource related variables

B1.2/3-fracture patients with non-surgical treatment underwent in median the same amount of plain radiographic examinations as is advocated by the PM suggesting compliance to the guidelines. In contrast, the patients with B1.1-fractures treated non-surgically were given a median number of two plain radiographic examinations, one at the A&E and one at follow up. In regard of the PM this is twice as many as recommended. The reason as to why the excessive use of radiographs occurs is uncertain, but one explanation could be patient experienced bother shortly after intervention, which the attending surgeon mistakes as a

potential sign of instability in the ankle that calls for an additional radiographic examination. Another explanation could be ignorance and poor compliance with the PM as by old tradition follow-up radiographic examinations is usually booked already at the visit to the A&E. Michelson et al. found no secondary displacement when reviewing radiographs following non-surgically treated B1-fractures [25], suggesting that stable lateral malleolar fractures does not displace. Jain et al. showed that the number of follow-up appointments and repeat radiographs contributes most to direct costs in the management of stable ankle fractures [40]. Taking this into account, while also regarding that radiographic examinations are linked to the number of visits to surgeon, the conclusion is that limiting the radiographic examinations to one would not only spare patients unnecessary radiation but also contribute to significant financial savings, without compromising patient safety, in the management of B1.1-fractures.

Regardless of fracture subgroup, the median number of visits to surgeon for non-surgically treated patients in the post-PM group was three. Looking at the patients with B1.1-fracture, this is one to many visits in relation to the PM. As already mentioned, the excessive use of radiographic examinations could be one explanation. Another reason as to why this occurs can be explained by the revisits to the A&E many patients made due to remaining stiffness or tenderness, which was discovered as a side note when reviewing the medical records. A way to address this problem accordingly could be to have the patients verbally informed of the healing process in the ankle with addition to easily readable pamphlets regarding symptoms following ankle fracture treatment and their timeframe. On the other hand, surgically treated patients made a median 4 visits to surgeon, which followed the PM recommendations. One factor to consider here following speculation is that surgically treated patients, compared to

non-surgically treated, are more well-informed of their treatment and subsequent symptom timeframe, reducing the likelihood to make ”unnecessary” visits to the A&E shortly after intervention.

Non-surgically treated patients, regardless of fracture subgroup, were rarely admitted to inpatient care with 93% not hospitalized which shows compliance to PM-guidelines. The proportion of inpatient care among surgically treated patients was only marginally higher and 65% still had outpatient surgery. Although the PM-guidelines states that inpatient care must be assessed on a case by case basis, the results here are deemed as favorable with compliance to the PM being acceptable in this regard.

The post-PM group had a median number of 42 immobilization days, regardless of treatment or fracture subgroup. Looking at the patients with B1.1-fractures this is not in line with the guidelines since the PM here advocate 28 days of immobilization. One reason to this might be that the attending physician is accustomed to the longer immobilization timeframe advocated before the introduction of the PM. Other explanations might be due to some patients having diabetes-comorbitity as the PM advocates prolonged immobilization time in such cases. The PM was however followed in regard to the patients with B1.2/3-fractures as the guidelines here recommends 42 days of immobilization.

Regarding conversion of treatment, only two cases were found where initial non-surgical treatment was abandoned at an early stage in favor of operation due to findings on follow-up radiographic examinations. In the review of these cases, both seemed to have been mistaken as unstable fractures suggesting unnecessary surgical intervention. Seeing the whole picture, this accounts for an utmost small proportion of the post-PM group. This would seem to

validate the PM-recommendation stipulating only one radiographic examination for B1.1-fractures. Furthermore it would also question whether the PM-recommendation stipulating the one week follow-up radiographic examination for B1.2/3-fractures is justified, since it seldomly leads to any conversion of treatment.

Treatment regime change over time

One of the key subjects of this report was to elucidate whether the treatment regime for B1-fractures had changed over time. The hypothesis was that fewer patients were surgically treated after the introduction of the PM. The pre-PM group had 130 (30%) treated surgically compared to 31 (10%) in the post-PM group. The results thus showed that the primary treatment for B1-fractures had changed over time confirmed by significant difference in treatment with fewer patients having surgical treatment since the introduction of the PM ($p < 0.001$). However, with the pre-PM encompassing 439 patients classified with B1-fractures, compared to 319 in the post-group, the groups differed in size. Addressing this, one explanation could be the positive effect that the PM has had on classification were unstable compared to stable fractures are more clearly distinguished. Another reason for the difference in size between the groups could be found in temporal variations with the pre-PM-period covering more of the fall and winter seasons compared to the post-PM-period. As found by Wynkoop et al., who retrospectively studied the epidemiology of ankle fractures presenting to an urban level 1 trauma center in the Midwestern United States, most ankle fractures of the malleolus occurs in fall and winter than in the spring and summer [41]. With this said, the conclusion is that the PM has had an effect on treatment over time in regard to the assessment between stable and unstable ankle fractures which further enables election of patients beneficiary to the right treatment.

Treatment oriented variable comparisons between the pre- and post-PM groups

In the comparison of the numerical variables (e.g. number of plain radiographic examinations) for patients treated non surgically, the results showed no significant difference between the groups. Worth to mention is that the numerical variables in the pre-PM group generally had a wider range of numbers with greater maximum values. The exception here was the inpatient care day variable where the range was modestly higher in the post-PM group. This suggest that the PM has contributed to a more cohesive management of B1-fractures, without it leading to any significant change when it comes to the variables mentioned above.

With this said, the categorical variables for non-surgically treated patients in the two different groups showed a difference. When it came to surgeon's advice on weight bearing following treatment there was a significant difference between the groups with a higher proportion of non-surgically treated patients in the post-PM group having received more degree of advice on full weight bearing ($p < 0{,}001$), with the pre-PM group having a higher proportion of no advice present. Being that these results only can be seen as an rough indicator, the interpretation of this suggest that the PM presumably has had an significant effect showing better compliance when it comes to weight bearing advice after the introduction of the PM.

In the comparison of signs of injury to the medial side of the ankle, descriptive analysis showed that examination here was commented on proportionally more often for non-surgically treated patients in the post-PM group compared to the pre-PM group. This suggests that the PM has had an effect in regard to compliance in the assessment of deltoid-ligament injury among patients with stable fractures. Despite this the results also suggest that there is still a considerable number of patients that might be misdiagnosed since nearly 25% of non-surgically treated patients in both groups had comments that assessed suspecting signs of

injury to the medial side of the ankle and thus should have been classified as a B2.1-fracture instead of B1-fracture.

Moving on, there was no significant difference in number of visits to surgeon or plain radiographic examinations between the groups for surgically treated patients. Yet, the results showed a significant reduction in both time immobilized ($p < 0,001$) and inpatient care days ($p = 0,001$) for surgically treated patients after the introduction of the PM. Additionally, the surgical treated patients also showed a significant difference in weight bearing advice, with patients in the post-PM group here also given more degree of full weight bearing when compared to the surgical treated patients in the pre-PM group ($p < 0,001$).

Surgically treated patients in the post-PM group descriptively also showed a higher proportion of cases were examination of the medial side of the ankle were commented on compared to the pre-PM group. Although the interpretation of this is troublesome, considering that a far lesser amount of patients were surgically treated in the post-PM period compared to the pre-PM period, it still suggests that the PM has had a positive effect on the assessment of ankle fractures.

SMFA-outcome

Another main focus of this report was to examine PROMs where selected questions from the SMFA-questionnaire was used to make comparisons between the two different groups.

When comparing the median ankle dysfunction and bother index scores at day zero to the one year follow up survey, the results showed a significant difference for each index score within both the pre- and post-PM groups. However, the comparisons of the non-surgically and surgically treated patients between the pre- and post-PM groups showed no significant

difference in the median index score outcome, suggesting that the PM has had no effect on PROMs in this regard. Although, surgically treated patients in the pre-PM group descriptively showed a considerable higher increase in both ankle dysfunction and bother one year after injury compared to the post-PM group. With this said, the PROM-outcome must here be interpreted with great modesty, as the method used to generate the index scores was new and not validated. Furthermore, the patients who were included in the comparisons of PROMs were relatively few in numbers, especially considering the post-PM group, with additional subgrouping of the patients based on given treatment making the number of patients even fewer in the comparisons made. Altogether, this renders the outcome of PROMs highly uncertain as a conclusion.

Methodological considerations

Strenghts

This report was made possible through the use of data collected from SFR. This is a strength as the register showcase a relative completeness in the registration of variables and since it is used by clinicians it can be considered to represent real life. Having PROMs included in this report is important when considering that it takes on the perspective of the patients receiving treatment, and as such should be considered a major strength.

Another strength of the current study is that it includes a large number of consecutive patients with prospectively collected data. It also included both out-patients and patients who were admitted to hospital.

Limitations

SFR still lack completeness in the registration of reoperations which demanded manual

review of the medical records in this regard. Furthermore, this report only encompassed patients with B1-fractures treated at SU. With the PM also including guidelines encompassing other ankle fractures, this report cannot make conclusions about the PM as a whole. Another limitation one has to take into account is that the results might not be representative on a nationwide scale as the report was limited to SU/M.

A two-year period was studied after the introduction of the PM. However the report did commence before it was ensured that PROM-results for the one year follow-up survey had been received. When it came to the review of PROMs, This consequently gave the post-PM group a substantial lesser amount of patients which left the groups considerable different in size at the time of the selected SMFA-outcome comparisons. With this said, Juto et al. indicated that non-responders report similar scores in the SMFA-questionnaires compared to those who had initially responded [35]. Considering this, the difference in size between the groups can be considered of less importance in this regard.

A major limitation of this report is the use of newly created indexes in order to evaluate the selected questions from the SMFA questionnaire and compare score results between the groups. Since the indexes had never been used in research before, the validity of them is questionable. The interpretation of the generated results thus remains uncertain when it comes to the SMFA-outcome. In order to fully interpret the SMFA-outcome relatable to ankle fracture, validation of the method used to generate the results is needed. Another approach to interpret patient outcome measures in this report could have been to look at PROMs in its entirety, with existing methods for this already having been validated. However, this option was ultimately dismissed in favor of only reviewing the SMFA-outcome of the selected questions, as the sooner would have generated a much wider array of results not applicable to

ankle function.

Clinical implications and future research

This report has finalized the study initiated in 2019 and in doing so given descriptive information regarding B1-fractures managed at SU/M after the implementation of a structured treatment algorithm for ankle fractures. Furthermore, comparisons between the period before and after the implementation of the algorithm have been made. The results from these comparisons can be of use in evaluating the compliance to the PM and in doing so hopefully improve it. Although PROM-data concerning fractures have been accessible through the SFR for quite some time, more research utilizing PROMs in relation to ankle fractures are warranted.

Conclusion

The most important findings of this report are that the PM has helped to reduce the number of operations being conducted on isolated lateral malleolar fractures. However, despite the existence of a proper treatment algorithm for ankle fractures, the guidelines are not always being followed. This is especially highlighted when it comes to assessing signs of injury to the medial side of the ankle and giving advice on weight bearing as this is still often missing in the medical records. Moreover, medial tenderness need to be taken into account more often when it comes to the classification of ankle fractures. The selected SMFA outcome in this report showed no significant effect since the introduction of the PM.

Populärvetenskaplig sammanfattning på svenska

”Fraktur på yttre fotknöl – Utvärdering av behandling efter införandet av en rutin för handläggning av fotledsfrakturer på Sahlgrenska universitetssjukhuset”

Denna studie har valt att fokusera på den vanligaste frakturen på den yttre fotknölen som betecknas AO-44B1 (B1-fraktur). Huruvida denna fraktur är stabila eller ej är svårt att avgöra eftersom man på en vanlig röntgenundersökning inte kan se eventuella skador på intilliggande ledband. Dock är det viktigt att särskilja mellan en stabil och en instabil fotledsfraktur då detta styr om behandlingen blir kirurgisk eller ej. För att gynna diagnostiken, behandlingen och uppföljningen av fotledsfrakturer inklusive B1-frakturer, införde man 2017 på Sahlgrenska universitetssjukhuset Mölndal (SU/M) en rutin (PM) för handläggning av fotledsfrakturer. Denna rutin hade 2020 varit i bruk i över två år. Ambitionen med denna studie har varit att jämföra patienter med B1-frakturer som behandlades före respektive efter rutinens införande för att se om rutinen haft effekt över tid samt i vilken omfattning man idag följer rutinen på SU/M. Vidare har syftet med denna studie varit att jämföra resultat utifrån utvalda delar av hälsoenkätundersökningar genom att kolla på s.k. Patient Reported Outcome Measures (PROMs) för att på så sätt se om det utifrån patientens perspektiv har blivit bättre efter rutinens införande.

Genom det Svenska Fraktur Registret gjordes datauttag som omfattande en tvåårsperiod efter rutinens införande och som inkluderade alla patienter som behandlats för fotledsfraktur. Komplettering av uppgifter rörande patienter med B1-frakturer genomfördes genom granskning av både journaler och röntgenundersökningar av fotleden. För att kunna se i vilken omfattning man följt rutinen valdes följande variabler ut: antal icke-kirurgiskt/kirurgiskt behandlade frakturer, antal slätröntgenundersökningar, antal läkarbesök, antal dagar i

gips/skena och antal inneliggande vårddagar. Vidare undersöktes också vilket råd patienten hade fått beträffande tillåten belastning på drabbad fotled efter frakturbehandling samt huruvida undersökning av den inre fotknölen var dokumenterad i journalen och om fanns misstanke om skada av densamme vilket i så fall skulle indikera att frakturen var instabil. Vad gällde hälsoenkätsundersökningen valdes nio frågor relevanta till fotleden ut ur den s.k. Short Musculoskeletal Function Assessment (SMFA) enkäten. Resultaten utifrån dessa frågor analyserades och jämfördes mellan de patienter som hade behandlats för B1-fraktur innan respektive efter införandet av rutinen.

Denna studiens resultat visade att antalet icke-kirurgiskt behandlade B1-frakturer dels hade signifikant ökat samt hade fått en signifikant ökning vad gällde fri belastning sedan införandet av rutinen. Vad gällde de kirurgiskt behandlade B1-frakturerna hade de en signifikant minskning avseende antal inneliggande vårddagar samt antal dagar i gips/skena sedan införandet av rutinen. Vidare hade dokumentation beträffande undersökning av den inre fotknölen deskriptivt ökat sedan införandet av rutinen. Analysen beträffande de utvalda frågorna ur hälsoenkäten SMFA indikerade att rutinen ännu ej haft någon signifikant effekt på dysfunktion eller besvär från fotleden ett år efter genomgången B1-fraktur.

Slutsatsen av denna studie är att det till stor del finns en följsamhet till rutinen. Dock föreligger utrymme för förbättring, fr.a. beträffande dokumentation och undersökning av den inre fotknölen. Antalet kirurgiskt behandlade B1-frakturer har minskat sedan införandet av rutinen. Detta tillsammans med ovan redovisade resultat antyder att det nu föreligger en bättre handläggning avseende B1-frakturer jämfört med innan. Dock behövs forskning avseende handläggning beträffande de andra typerna av fotledsfrakturer också genomföras för att fullt ut utvärdera rutinens effekt.

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Appendix

Optimal Performance Physical Therapy

Short Musculoskeletal Function Assessment

Name: _____ **Signature:** _____ **Date:** _____

Instructions: We are interested in finding out how you are managing with your injury or arthritis this week. We would like to know about any problems you may be having with your daily activities because of your injury or arthritis. Please answer each question by putting a check in the box corresponding to the choice that best describes you.

These questions are about how much difficulty you may be having this week with your daily activities because of your injury o arthritis.

	Not at all Difficult A	A Little Difficult B	Moderately Difficult C	Very Difficult D	Unable to do E
1. How difficult is it for you to get in or out of a low chair?	☐	☐	☐	☐	☐
2. How difficult is it for you to open medicine bottles or jars?	☐	☐	☐	☐	☐
3. How difficult is it for you to shop for groceries or other things?	☐	☐	☐	☐	☐
4. How difficult is it for you to climb stairs?	☐	☐	☐	☐	☐
5. How difficult is it for you to make a tight fist?	☐	☐	☐	☐	☐
6. How difficult is it for you to get in or out of the bathtub or shower?	☐	☐	☐	☐	☐
7. How difficult is it for you to get comfortable to sleep?	☐	☐	☐	☐	☐
8. How difficult is it for you to bend or kneel down?	☐	☐	☐	☐	☐
9. How difficult is it for you to use buttons, snaps, hooks, or zippers?	☐	☐	☐	☐	☐
10. How difficult is it for you to cut your own fingernails?	☐	☐	☐	☐	☐
11. How difficult is it for you to dress yourself?	☐	☐	☐	☐	☐
12. How difficult is it for you to walk?	☐	☐	☐	☐	☐
13. How difficult is it for you to get moving after you have been sitting or lying down?	☐	☐	☐	☐	☐
14. How difficult is it for you to go out by yourself?	☐	☐	☐	☐	☐
15. How difficult is it for you to drive?	☐	☐	☐	☐	☐
16. How difficult is it for you to clean yourself after going to the bathroom?	☐	☐	☐	☐	☐
17. How difficult is it for you to turn knobs or levers (for example, to open doors or to roll down car windows)?	☐	☐	☐	☐	☐
18. How difficult is it for to write or type?	☐	☐	☐	☐	☐
19. How difficult is it for you to pivot?	☐	☐	☐	☐	☐
20. How difficult is it for you to do your usual physical recreational activities, such as bicycling, jogging, or walking?	☐	☐	☐	☐	☐
21. How difficult is it for you to do your usual leisure activities, such as hobbies, crafts, gardening, card-playing, or going out with friends?	☐	☐	☐	☐	☐
22. How much difficulty are you having with sexual activity?	☐	☐	☐	☐	☐
23. How difficult is it for you to do light housework or yard work, such as dusting, washing dishes, or watering plants?	☐	☐	☐	☐	☐
24. How difficult is it for you to do heavy housework or yard work, such as washing floors, vacuuming, or mowing lawns?	☐	☐	☐	☐	☐
25. How difficult is it for you to do your usual work, such as a paid job, housework, or volunteer activities?	☐	☐	☐	☐	☐

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These next questions ask how often you are experiencing problems this week because of your injury or arthritis.

	None of the Time A	A Little of the Time B	Some of the Time C	Most of the Time D	All of the Time E
26. How often do you walk with a limp?	☐	☐	☐	☐	☐
27. How often do you avoid using your painful limb(s) or back?	☐	☐	☐	☐	☐
28. How often does your leg lock or give way?	☐	☐	☐	☐	☐
29. How often do you have problems with concentrating?	☐	☐	☐	☐	☐
30. How often does doing too much in one way affect what you do the next day?	☐	☐	☐	☐	☐
31. How often do you act irritable toward those around you(for example, snap at people, give sharp answers, or criticize easily)?	☐	☐	☐	☐	☐
32. How often are you tired?	☐	☐	☐	☐	☐
33. How often do you feel disabled?	☐	☐	☐	☐	☐
34. How often do you feel angry or frustrated that you have this injury or arthritis?	☐	☐	☐	☐	☐

These questions are about how much you are bothered by problems you are having this week because of your injury or arthrit

	Not at All Bothered A	A Little Bothered B	Moderately Bothered C	Very Bothered D	Extremely Bothered E
35. How much are you bothered by problems using your hands, arms, or legs?	☐	☐	☐	☐	☐
36. How much are you bothered by problems with your back?	☐	☐	☐	☐	☐
37. How much are you bothered by problems doing work around your home?	☐	☐	☐	☐	☐
38. How much are you bothered by problems with bathing, dressing, toileting, or other personal care?	☐	☐	☐	☐	☐
39. How much are you bothered by problems with sleep and rest?	☐	☐	☐	☐	☐
40. How much are you bothered by problems with leisure or recreational activities?	☐	☐	☐	☐	☐
41. How much are you bothered by problems with your friends, family, or other important people in your life?	☐	☐	☐	☐	☐
42. How much are you bothered by problems with thinking, concentrating, or remembering?	☐	☐	☐	☐	☐
43. How much are you bothered by problems adjusting or coping with your injury or arthritis?	☐	☐	☐	☐	☐
44. How much are you bothered by problems doing your usual work?	☐	☐	☐	☐	☐
45. How much are you bothered with feeling dependent on others?	☐	☐	☐	☐	☐
46. How much are you bothered with stiffness and pain?	☐	☐	☐	☐	☐

Name: _____ Page 2 of 2 Date: _____