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# Intramedullary fixation in severe Charcot osteo-neuroarthropathy with foot deformity results in adequate correction without loss of correction – Results from a multi-centre study

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ABSTRACT

*Background:* Charcot osteo-neuroarthropathy (CN) of the foot can induce severe instability and deformity. Results of a consecutive clinical multi-centre study with Midfoot Fusion Bolt (MFB, Synthes GmbH, Oberdorf, Switzerland) are reported.

*Methods:* All patients (aged 18 years and older) treated between 2009 and 2013 with surgical reconstruction of the midfoot with MFB for CN were included. Demographics, pre-surgical health status, details of foot pathology, details of surgery, postoperative treatment, treatment failure, and adverse events were registered. The following radiographic angles were measured on pre-op, post-op and last follow-up radiographs: talo-1st metatarsal (TMT) angle dorsoplantar and lateral view, and calcaneo-5th metatarsal angle.

*Results:* Forty-seven patients (48 feet) were included in three centres. In 38 patients (80.1%) diabetes was diagnosed. Wound healing problems occurred in 21% of patients and recurrent ulceration in 13%. Revision surgery for loss of correction was performed in three cases (6%). Union rate at final follow-up was 98%. Major amputation for deep infection was performed in two patients (4%), minor amputation at the foot level in three cases (6%). Failure was more frequent when only one MFB (instead of 2 or 3) was used and no Gastrocnemius lengthening was performed. Radiographic alignment significantly improved pre- versus postoperatively and preoperatively versus follow-up.

*Conclusions:* Realignment and fixation with MFB in severe CN result in adequate correction with minimal loss of correction in the observed clinical course. The non-union rate was lower than previously reported. Stable fixation with MFB is a valuable treatment option for CN with minimal loss of correction and high union rates. The use of a minimum of two bolts is recommended to avoid recurrent deformity.
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## 1. Introduction

Charcot osteo-neuroarthropathy (CN) of the feet can induce severe instability and deformity with subsequent plantar ulceration leading to substantial disability or even amputation [1–3]. Traditionally, nonoperative treatment is regarded as the primary option of treatment while surgery is restricted to treating complications or failure of nonoperative treatment [1–6]. Failed nonoperative treatment substantially prolongs the treatment period [1–3,6,7]. Early surgical reconstruction in high-risk patients can provide timely restoration of a plantigrade and stable foot and improved quality of life for the patient with complication rates comparable to those after secondary surgery following nonoperative treatment [2]. However, in the early postoperative period, problems occur frequently due to inadequate correction, unstable internal fixation and especially loss of correction [2], which are

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associated both with the different types of internal fixation (using plates, staples and screws) and/or external fixation [2,8–10]. Intramedullary fixation with solid bolts (Midfoot Fusion Bolt [MFB], MFB, Synthes GmbH, Oberdorf, Switzerland, Fig. 1a and b) has been introduced as an option for fixation with high stability [2,3,6]. Based on the first promising experiences, an operative treatment regimen for CN with correction and intramedullary fixation with MFB was developed [2,3,6]. In the present study, preliminary results of a consecutive clinical multi-centre study are described. Primary objective was to assess the proportion of patients who experience treatment failure within the first year after surgery. Secondary objectives were to assess the proportion of patients who experienced a treatment failure within the first 2 years after surgery, the proportion of patients who experienced adverse events related to the midfoot reconstruction or to the MFB within the first 2 years after surgery, the duration of postoperative immobilization and non- or partial weight bearing, and to analyse the changes in the angular measurements in the radiographs from the time point of surgery until 1 year after surgery.

## 2. Methods

The study was carried out as multi-centre study in three locations (Department for Foot and Ankle Surgery, Sana Hospital Rummelsberg and Nuremberg, Germany (Rummelsberg), Department of Trauma, Hand and Reconstructive Surgery, Rostock University Medical Center, Germany (Rostock), University Center for Orthopaedics and Traumatology, University Hospital Carl Gustav Carus, Dresden, Germany (Dresden)). All patients with surgical reconstruction of the midfoot with MFB (for an indication of neuro-osteoarthropathy (Charcot foot) or deformity of the foot with neurological impairment) were eligible for inclusion. The indication was not disease specific, but related to the CN which is a multifactorial condition. Exclusion criteria were patient age below 18 years, inability to provide informed consent, and imprisonment. Approval for the study from the local responsible ethics committee was granted for all three study centres. Demographics, pre-surgical health status, details of foot pathology, details of surgery, postoperative treatment, treatment failure, and adverse events were registered. The pre-surgical health status was classified based on the Charlson Comorbidity Index (CCI) [11]. The foot pathologies were classified due to Eichenholtz, Sella and Barette, and Schon [12–14]. Radiographs and CT or PedCAT were obtained as follows (Fig. 2a–i) [15]: radiographs (bilateral dorsoplantar and lateral views of the entire foot) with full weight bearing (if possible due to the general condition of the patient) were obtained during the entire clinical course (pre-operatively (Fig. 2a and b), post-operatively, at 6 weeks, 12 weeks, 6 months, 12 months, and 24 months (Fig. 2f and g)) [16]. CT or PedCAT was not part of the study protocol but was obtained if indicated following the local standards, for example preoperatively (Fig. 2c and d), and at 1 year-follow-up (Fig. 2h and i). The local standard in two of the centres (Rostock and Dresden) was to obtain CT, and in the third centre (Rummelsberg) to obtain CT before PedCAT was available and PedCAT later.

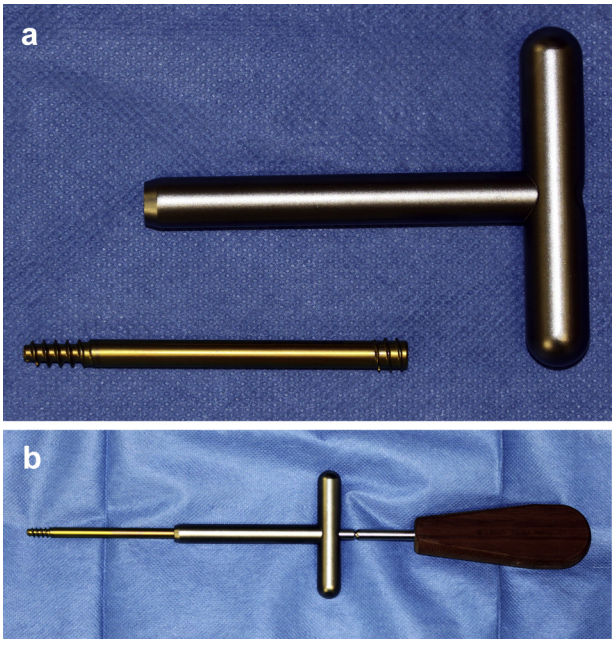


**Fig. 1.** (a and b) Midfoot Fusion Bolt (MFB) system. (a) Shows the MFB and the insertion handle. The inner diameter of the MFB tip is 5.0 mm and the diameter of the remaining MFB is 6.5 mm. The handle is cannulated with threads that correspond to those on the MFB. (b) Shows the MFB connected to the handle and with the screwdriver inserted to fit through the handle into the MFB. During insertion the far threads get bony purchase and the compression is generated by the handle pushing the near bone(s) towards the bone in which the far threads are positioned. The screwdriver further inserts the MFB while maintaining compression.

### 2.1. Assessment of radiographs (Fig. 2a, b, f, g)

The location of the deformity was classified according to Sanders and Frykberg [1]. The following angles were digitally measured by an independent radiologist in blinded manner on pre-operative, post-operative (13.1 days on average) and last follow-up radiographs: talo-1st metatarsal (TMT) angle dorsoplantar and lateral view, and calcaneo-5th metatarsal angle [17]. The TMT angle was defined as the angle created between the axis of the 1st metatarsal and the talus [17]. The dorsoplantar TMT angle was measured in the dorsoplantar view (Fig. 2a and f), and the lateral TMT angle was measured in the lateral view (Fig. 2b and g). The calcaneo-5th metatarsal angle was defined as the angle created between the line connecting the lowest point of the anterior and posterior process of the calcaneus, and the axis of the 5th metatarsal in the lateral view (Fig. 2b and g). All bone axes (Talus, metatarsals) were defined as the straight line between the centres of the bones proximally and distally. These bone centres were defined by linear measurements. The TMT angles were defined to be negative for abduction in the dorsoplantar radiographs and for dorsiflexion in the lateral radiographs [17].

### 2.2. Surgical technique

The surgical technique slightly differed between the centres, especially with respect to the number of MFBs introduced. The surgical technique most frequently applied (Rummelsberg), is described. The patient was positioned in a prone position with the heel over the distal edge of the table. General anaesthesia was performed. Additionally a pain-control-catheter was placed at the popliteal nerve for continuous postoperative local anaesthetic infiltration. A tourniquet was placed at the thigh followed by sterile draping. The leg was exsanguinated with an Esmarch bandage and the tourniquet was inflated with 350 mmHg. Gastrocnemius tendon lengthening was performed in cases with positive Silvferskiöld test through a 3 cm longitudinal incision posteromedially at the tendon–muscle intersection of the gastrocnemius tendon. The fascia was split and the gastrocnemius tendon was completely sectioned transversely close to its tendon–muscle intersection. A suture was placed into the tendon stumps to stabilize the tendon in the correct length. Alternatively, in patients with a negative Silvferskiöld test but lack of ankle dorsiflexion, Achilles tendon lengthening was carried out, preferably in a percutaneous manner.

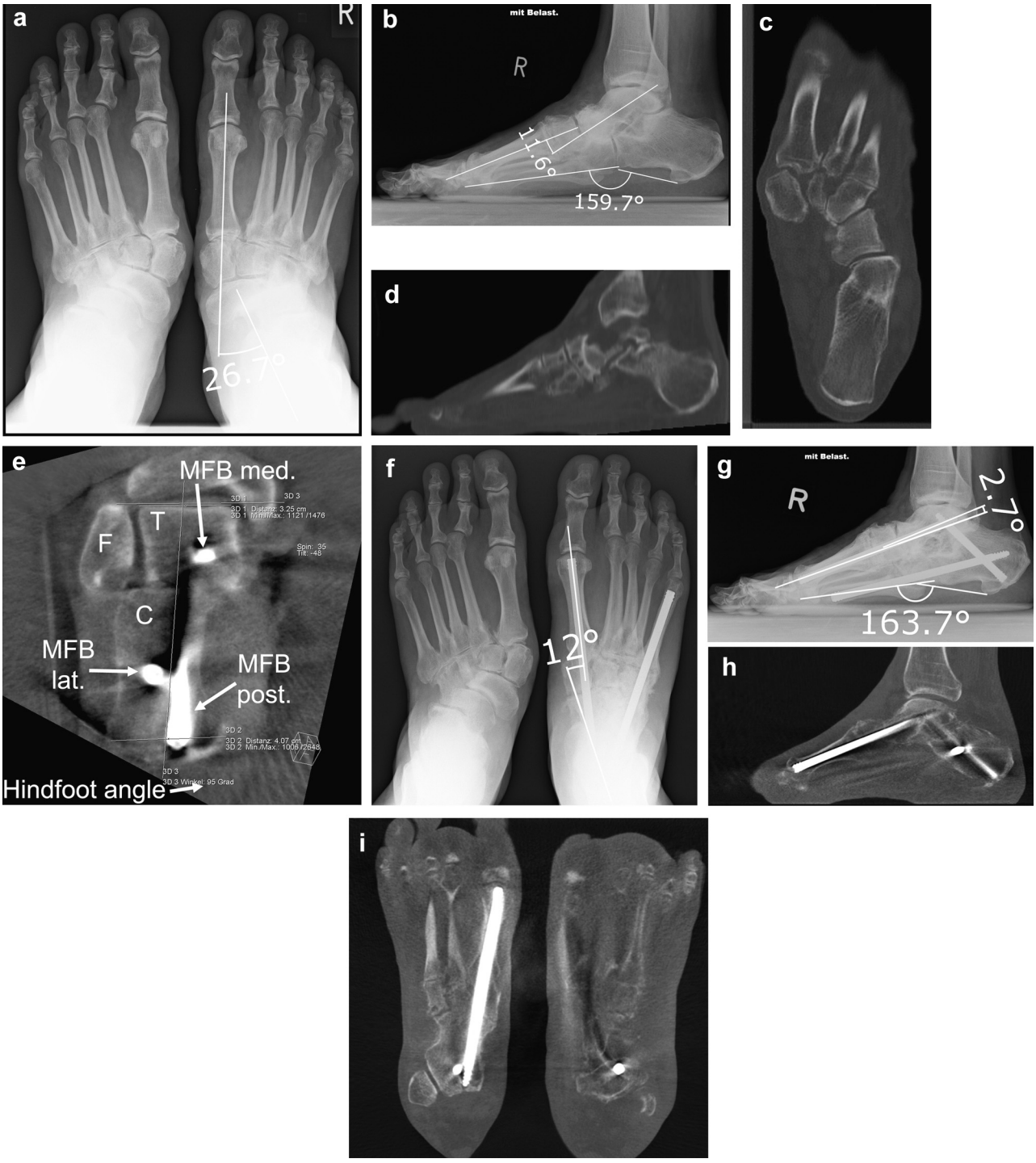


**Fig. 2.** (a–i) Case/foot with three MFBs. (a and b) Preoperative radiographs. Eichenholtz Stage 1, Sella and Barrette Stage 3, talo-1st metatarsal angle – dorsoplantar −26.7° and lateral −11.6°, calcaneo-5th metatarsal angle 159.7°. (c and d) Preoperative CT. (e) Intraoperative CT, paracoronar reformation (T, talus; C, calcaneus; F, fibula; MFB post., MFB calcaneus – talus; MFB med., MFB medial column; MFB lat., MFB lateral column; hindfoot angle, 95° corresponding to 5° hindfoot valgus). (f and g) Radiographs at 1 year-follow-up. Talo-1st metatarsal angle – dorsoplantar −12° and lateral −2.7°, calcaneo-5th metatarsal angle 163.7°. (h and i) PedCAT images (3D-imaging with weight bearing) at 1 year-follow-up [15].

A medial incision at the foot starting at the medial malleolus towards the first metatarsophalangeal joint followed. Through this approach the following joints were exposed: subtalar joint, talonavicular joint, naviculocuneiform joint, 1st tarsometatarsal joint and 1st metatarsophalangeal joint. After that, a lateral approach was performed, starting distal to the lateral malleolus and ending above the base of the 4th and 5th metatarsal. Through the lateral approach, the following joints were exposed: calcaneocuboidal joint, 2nd to 5th tarsometatarsal joints. An additional approach was performed laterally above the 5th metatarsophalangeal joint to also expose this joint. All joints except the metatarsophalangeal joints were prepared further with synovectomy and removal of the remaining cartilage (including penetration of the subchondral bone plate). The entire remaining cartilage was

removed. For this preparation 1.6 mm K-wires were placed into the neighbouring bones and a special laminar spreader with holes for the wires was used to expose the joints. If necessary, corrective osteotomies were carried out. For example, in a typical flatfoot deformity more bone was removed plantarly than dorsally at and under the subchondral bone plate. In cases with the typical abduction of the mid- and forefoot, more bone was removed on the medial side than on the lateral side. In typical cases with an increased hindfoot valgus more bone was removed on the medial than on the lateral side. Corrective osteotomies were performed until the foot could be positioned in a plantigrade position. Thereafter, autologous cancellous bone graft was harvested at the proximal tibia. A 3 cm incision between the attachment of the patellar tendon and pes anserinus followed. The tibial cortex was opened with a chisel and cancellous bone was harvested. Afterwards, the subchondral bone plate in the foot joints was penetrated with a 2.0 mm drill and cancellous bone allograft was placed into each joint. Subsequently, the guide wires for the midfoot fusion bolts were placed. First the hindfoot was corrected to achieve the desired hindfoot valgus position of 5° and the first guidewire was placed from plantar through the tuberosity of the calcaneus through the posterior facet of the subtalar joint into the talar body. The second wire was placed in a retrograde fashion through the exposed first metatarsophalangeal joint through the 1st metatarsal, the 1st cuneiform, and the navicular into the talar head, neck and body. The 3rd wire was placed in a retrograde fashion through the exposed 5th metatarsophalangeal joint, the 5th metatarsal, and the cuboid into the calcaneus. Drilling was performed with cannulated drill bits (5.0 mm and 6.5 mm) over the guidewires and the MFBs were inserted in the standard compression mode (course of MFB and guidewires shown in Fig. 2e and f). Intraoperative fluoroscopic imaging including 3D-imaging was performed to ensure proper positioning (Fig. 2e). Drains were inserted and the wounds were closed in layers. Antibiotics (type defined by local standard) were given perioperatively and 3 days postoperatively. Aftertreatment consisted of a minimum of 6 weeks of 15 kg partial weight bearing in an orthosis (Vacodiaped, Oped, Valley, Germany), and alternatively in a split or closed below knee cast at other centres. If the patient was not able to perform partial weight bearing, mobilization in a wheel chair was performed. Full weight bearing was allowed when the joints were considered to have fused. The first radiological assessment (radiographs entire foot dorsoplantar, lateral and oblique views) regarding fusion was performed after 6 weeks. If fusion was sufficient, further partial weight bearing with 30 kg in the orthosis was performed. Further assessments were carried out at 9 and 12 weeks as well as during the later follow-up (see below). Full weight-bearing was allowed when radiographic fusion was confirmed at 9 or 12 weeks postoperatively.

### 2.3. Outcome measures

Primary outcome measures were occurrence and time of a secondary surgical intervention for correction of deformity or an amputation within the first year after surgery. Secondary outcome measures were occurrence and time of secondary surgical intervention for correction of deformity or amputation within the first 2 years after surgery; occurrence, type, and time of adverse event within the first 2 years after surgery; duration and type of postoperative immobilization and non- or partial weight bearing; changes of angular measurements on the radiographs from surgery to 1 or 2 years post-surgery as described above. Treatment failure was defined as occurrence of secondary surgical intervention for correction of deformity or amputation. Adverse events were defined as advents related to the midfoot reconstruction or the MFB itself.

### 2.4. Statistical methodology

Continuous variables were summarized using mean, minimum and maximum values, whereas for categorical variables, actual frequencies and percentages (based on the non-missing information) were used. Adverse events were reported by category at the patient level. When calculating adverse event rates, the denominator was the total population size, irrespective of dropouts during the course of follow-up. In addition, characteristics of adverse events (e.g. time period of occurrence, relation to MFB, etc.) were presented at the adverse event level. The preoperative, postoperative and follow-up measurements of radiographic angles were compared with paired *t*-tests with a significance level of 0.05. A test for normal distribution as a prerequisite for application of a *t*-test was successfully performed. Comparisons between groups with or without failure and/or adverse events with respect to classification systems (Eichenholtz, Sella and Barette, Schon) and Gastrocnemius and/or Achilles tendon lengthening were performed with Fisher's exact test, Chi-square test, or *t*-test with a significance level of 0.05. The statistical analyses were performed using SAS software version 9.2 (SAS Institute, Cary, NC).

## 3. Results

Forty-seven patients were included in all three centres (Rummelsberg, $n = 28$; Rostock, $n = 13$; Dresden, $n = 6$). The first patient that met the inclusion criteria was operated on in April 2009 and the last in June 2013. The mean follow-up time was 12 months (range, 1–35). 19 patients (40.4%) completed 1 year follow-up, and 11 (23.4%) 2 year follow-up.

### 3.1. Demographics

Mean patient age at the time of surgery was 60.1 years (range, 35–78). Twenty-eight (59.6%) patients were male. Mean height was 173.7 cm (range, 153–202), mean weight 95.4 kg (range, 60–135), and mean body mass index (BMI) 31.5 kg/m$^2$ (range, 22–42). The left foot was treated in 19 (40.4%) patients, the right foot in 27 (57.4%) patients, and both feet in 1 (2.1%) patient, resulting in 48 treated feet. The patient with bilateral involvement was treated with an 8-month interval between correction of the first and second foot.

### 3.2. Pre-surgical health status (Table 1)

Table 1 shows the comorbities of included patients. In 38 (80.9%) patients, diabetes with or without end organ failure was registered. The mean CCI was 2.7 (range, 1–7) [11]. Fourteen (32.6%) patients had a CCI of 1 and 11 (25.6%) had a CCI of 2.

### 3.3. Details of foot pathology (Table 2)

Table 2 shows the details of the acquired foot pathologies. The main deformity was located at the tarso-metatarsal joint region (Sanders 2) in all cases. 26 (54.2%) feet were classified Eichenholtz stage 1 and 34 (70.8%) Sella and Barette stage 3. Surgical and/or conservative treatment prior to the surgical correction by MFBs was found in 15 (31.3%) and 20 (41.7%) feet respectively.

### 3.4. Details of surgery

In a total of 27 (56.3%) feet, three MFBs were inserted (as described above), in 6 (12.5%) feet, two MFBs were inserted, and for 15 (31.3%) feet, one MFB was used. Additional implants were used in 32 (66.7%) feet (plates: $n = 6$ [12.5%]; screws: $n = 26$ [54.2%], wires: $n = 4$ [8.3%], others: $n = 1$ [2.1%]). Bone grafting was

**Table 1**
Summary of Charlson Comorbidity Score items [11].

| Characteristic | *n* (%) |
|---|---|
| Myocardial infarction | 5 (11.6) |
| Congestive heart failure | 9 (20.9) |
| Peripheral vascular disease | 13 (30.2) |
| Cerebrovascular disease | – |
| Dementia | 1 (2.3) |
| Chronic pulmonary disease | 5 (11.6) |
| Connective tissue disease | 2 (4.7) |
| Ulcer disease | 3 (7.0) |
| Mild liver disease[a] | 6 (14.0) |
| Diabetes[b] | 27 (62.8) |
| Diabetes with end organ damage | 11 (25.6) |
| Hemiplegia | – |
| Moderate or severe renal disease | 9 (20.9) |
| Tumour including leukaemia and lymphoma | 1 (2.3) |
| Moderate or severe liver disease | 1 (2.3) |
| Metastatic solid tumour | – |
| AIDS | – |

*Note*: Four patients who did not complete none of the Charlson Comorbidity Score items are excluded from the tabulation.
[a] Response was set to 'No' if response was 'Yes' for 'Moderate or severe liver disease'.
[b] Response was set to 'No' if response was 'Yes' for 'Diabetes with end organ damage'.

performed in 42 (87.5%) feet, Achilles tendon lengthening in 8 (16.7%), and Gastrocnemius release/lengthening in 28 (58.3%). The mean surgical time (skin-to-skin) was 141.6 min (range, 62–245). Table 3 shows the immediate postoperative radiographic angles. All radiographic angles improved significantly compared to the preoperative measurements. The minimum, i.e. most negative TMT dorsoplantar angle was substantially increased from −47° preoperatively to −23° postoperatively and the minimum lateral TMT angle from −40° preoperatively to −10° postoperatively.

**Table 2**
Details of foot pathologies.

| Characteristic | *n* (%) |
|---|---|
| Eichenholtz | |
| Stage 0: Inflammatory | 0 |
| Stage 1: Development | 26 (54.2) |
| Stage 2: Coalescence | 6 (12.5) |
| Stage 3: Remodelling | 6 (12.5) |
| Not assessed | 10 (20.8) |
| Sella and Barrette | |
| Stage 0 Localized heat | 0 |
| Stage 1 Localized osteoporosis | 1 (2.1) |
| Stage 2 Joint subluxations | 4 (8.3) |
| Stage 3 Joint dislocations and joint destruction | 34 (70.8) |
| Stage 4 Sclerosis/ankylosis | 3 (6.3) |
| Not assessed | 6 (12.5) |
| Schon | |
| Stage A | 3 (6.3) |
| Stage B | 8 (16.7) |
| Stage C | 30 (62.5) |
| Not assessed | 7 (14.6) |
| Time elapsed between diagnosis of CN and surgery, *n* (%) | |
| <1 year | 12 (25.0) |
| 1–5 years | 8 (16.7) |
| 5–10 years | 1 (2.1) |
| >10 years | 1 (2.1) |
| Not assessed | 26 (54.2) |
| Previous history of CN on the other foot, *n* (%) | |
| No | 26 (54.2) |
| Yes | 20 (41.7) |
| Not assessed | 2 (4.2) |
| Ulcer on the treated foot at the time of surgery, *n* (%) | |
| No | 42 (87.5) |
| Yes | 5 (10.4) |
| Not assessed | 1 (2.1) |

CN, Charcot osteo-neuroarthropathy.

### 3.5. Postoperative treatment

All 48 feet/cases were immobilized postoperatively (total contact cast: $n = 8$ [16.7%]; removable cast walker: $n = 7$ [14.6%]; foot/ankle orthosis: $n = 26$ [54.2%]; others: $n = 7$ [14.6%]). The mean duration of immobilization was 11.1 weeks (range, 4–18). Walking aids were used in 47 (97.9%) cases (crutches: $n = 42$ [87.5%]; wheelchair: $n = 2$ [4.2%]) for an average of 12 (range, 4–36) weeks. In two cases (4.2%) no weight bearing was performed (one with wheelchair mobilization), in the remaining 46 (95.8%) partial weight bearing. The mean duration of hospital stay was 27 (range, 6–166) nights.

### 3.6. Adverse events (AE) (Tables 4 and 5)

In 30 (63.8%) patients, at least one AE ($n = 52$ AEs in total) was registered (Table 4). The most common AE was a wound healing problem ($n = 10$; 21.3%). Deep wound infections were observed in eight (17%) patients. Recurrent ulceration was noted in six (12.8%) patients, MFB loosening in three (6.4%), and non-union in one (2.1%). Delayed bone healing beyond 16 weeks was not observed. In 16 patients (53.3% of patients with AE) one AE was observed, in 8 (26.7%) two, in 4 (13.3%) three and in 2 (6.7%) four. Table 5 shows the characteristics of the 52 AE in detail. The incidence of adverse events was not affected by any of the classification systems (Eichenholtz, Sella and Barette, Schon; Chi-square test, each $p > 0.05$) nor was it related to Gastrocnemius and/or Achilles tendon lengthening (Fisher's exact test or Chi-square test, each $p > 0.05$).

### 3.7. Treatment failure

Treatment failure as defined was observed in eight (16.7%) feet/cases. Among those eight feet/cases, three surgical revisions due to loss of correction (6.3%) and five amputations due to infection/sepsis (10.4%) were performed. The reported amputation levels were below knee ($n = 2$ [4.2%]), midfoot level ($n = 1$ [2.1%]), and forefoot level ($n = 2$ [4.2%]). On average, surgery due to treatment failure was performed 237 days (range, 28–808) after the initial corrective surgery. In one (13%) case with treatment failure Achilles tendon lengthening was performed and in none Gastrocnemius tendon lengthening (0%). In the group without treatment failure ($n = 40$), in 7 (18%) cases Achilles tendon lengthening was performed and in 28 (80%) Gastrocnemius tendon lengthening. Vice versa, none of the 28 cases with Gastrocnemius tendon lengthening failed, and in one (13%) of the cases Achilles tendon lengthening failed. The incidence of treatment failure was significantly lower when Gastrocnemius tendon lengthening had been performed (Fisher's exact test, $p < 0.0001$) but was not influenced by Achilles tendon lengthening (Fisher's exact test, $p = 0.999$). The incidence of treatment failure was influenced by the Eichenholtz classification (Fisher's exact test, $p = 0.022$) but not by the Sella and Barette classification (Fisher's exact test, $p = 0.999$). Eichenholtz stage 1 was registered in 62.5% of cases without failure and in 12.5% of cases with failure whereas 25% of cases with failure were stage 3 and 10% without.

### 3.8. Radiographic angles

Table 3 presents the time course of the radiographic measurements. All angles showed a significant improvement from preoperative to postoperative and from preoperative to last follow-up measurement. The angles did not significantly change

**Table 3**
Radiographic angles pre-, postoperative and last at follow-up, and changes of the angles.

| Parameter | Time | Mean (°) | Range (°) | Change (°) | $p$ (paired $t$-test) |
|---|---|---|---|---|---|
| Pre- versus postoperative | | | | | |
| TMT lat | Pre-OP | −11.42 | −40 to −5 | 5.81 | <0.001 |
| | Post-OP | −5.71 | −10 to −3 | | |
| TMT dp | Pre-OP | −17.27 | −47 to −6 | 6.90 | <0.001 |
| | Post-OP | −10.55 | −23 to −4 | | |
| Cal-5 | Pre-OP | 164.9 | 142 to 180 | −6.55 | 0.001 |
| | Post-OP | 158.0 | 146 to 179 | | |
| Preoperative versus last follow-up | | | | | |
| TMT lat | Pre-OP | −11.42 | −40 to −5 | 5.77 | <0.001 |
| | Last follow-up | −5.65 | −11 to −4 | | |
| TMT dp | Pre-OP | −17.27 | −47 to −6 | 7.43 | <0.001 |
| | Last follow-up | −10.02 | −16 to −5 | | |
| Cal-5 | Pre-OP | 164.9 | 142 to 180 | −3.77 | 0.047 |
| | Last follow-up | 161.1 | 142 to 179 | | |
| Postoperative versus last follow-up | | | | | |
| TMT lat | Post-OP | −5.71 | −10 to −3 | 0.14 | 0.654 |
| | Last follow-up | −5.65 | −11 to −4 | | |
| TMT dp | Post-OP | −10.55 | −23 to −4 | 0.49 | 0.318 |
| | Last follow-up | −10.02 | −16 to −5 | | |
| Cal-5 | Post-OP | 158.0 | 146 to 179 | 3.21 | 0.004 |
| | Last follow-up | 161.1 | 142 to 179 | | |

TMT lat, lateral talo-1st metatarsal angle; TMT dp, dorsoplantar talo-1st metatarsal angle; Calc-5, calcaneo-5th metatarsal angle; Pre-OP, preoperative; Post-OP, postoperative. The TMT angles were defined to be negative for abduction in the dorsoplantar radiographs and for dorsiflexion in the lateral radiographs (13).

from postoperative to last follow-up except for the calcaneo-5th metatarsal angle ($p = 0.004$). Further analyses of the calcaneo-5th metatarsal angle between the postoperative radiograph and the last available follow-up radiograph, revealed significant changes after the insertion of one or two MFBs when two MFBs were inserted into the medial and lateral column as described ($p = 0.015$, $p = 0.037$, respectively). No changes were seen after the insertion of three MFBs, when the third MFB running from the calcaneus into the talus as described ($p = 0.209$). For the other angles (talar-first metatarsal angle lateral radiograph and anterior–posterior radiograph) no significant differences between the postoperative and last available follow-up radiograph could be found when using one, two or three MFBs. The incidence of angular change, i.e. loss of reduction was not influenced by Gastrocnemius and/or Achilles tendon lengthening except the change of calcaneal-5th metatarsal angle which was lower with Gastrocnemius lengthening than without ($t$-test, $p = 0.006$, all other $p > 0.05$).

**Table 4**
Adverse events (AE) on patient level.

| AE type | $n$ | % |
|---|---|---|
| Any AE specified below | 30 | 63.8 |
| Worsening of foot deformity | 1 | 2.1 |
| New foot deformity | – | – |
| Iatrogenic fracture | 1 | 2.1 |
| Other intraoperative AE | – | – |
| MFB loosening | 3 | 6.4 |
| MFB breakage | 1 | 2.1 |
| MFB bending | – | – |
| Delayed bone healing | – | – |
| Non-union | 1 | 2.1 |
| Pseudarthrosis | – | – |
| Osteomyelitis | 2 | 4.3 |
| Bone necrosis | 1 | 2.1 |
| Ulceration | 6 | 12.8 |
| Superficial wound infection | 2 | 4.3 |
| Deep wound infection | 8 | 17.0 |
| Wound haematoma | 2 | 4.3 |
| Neurovascular injury | – | – |
| Sepsis | 1 | 2.1 |
| Thrombosis | – | – |
| Embolism | – | – |
| Pneumonia | – | – |
| Compartment syndrome | – | – |
| Wound healing problem | 10 | 21.3 |
| Other adverse event | 4 | 8.5 |

Calculations on patient level (number/proportion of subjects experiencing at least one AE of the given category).

## 4. Discussion

Charcot osteo-neuroarthropathy (CN) is severe condition of the foot, mainly affecting patients with diabetes mellitus

**Table 5**
Characteristics of adverse events (AE, $n = 52$ in total).

| Characteristic | $n$ (%) |
|---|---|
| Time period of the AE occurrence | |
| Intraoperatively | 1 (1.9) |
| Up to 15 days postoperatively | 15 (28.8) |
| >15 days to 1 month postoperatively | 2 (3.8) |
| >1–3 months postoperatively | 14 (26.9) |
| >3–6 months postoperatively | 9 (17.3) |
| >6 months to 1 year postoperatively | 4 (7.7) |
| >1 year postoperatively | 7 (13.5) |
| AE related to MFB | |
| No | 44 (84.6) |
| Yes | 6 (11.5) |
| Possible | 2 (3.8) |
| Unknown | 0 |
| AE related to midfoot reconstruction | |
| No | 8 (15.4) |
| Yes | 43 (82.7) |
| Possible | 1 (1.9) |
| Unknown | 0 |
| Final outcome of the AE | |
| Unknown | 3 (5.8) |
| Recovery in progress | 25 (48.1) |
| Patient recovered without persistent damage | 21 (40.4) |
| Patient recovered with persistent damage | 3 (5.8) |
| Part of the body affected by the AE | |
| Local AE | 23 (100.0) |
| General AE | 0 |
| Foot affected | |
| Left | 24 (46.2) |
| Right | 28 (53.8) |

[3,18–21]. The detailed aetiology of CN is still poorly understood, but important causative factors are repetitive overloading due to non-perceived trauma, local inflammatory changes, poor bone quality due to metabolic changes and dysbalances between osteoblasts and osteoclasts [6,22,23]. Early diagnosis is difficult due to the fact that neuropathic patients are usually free of pain [18–20]. The first clinical symptoms of CN are a warm, red, and swollen foot [24]. In the advanced, chronic stage, CN affects the bony structure leading to joint dislocations, pathological fractures, and instability of the foot [24–26]. This process can be completed within a few weeks or take several months [27]. Most commonly, CN develops is in the midfoot region involving more than one anatomical foot region [18,27–30]. The consequence of bone breakdown is an irreversible, so-called rocker bottom deformity of the foot which may further cause severe ulceration [31]. Patients affected by this stage of CN suffer from a dramatic decrease in quality of life and the risk of losing their foot [29]. There are several different treatment options for CN, all of them aiming for the maintenance or recovery of a plantigrade foot, achievement of osseous stability, and prevention of ulceration [3,6,18,20,21,32]. Most early-stage patients are treated conservatively; immobilization with a total contact cast and off-loading of the affected foot included [24,25,33,34]. Surgical intervention is mainly applied to patients in a later stage or after failure of conservative treatment; nevertheless, there are some reports of successful surgical treatment of early-stage CN patients [3,21].

Few literature on the surgical management of CN is available and the clinical evidence of published studies is low [18]. A consensus regarding the best surgical treatment is still missing. However, surgical arthrodesis of the midfoot using plates, standard screws compression osteosynthesis or intramedullary placement of screws seem to be the most commonly used techniques [3,18,21]. Following surgical stabilization, neuropathic patients often have difficulties controlling the amount of weight bearing [3,35]. Therefore, implants are exposed to high loads which may cause implant failure in up to 100% [3,35,36]. To overcome this problem, solid 6.5 mm intramedullary bolts (Midfoot Fusion Bolt (MFB), Synthes GmbH, Oberdorf, Switzerland) with threaded tips were developed to withstand higher loads than conventional screws and plates and thus decrease the risk of implant failure and consecutive loss of correction has been introduced [2,3].

In this study, the major amputation rate was 4% which is lower than previously reported [2,8–10]. The achieved correction was favourable. In particular, the minimum, i.e. most negative TMT dorsoplantar and lateral angles were substantially improved, i.e. the most extreme deformities were also corrected sufficiently. The long inpatient time was caused by the comorbidities. The health system in the country where the study was performed allows long hospital stay and provides sufficient reimbursement in cases with such (co)morbidities.

The typical deformity in CN is flatfoot with its apex at the midfoot (i.e. dorsiflexion of the forefoot with respect to the hindfoot) which corresponds to negative lateral TMT angles, and abduction which corresponds to negative dorsoplantar TMT angles. No significant loss of reduction occurred in the observed clinical course which is in contradiction with the literature where loss of reduction is reported as typical problem [2,3,8–10,36]. This seems to be a crucial issue in correction of CN because loss of correction might lead to non-union and re-ulceration in 16–60% [2,3,8–10]. In this study, the non-union rate was low (2%), and the re-ulceration rate was acceptable (13%) [2,3,8–10]. Stable fixation with MFB prevented loss of correction in 94% of cases included in our study and resulted in a union rate of 98% at final follow-up.

Because there was no previous experience with the MFB, the number of bolts used for fixation was left to the surgeons' discretion which allowed us to compare the failure rates with different constructs. When further analysing our data, we found that the most stable fixation with least loss of correction was provided by the use of three MFB using one MFB in the medial column, one in the lateral column, and one in the hindfoot (calcaneus to talus). Even with a slight dislocation of the MFB in the medial and/or lateral column, no signification loss of correction was observed. Addressing single foot columns with the MFB as a stand-alone implant leads to a high rate of complications and recurrent instability [37]. The initial instruction manual of the MFB system stated that a "stand alone" use of MFB is not recommended. After extensive discussion among the authors and consultation with the AO Foot and Ankle Expert Group we came to the conclusion that "stand alone" should be interpreted as one single MFB alone, i.e. without any further implants of any kind (MFB or other). So, the use of two or three MFB as recommended in the manuscript would not be "stand alone" [37].

One MFB alone acts as a centre of rotation, thus an unstable construct. With two or even three MFBs diverging along different axis in the foot this problem is overcome [37]. Alternatively, other implants than a second or third MFB like plates and screws may be added to achieve a stable "superconstruct" to avoid implant failure and recurrent deformity under the conditions of manifest CN. We also believe that further compression across the segments adds to the stability. These recommendations are supported by the low failure rate seen in our study. The high number of AEs reported in our study, reflects the extreme morbidity of this pathology and was described previously [2,3,8–10,36].

Gastrocnemius or Achilles tendon lengthening reportedly removes a deforming force in Charcot midfoot collapse [38]. We found a clear correlation between Achilles tendon and Gastrocnemius tendon lengthening and treatment success or better prevention of failure. Therefore, as a result of our study we recommend Gastrocnemius tendon lengthening (28 cases, no failure) and Achilles tendon lengthening (8 cases, 25% failure) as indicated by a positive or negative Silverskiöld test, respectively. Nevertheless it has to be mentioned, that, although statistical significant, our results with regard to prevention of mechanical failure have to be considered with caution, as we deal with a low number of mechanical failures ("events"), which makes it susceptible to errors.

### 4.1. Limitations of the study

There are numerous shortcomings of the study such as the relatively low case number, a missing control group, non-uniform treatment, short follow-up time and incomplete follow-up. However, as CN is not a common pathology, its clinical presentation is highly variable, and there is a high occurrence of comorbidities, clinical studies are difficult to perform [3]. To achieve an acceptable case number, three centres were included. There are studies with larger case numbers dealing with this kind of pathology, but these studies did not focus on CN as such, but more on diabetic foot syndrome with ulceration and deformity [3,26]. The missing control group is a typical shortcoming of studies dealing with uncommon pathologies. The high variability, the clinical presentation, and comorbidities also present a considerable number of possible confounders. Surgeries were performed by three senior surgeons (one per centre) using different surgical techniques. In particular, the number of MFBs varied. However, this non-uniformity provided the opportunity to further analyse differences in the effect of MFB number as described above. The short and incomplete follow-up again reflects the extremely problematic patient group with a relatively poor compliance [3]. However, when focusing on the extent of correction and the loss of correction, a follow-up time of 1, respectively 2 years as performed in our study seems acceptable as

correction was achieved during the initial surgery and loss of correction typically occurs in the early clinical course [2,3,8–10].

In conclusion, fixation with MFB in severe Charcot osteoneuroarthropathy results in adequate correction without loss of reduction in 94% during the first 1–2 years after surgery. The nonunion rate of 2% at final follow-up was lower than reported previously. This implies that stable fixation with MFB is a viable treatment option for CN that prevents loss of correction and provides high union rates. The use of a minimum of two bolts is recommended to avoid recurrent deformity. The incidence of failure was significantly less when additional Gastrocnemius lengthening was performed.

## Conflict of interest

None of the authors received funding in relation to this study. The corresponding author is consultant of Curvebeam, Stryker, Small Bone Innovations and Intercus, proprietor of R-Innovation, and joint proprietor of First Worldwide Orthopaedics. Stefan Rammelt is a member of the AO Foot and Ankle Expert Group and receives travel support from AOTrauma and DePuySynthes. Per-Henrik Agren is proprietor of Stockholms Fotkirurgklinik and is former member of the AO Foot and Ankle Expert Group.

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