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Four-stage regimen for operative treatment of diabetic foot ulcer with deformity – Results of 300 patients

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A R T I C L E I N F O

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Background: An operative four-stage regimen (stage 1, debridement; stage 2, closure; stage 3, unloading; stage 4, correction) for operative treatment of diabetic foot ulcer with deformity, and first clinical results are introduced.

Methods and results: 335 patients entered stage 1 between 01/09/2006 and 31/08/2010.

Stage 1: In 189 cases (56%), one debridement resulted in sterile postoperative specimens.

Stage 2: 210 cases (63%) sustained secondary closure, 97 (29%) local shifted skin graft, and 20 (6%) functional amputation.

Stage 3: 304 (90%) finished stage 3, 14 (4%) presented with recurrent ulcer.

Stage 4: In 185 cases (55%), correction arthrodeses were performed successfully.

Follow-up: 300 (90%) completed follow-up at 26 months on average (12–48 months). Recurrent ulcer was registered in 46 (15%). Overall amputation rate was 14%, the majority at digital or midfoot level. Four cases (1%) required a below-knee amputation.

Conclusions: The management of diabetic foot ulcer combined with deformity with the introduced regimen showed low major amputation rate and low recurrent ulcer rate compared with the literature.

1. Introduction

Diabetes mellitus is a severe metabolic disorder although the pathophysiology of type I and type II is totally different. In the long-term, a decompensated blood sugar level damages all blood vessels [1–5]. Generally, it is the neuropathy that leads to mal perforans ulcers and it is decreased circulation that results in compromised healing [1–5]. It is medical knowledge that after ten years consequential damages occur due to decreased blood supply [1–5]. The worldwide prevalence of diabetes mellitus is 6.4% or 285 million [5]. Around 6 million diabetic patients suffer from a diabetic foot worldwide [3–5]. Among these patients, in 5–15%, a diabetic foot ulcer is present and in 3% an additional foot and/or ankle deformity [3–5]. The diabetic foot is an often neglected sequel of diabetes [1–5,5]. Due to insufficient management, later major amputations are a common course of the disease [1–5]. A secondary prevention is at best possible with an early interdisciplinary management, and the rate of amputation could be minimized or limited to a more distal level [1–5]. The annual worldwide amputation rate is considered to be higher than 2 million cases, typically caused by uncontrollable infection in combination with general and cellular immunodeficiency, neuritis, micro- and macroangiopathy [3,4]. Two different types of diabetic foot have been defined [1–4].

1. The neuropathic-infected foot that accounts for up to 70% of all diabetic feet. Hereby, the peripheral nerves are damaged by insufficient blood supply over years. Peripheral nerve damage secondary to decreased blood supply is only one theory. Persistent hyperglycaemia activates the aldose-reductase pathway which results in conversion of glucose to polyol with a side product of sorbitol that are cellular toxic. This substance is deposited in the endoneurium and results in an osmotically induced oedema which interferes with conduction [6–8]. Protein kinase C and glycosylated proteins are also increased which are also cellular and especially neurotoxic [6–8]. A very severe special type is the Charcot foot that requires a combination of neuropathy and good circulation. It is the shunting that leads to resorptive changes, fractures, and deformity [6–8]. Another theory is that a series of hyperglycaemic events lead to the glycolysis and subsequent rupture of the plantar fascia which probably is causative to the development of neuroosteoarthropathy/charcot.

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2. The ischaemic – gangrenous foot that is caused by insufficient peripheral arterial blood supply due to microangiopathy. This type accounts for 20–30% of all diabetic feet. Ischaemia can also be caused by large vessel disease proximally that results in decreased pressure and perfusion distally. Generally, an ankle pressure of 90 mm Hg is needed for healing.

A foot deformity is often jointly responsible for foot ulcers in diabetic feet [1,2,5,9,10]. Consequently, the correction of deformities is considered as an important preventive measure for recurrent foot ulcers [1,2,5,9,10]. The management of diabetic foot ulcer combined with deformity is challenging, because contaminated or even infected ulcers could conflict with corrective procedures [1,2,5,9,10].

An operative four-stage regimen (debridement; closure; unloading; correction) is introduced, and the clinical results of in 257 patients treated with this regimen are shown.

2. Methods

All patients (age 18 years and older) with diabetes mellitus, unilateral foot ulcer and foot and/or ankle deformity treated at the authors institution between September 1, 2006, and August 31, 2010 were included in the study. The decision about the existence of a deformity and the classification of that deformity was performed by the head of the institutional foot and ankle outpatient clinic based on the clinical examination, radiographs, and pedography (groups see below).

2.1. Diagnostics/evaluation

The diagnostics/evaluation before stages 1 and 4, and at follow-up (minimum follow-up time 12 months) included:

- Medical history
- Clinical examination
- Radiographs in standing position with full weight bearing (dorsoplantar, lateral, metatarsal head panorama view) (Figs. 1, 3 and 5)
- Pedography with video documentation (Figs. 2 and 4)
- Sensory assessment (Caloric test, Monofilament test, Vibration test).
- Blood investigation (for example HbA1c)
- Vascular assessment with Doppler ultrasound and if pathological consultation of a vascular surgeon and optional angiography.
- Score registration and analysis (Screening locomotive system, Visual Analogue-Scale Foot and Ankle (VAS FA), Sanders/Frykberg, Eichenholtz, Wagner/Armstrong, PEDIS, American Orthopaedic Foot and Ankle Society Score (AOFAS Score)) [3–8,11–13].
- Photographic documentation
- Registration of type of shoe and/or orthosis (standard shoe, special diabetic shoe, orthopaedic corrective shoe, type of insole).
- Registration of type of mobilization (canes, crutches, wheelchair)
- Classification of the deformities in the following groups: Forefoot/isolated Hallux valgus; Forefoot/Hallux valgus & claw toes; Forefoot others; Midfoot/flatfoot; Midfoot/cavus foot; Midfoot others; Hindfoot/varus deformity; Hindfoot/valgus deformity. Hindfoot/Equinus; Hindfoot others. Other deformities comprised also combined deformities such as for example a combined equinus-varus-hindfoot deformity.

The analysis of the above mentioned parameters is only partly included in this manuscript. Instead, the following principle parameters were defined: amputation rate and location, rate or recurrent ulcer, type of mobilization (canes, crutches, wheelchair), type of shoe and/or orthosis (standard shoe, special diabetic shoe, orthopaedic corrective shoe, type of insole), AOFAS and VAS FA Score.

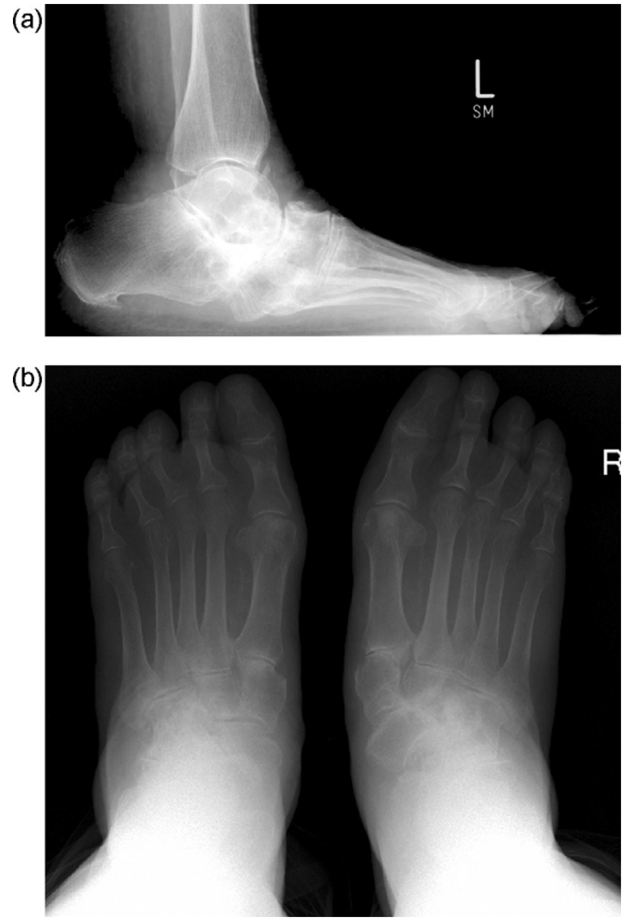

Fig. 1. Preoperative radiographs in standing position with full weight bearing showing a severe flatfoot (a, lateral view; b, dorsoplantar view). The ulcer was located in the centre of the foot sole (midfoot). This case was classified as Charcot-arthropathy Sanders/Frykberg 3, Eichenholtz 2, Wagner/Armstrong 3B, PEDIS 3.

2.2. Therapy

All patients underwent a four-stage regimen as follows:

2.2.1. Stage 1 (debridement)

Debridement with the goal to achieve a sterile situation and to remove all non vital tissue was performed. Vacuum Assisted Sealing (Vacuseal^{TM}, KCI, San Antonio, Texas, USA) followed. Intraoperative microbiologic specimens were obtained to specify the necessary antibiotic therapy. On the first postoperative day, a microbiologic specimen was taken from the Vacuseal system. The debridement was repeated after 6 days when the postoperative specimen from the Vacuseal system was not sterile. When the postoperative specimen from the Vacuseal system was not sterile after five repetitive debridements, and amputation with closure was performed as 6th surgical procedure (Amputation level see Section 3.5). In cases with amputation, a so-called functional amputation was performed (see Section 4). Nutrition consultation, review of the medication and necessary vascular examinations were performed parallel to the surgical procedures in phase 1. No weight bearing was allowed in phase 1. In cases with distal ulcer, a special orthosis that limited the loading to the heel was utilized. In cases with more proximal ulcers, mobilization with crutches if

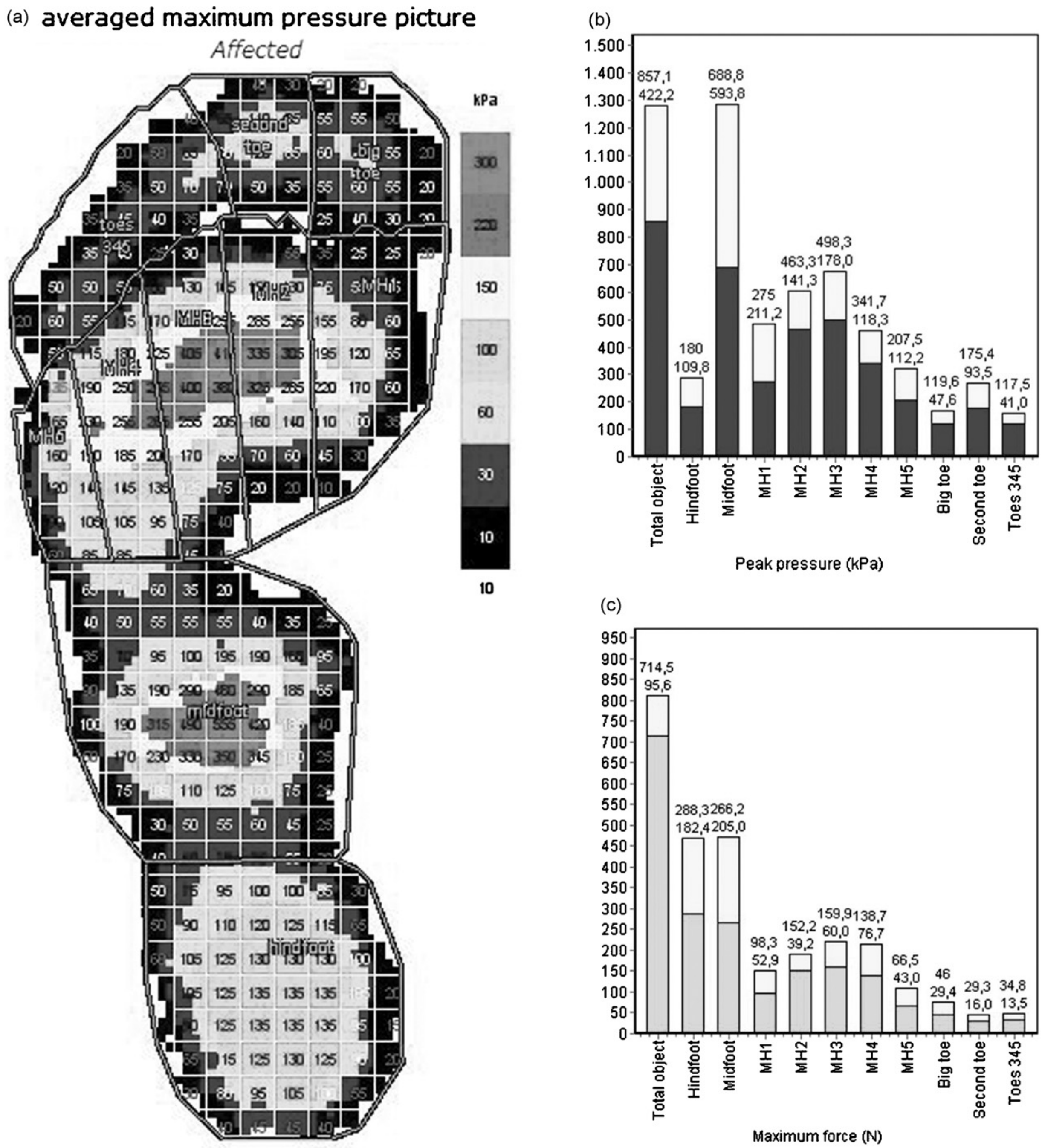

Fig. 2. Same patient as Fig. 1. Preoperative pedographic findings. Same patient as in Fig. 1. Massively increased contact area in the midfoot region (a) with very high maximum pressure (b) and high maximum force (c).

possible in the individual situation was performed. The mobilization in a wheelchair was performed to ensure complete unloading in the remaining cases.

2.2.2. Stage 2 (closure)

After achieving a sterile situation, closure was performed during the same hospital stay. A closure with sutures and not with granulation of open wounds was aspired. Secondary closure (sutures, not granulation) was the first choice, followed by local shifted skin graft, partly combined with meshgraft. If these options were not successful, functional amputation was considered for closure (Amputation level see Section 3, definition functional amputation see Section 4). Free vascular grafts were not utilized.

2.2.3. Stage 3 (unloading)

The closed ulcer was completely unloaded for 6 weeks. Different orthoses were used. In cases with distal ulcer, a special orthosis for loading limited to the heel was utilized. In cases with more proximal ulcers, mobilization with crutches if possible in the individual situation was performed. The mobilization in a wheelchair was performed to ensure complete unloading in the remaining cases.

2.2.4. Stage 4 (correction)

Relevant deformities such as flatfoot and cavus foot that were considered to increase the risk for repetitive ulcer were corrected with correction arthrodeses. Accommodative (not functional) orthoses were not tried before proceeding with surgical intervention. The postoperative management after the corrections

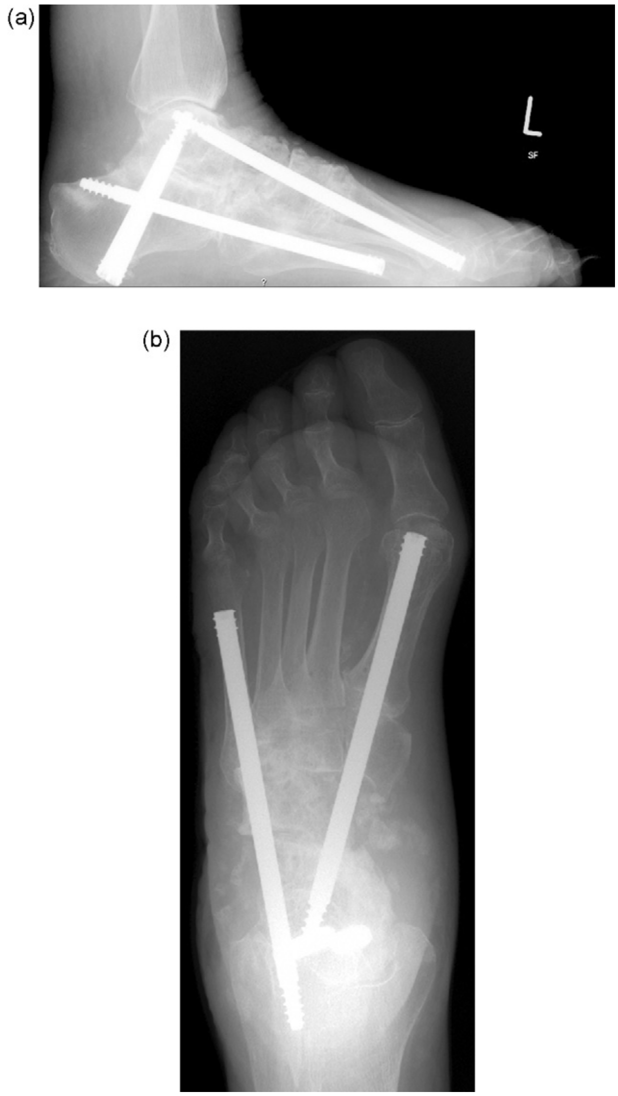

Fig. 3. Same patient as Figs. 1 and 2. Radiographs in standing position with full weight bearing of healed pan-correction-arthrodesis 3 months after completion of stage 4 (correction). Before, the stages 1–3 (Debridement, Closure, Unloading) had been completed (a, lateral view; b: dorsoplantar view).

included 15 kg partial weight bearing for at least 6 weeks if possible, and mobilization in a wheelchair if partial weight bearing was not possible.

The subjects were treated as inpatient during stages 1 and 2. During stages 3 and 4, the subjects were partly treated as inpatient until the wounds were completely healed. A treatment as outpatient followed for the remaining time of stages 3 and 4, and after stage 4. An evaluation including pedography was performed 3 months after the final corrective procedure and customized insoles and/or special diabetic shoes or orthopaedic corrective shoes were manufactured.

The parameters from study starting point and follow-up were compared with a *t*-test or a χ^2-test.

IRB approval from the local responsible ethical committee was obtained.

3. Results

335 patients entered stage 1 (mean age 64 years, 67% female). 306 (93%) were able to walk (220 (66%) without canes/crutches, 62 (19%) with one cane/crutch, 24 (7%) with two crutches). 29 (9%) could not walk and were mobilized in a wheelchair. Special shoe wear was present in 150 (45%) cases (Special diabetic shoes, n = 92 (27%); orthopaedic corrective shoes, n = 50 (15%)), and customized insoles in 181 (54%) cases. The scores were: AOFAS, 57 (26–92); VAS FA, 54 (17–90).

Table 1
Classification of the deformities.

Type of deformity	*n*	%
Forefoot/isolated hallux valgus	68	20
Forefoot/hallux valgus & claw toes	75	22
Forefoot others	27	8
Midfoot/flatfoot	53	16
Midfoot/cavus foot	25	7
Midfoot others	18	5
Hindfoot/varus deformity	25	7
Hindfoot/valgus deformity	38	11
Hindfoot/equinus	14	4
Hindfoot others	69	21
Combined	99	30

Table 1 shows the classification of the deformities. 99 feet (30%) were grouped in more than one group such as for example midfoot/flatfoot and forefoot/isolated Hallux valgus. 62 (21%) cases were classified as Charcot arthropathy. Table 2 indicates the location of the ulcers. Foot pulses were not palpable in 102 (30%) feet. From these, Doppler ultrasound did not detect pulses in 3 (1%) cases. In these patients a vascular surgeon was consulted who did not indicate vascular intervention such as percutaneous angioplasty or vascular surgery.

3.1. Stage 1 (debridement)

In 189 cases (56%), one debridement resulted in sterile postoperative specimens, in 63 (19%) two, in 31 (9%) three, in 26 (8%) four and in 18 (5%) five. In 8 (2%) cases, five debridements did not result in sterile postoperative specimens and amputation was performed (Amputation level see below).

3.2. Stage 2 (closure)

All 327 cases (98%) without amputation entered stage 2. 210 cases (63%) sustained secondary closure, 97 (29%) local shifted skin graft (20 (6%) combined with meshgraft), and 20 (6%) functional amputation (Amputation level see below).

3.3. Stage 3 (unloading)

304 (91%) finished stage 3, 14 (4%) presented with recurrent ulcer, and 9 (3%) did not finish stage 3 because of incompliance.

3.4. Stage 4 (correction)

In 185 cases (55%), correction arthrodeses were performed successfully (correction arthrodeses at ankle, n = 29 (9%); subtalar joint n = 33 (10%); midfoot/TMT, n = 98 (29%); others, n = 25 (7%)).

Table 2
Location of ulcers.

Ulcer location	*n*	%
Sole/total	259	77
Sole/hindfoot	14	4
Sole/midfoot	74	22
Sole/forefoot	171	51
Dorsum/total	50	15
Dorsum/excluding toes	12	4
Dorsum/toes	38	11
Multiple	26	8

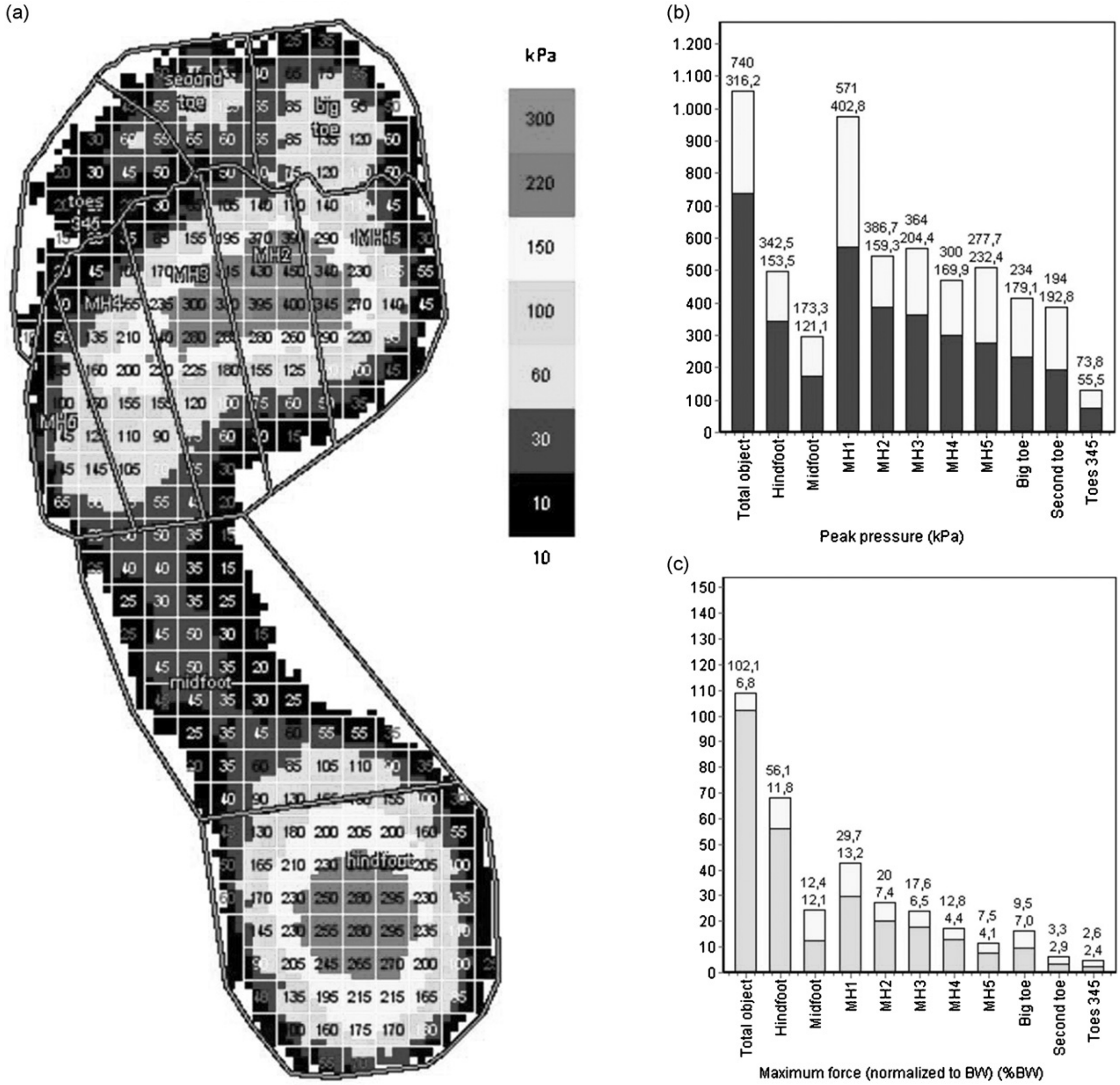

Fig. 4. Same patient as Figs. 1–3. Pedographic findings 3 months after completion of stage 4. 3 months postoperative. Minimal increase of the contact area in the midfoot region (a) with low maximum pressure (b) and low maximum force (c). Increased maximum pressure and force in the region of 1st metatarsal head and 1st toe but no ulcer in this region.

107 (32%) were not treated with correction arthrodeses but with shoes and insoles, and 13 (4%) received amputation (Amputation level see below).

3.5. Follow-up

300 (90%) completed follow-up at mean of 26 (12–48) months. In 46 (15%), recurrent ulcer was registered. Overall amputation rate was 14%, the majority at digital or midfoot level. Four cases (1%) required a below-knee amputation (Amputation level: lower leg, $n = 4$ (1%); midfoot/TMT, $n = 8$ (3%); transmetatarsal, $n = 5$ (2%); toes, $n = 26$ (9%)). 295 (98%) cases were able to walk (201 (86%) without canes/crutches, 37 (12%) with one cane/crutch, 19 (6%) with two crutches). 5 (2%) cases could not walk and were mobilized in a wheelchair. Special shoe wear was present in 293 (98%) cases (Special diabetic shoe, $n = 255$ (85%); orthopaedic corrective shoe, $n = 40$ (13%)), and customized insoles in 293 (98%) cases. A lower leg prosthesis was customized in 4 (1%) cases.

The scores were as follows, AOFAS, 85 (38–98); VAS FA 86 (34–100). The percentages of walking ability, and equipment with special diabetic shoes and customized insoles increased significantly from starting point to follow-up (χ^2-test, $p < .05$). The percentage of cane/crutch usage, and equipment with orthopaedic corrective shoes did not change significantly (χ^2-test, $p > .05$). The scores did significantly improve (*t*-test, $p < .05$).

4. Discussion

The main principles of the therapy of the diabetic foot are an optimization of the metabolism, controlling of infections, revascularization, corrective surgical procedures and optimal shoe/insole supply [1–5,14]. It has been estimated that amputations could be reduced 75% (or to less than 500,000) worldwide if everyone followed optimal treatment protocols [3,4]. In many cases, foot deformities as one important factor causing foot ulcers are present [3–5]. As in non-diabetic patients, deformities in adults are only correctable by surgical procedures and never with orthosis, casts or shoes [5,9,15,16]. Considering the literature and our own experience, we do mention the importance of a complete analysis including pedography with gait analysis, neurological and vascular assessment [5,17–21]. The rate of vascular intervention on our patient cohort was very low (1%). We think that this low rate is caused by a selection of neuropathic type diabetic feet. This selection could be caused by the diagnostic and treatment strategies that are effective for the entire medical community in our and other countries. Patients with vascular problems (no matter if diabetes and/or foot deformities are existing or not) are transferred to vascular specialists/surgeons. These vascular specialists/surgeons treat the vascular problems usually by themselves, and often until amputation has finally been done. Therefore, these patients do not reach the foot and ankle specialist/surgeon at all. In contrast, the neuropathic type is not primarily transferred to vascular specialists/surgeons, and has a chance to reach a foot and ankle specialist/surgeon before amputation.

4.1. Why four stages?

The introduced operative four-stage regimen is doubtless a very complex and expensive management. Of course, this is not the only option to manage these difficult and complex cases. We are aware that this management with long-term inpatient treatment is not really practicable in regions without or only private healthcare. This regimen was developed based on the high ulcer recurrence rate (20–65%) and major amputation rate (3–21%) of more simple regimens from the literature and our own earlier experience [1,2,6,14,19,22–27]. One could argue that cases without severe or missing infection could be easier and as successfully treated with a single-stage-procedure. We see the problem that it is never sure if there is really no contamination or even infection. Missing signs of infection are not a guarantee that no bacteria are there. Since we did not know how to identify the complicated cases from the non complicated cases, we utilized the same regimen for all cases. Another argument is that an infection after a single-stage-procedure would be much worse to deal with than to start the described four-stage-regimen. One could further argue that the long time as inpatient put the patients at high risk for acquired infection which is without any doubt a risk for every kind of inpatient treatment. However, this was not observed in our study. Our results showed positive cultures in 44% during the first surgical procedure, which decreased to 2% during the fifth debridement. In contrast, we did not register new positive cultures during the surgical closure which followed the previous debridement without positive culture which would signify an acquired infection.

In short summery, we could achieve a major amputation rate of 1% and recurrent ulcers in 16% during a sufficient follow-up time of two years on average which is superior to the results in the literature [9,10,19,22,23,26–31]. Regarding the cost, it is important to mention that above all a low rate of major amputation is decisive [1,4,5,32]. It is medical knowledge that major amputations are responsible for highest cost by far during the clinical course [1,4,32]. The calculation of the cost of our regimen is difficult to calculate, and there is no data for comparison, but we suspect the low major amputation rate would provide lower cost than with other strategies. Again, what is known, is the high cost of recurrent ulcer and especially major amputations, which is independent of the environment [2,32,33]. The effect of the single stages on the outcome is not known. We feel that the combination of all stages might be the reason for the success. When we would have to decide which is the most important detail of the regimen, we would clearly state that the successful correction of the deformity would be the key to avoid recurrent ulcer and amputation.

4.2. Stage 1 (debridement)

The vacuum-assisted wound conditioning has massively simplified and improved the wound management [5,28,34,35]. This therapy has been proven to be superior regarding heeling rate and cost effectiveness regarding other methods [33,36,37]. For example, Flack et al. demonstrated improved healing rates (61% versus 59%), and an overall lower cost of care ($52,830 versus $61,757 per person) for patients treated with VAC therapy compared with advanced dressings. However, it is very important to mention that the vacuum-assisted wound closure is not effective alone but an effective debridement is the main factor [5,28,34,35]. Therefore, tendencies to delegate the vacuum-assisted wound management to non-surgical personnel such as wound nurses are not useful because the debridement is not performed but only repetitive wound sealing like a simple dressing exchange [5,28,34,35]. Again, the decisive factor is the surgical debridement and not one or another dressing technique no matter how sophisticated this technique could be [5]. Consequently, the wound management belongs to surgical hands [1,5,10,22,25–29,34,35].

4.3. Stage 2 (closure)

Local measures like secondary closure or local flaps were utilized [10,28,34,35]. Free vascularized flaps were not used due to the risk profile of the patients [10,28,34,35]. Meshgraft was, based on its vulnerability, especially used to cover the lifting defects from locally shifted flaps.

4.4. Stage 3 (unloading)

Why was the correction not performed directly after stage 2 but a relatively long time with complete unloading interpolated? The reason for stage 3 was the supposed increased safety especially regarding sterility before the correction [5,38]. The long period of 6 weeks is problematic in cases with limited compliance because many patients do not even realize the importance of shoe/insole supplement or even a correction when the ulcer is healed [5]. We lost 3% of patients in this stage which is a favourably low rate. Though, the patients were excessively informed about the importance of stage 4 before entering stage one, and this information was repeated at any contacts. Another potential problem is the questionable compliance of the complete unloading [5]. We observed 4% recurrent ulcers within the unloading stage and interpret this as evidence for not completely unloading [5]. The compliance, information and guidance play an important role [5]. The patients with recurrent ulcer entered again stage 1 representing an enormous effort. We considered starting with stage 1 again to be a better option than performing a surgical correction in a patient with questionable compliance regarding the ability to perform limited weight bearing.

4.5. Stage 4 (correction)

Relevant deformities such as flatfoot and cavus foot that were considered to increase the risk for repetitive ulcer were corrected with correction arthrodeses [9]. We did not consider accommodative (not functional) orthoses as alternative for corrective surgery due to our extensive experience with failed recurrent ulcer in this type of orthosis. Based on this experience our first choice is clearly corrective surgery. For the corrective surgeries, methods like computer assisted surgery, intraoperative three-dimensional imaging, and intraoperative pedography were utilized if they were considered to be useful [39–41]. The goal of all corrections was a plantigrade and loadable foot with even force and pressure

Fig. 5. Ulcer at the stump after amputation at a different institution. (a) shows a lateral view in standing position with full weight bearing with equinus deformity and deeply placed cuboid with ulcer below. b (lateral view) and c (anteroposterior view) are radiographs in standing position with full weight bearing 3 months after functional amputation (stage 1), closure (stage 2), unloading (stage 3) and hindfoot correction arthrodesis (stage 4) with physiological load on the posterior calcaneal process.

distribution [5,9,16]. Thereby, the ambulation which is important for an optimized metabolism, and prevention of recurrent ulcer should be reached at best [1–5,16]. Meanwhile, corrections of deformities after amputations have unfortunately developed to one of our specialties. This manifests that an amputation alone without consideration of the later function is not successful [1,5,27]. In all cases with necessary amputation, we do not perform anymore an amputation strictly limited to the region of minor vascular supply but a so-called functional amputation [5,27]. This means that also "healthy" tissue is removed to achieve optimal function (functional amputation) and not a minimal amount of tissue [5,27]. Amputations have sometimes to be combined with a correction (arthrodesis) to achieve an optimal, safe and reliable function (for example see Fig. 5, hindfoot correction arthrodesis after midfoot/Chopart amputation) [5,27].

An optimal shoe/insole is a very important factor within the management. As part of stage four, we recommended a customized diabetic shoe with insole, and we increased the rate of this kind of shoe equipment from 45% to 98%. A specialized shoe- and insole maker is part of our team, and all shoes and insoles are customized based on pedography.

In our opinion, the wound management belongs to surgical hands. It is our great concern to convey that deformities in adults could only be corrected with surgical procedures and that amputations should consider an optimal later function. Consequently, the combination of amputation and correction is often the optimal solution.

We are aware of the following shortcomings of our study: missing control group, short follow-up time, extreme nonuniform cohort with different ulcer and deformity location, and usage of non-validated AOFAS score. Regarding the missing control group, we feel that it would be extremely difficult if not impossible to form groups with different types of intervention. The management of these very complex situations is very complex with just one group, and we felt that we would not be able to handle this with different types of treatment. The follow-up time is short but 90% follow-up with more than 2 years on average was found to be sufficient for a first report. The same is our opinion regarding the large cohort of nonuniform ulcer and deformity locations. This is a first report about this management algorithm, and we felt that breaking up this into different groups, for example with/without Charcot foot might be the next step after defining a kind of baseline with the entire cohort. The AOFAS score is under debate due to its missing validation. Even the AOFAS concludes that this score should not be used as single outcome measurement [42]. However, the AOFAS score is still the most common score, and we decided to use it to give at least some kind of comparability with other publications. Still, our main and more important outcome measurement is the validated VAS FA score, and we would like to put the focus on the results of this score [11,13].

In conclusion, 300 patients completed follow-up after the introduced operative four-stage regimen (debridement, closure, unloading, correction) for treatment of diabetic foot ulcer with deformity in 335 patients. 185 correction arthrodeses were performed (stage 4). The rate of major amputations (1%) and recurrent ulcers (15%) during a sufficient follow-up time of more than two years on average was very low. The rate of walking ability improved from 93% to 98%. We consider an optimal shoe and insole as an important factor as the increased rate from 45% to 98% customized shoe/insole equipment shows.

Conflict of interest statement

None of the authors or the authors' institution received funding in relation to this study.

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