Recurrent diabetic foot ulcers: results of a maximal multidisciplinary approach including reconstructive foot/ankle surgery

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ORIGINAL ARTICLE

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Recurrent diabetic foot ulcers: Results of a maximal multidisciplinary approach including reconstructive foot/ankle surgery

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Abstract

The diabetic foot ulcer (DFU) and Charcot Neuroarthropathy (CN) are serious complications of diabetes mellitus in which wound closure is complex to achieve. Treating recurrent DFU in patients with a combination of infection, ischemia, and deformities is extremely challenging and this group of patients has a very poor outcome. This case series describes the outcomes of patients with a recurrent DFU and CN, with a mean SINBAD score of 4 and of which 40% had a TCS of D3, using a multidisciplinary protocol that includes reconstructive foot and ankle surgery. In 24/35 (69%) of patients, wound closure was achieved after a mean of 75 days postoperatively. The mean ulcer-free period was 358 days. The mean number of interventions was 6.7 (range 3–9). Post treatment 27/35 (77%) of patients was mobile, without additional amputation or ulcer recurrence. This study shows that wound closure and a long ulcer-free period can be achieved in patients with a DFU and CN and its multifactorial underlying diseases when treated in a multidisciplinary team, including reconstructive foot and ankle surgery.

KEYWORDS

diabetic foot ulcer, multidisciplinary team, reconstructive surgery, recurrence, wound healing

Key Messages

- the complex diabetic foot (ulcers) should always be treated by an extended multidisciplinary team
- in addition to the participants of a multidisciplinary team advised in the IWGDF guideline, this study demonstrates the need for the presence of a specialist foot/ankle surgeon in the diabetic foot team, who is proficient in

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specific techniques regarding CN (super construct) and DFU in addition to the standard techniques
- when the multifactorial pathology associated with a DFU is optimized, it is safe to apply reconstructive foot and ankle surgery

1 | INTRODUCTION

The diabetic foot ulcer (DFU) is a serious complication of diabetes mellitus (DM). In Western countries, the incidence of foot ulcers is between 2% and 4%.[1,2] The lifetime incidence of foot ulcers in diabetic patients is between 19%–34%.[3] The 5-year mortality risk in patients with DFU is 2.5 times increased compared to patients without DFU.[4] A DFU has a major impact on physical functioning, morbidity, and costs.[5,6] For example, the costs of diabetic foot care in the United Kingdom exceed the combined costs of lung, prostate, and breast cancer.[7] The morbidity is partially defined by ischemia which is present in 49% of these patients and 58% of DFU become infected.[8] The risk of recurrent DFU is high with a 40% recurrence rate within 1 year and approximately 60% within 3 years.[3] A DFU is often complicated by peripheral neuropathy, which is a major risk factor for developing a Charcot neuroarthropathy of the foot and/or ankle (CN).[9] CN is a serious and potentially limb-threatening lower-extremity complication.[10] The reported prevalence of CN varies from 0.1% to 0.4%.[11-13] The deformities caused by CN often lead to DFU. Because of the heterogeneity and characteristics of patients with this pathology, no standard treatment protocol is available. Reconstructive foot/ankle surgery (RFS) to better distribute plantar pressure is required in case of an unstable CN. CN is considered unstable when the foot cannot be repositioned by total contact cast and orthopaedic shoes or a foot has a Meary's angle of more than 27°.[14] The concept of a "super construct" is used as a technique in the Alrijne Wound Centre (AWC), Alrijne Hospital, The Netherlands, to stabilise the Charcot foot.[15] Furthermore, RFS is also an option for diabetic patients with a neuropathic plantar metatarsal head ulcer. In which case, an Achilles tendon lengthening (ATL), metatarsal head resection(s), or joint arthroplasty to promote healing of the ulcer can be considered.[16] Treating recurrent DFU in patients with a combination of infection, ischemia, and deformities is extremely challenging.[4,17-19] Patients with this combination have a 6.02-fold (SINBAD 5) and a 78.5-fold (SINBAD 6) risk of a lower extremity amputation (LEA) compared to those with a low-grade ulcer (defined as SINBAD 1–2).[20] The major factors that must be properly diagnosed and (if possible) treated to achieve wound healing are peripheral neuropathy, foot deformities, and peripheral artery disease.[3,21] In addition, glycaemic control and treatment of infection are essential.[22,23] Given these multiple components, a multidisciplinary team is conditional to treat DFU's successfully.[24-26] In addition, RFS is essential for prevention of recurrent DFU.[27]

The AWC specialises in triage, diagnosis, and treatment of complex wounds.[28] Since 2019, the diabetic foot multidisciplinary team (DFMT) has expanded to 11 different specialists. Specialised and dedicated Wound Physicians (WP) are overall supervisor (Figure 1). The approach to treat the DFU is based on optimisation of 4 key factors (Figure 2) Hyperglycaemia, Infection (including osteomyelitis), Pressure and Arterial blood flow (HIPA). Patients are all registered and triaged using the WIFi score, SINBAD, Texas Classification Score (TCS), and the infection score of the International Working Group on the Diabetic Foot (IWDF).[17,23,29,30]

This case series describes the treatment outcomes of patients with recurrent DFU using a multidisciplinary protocol that includes maximal glycaemic control, arterial analysis and revascularisation, treatment of infection and pressure offloading. The focus of this article will be on the group of patients where foot deformities were surgically corrected (RFS).

2 | METHODS

All patients that were treated in the AWC without adequate healing tendency or with recurrent DFU despite adequate baseline therapy in the period from November 2019 to May 2021 were included. The indication for RFS in the described group of patients was a SINBAD score higher than three with a recurrent ulcer or an unstable CN.

Patient characteristics, ulcer scores, interventions and main outcomes, such as complete healing of the foot and the ulcer free period (UFP) are reported. The following interventions were scored as separate intervention: ATL/Proximal Medial Gatrocnemius Release (PMGR), other foot correction (besides a primary amputation and/or ATL), revascularisation, primary amputation (reconstruction of the metatarsals), glucose regulation optimisation, antibiotics (intravenous or oral), total contact cast (TCC), use of an orthopaedic shoe or custom made foot orthoses, hospitalisation, hyperbaric oxygen therapy (HBOT), minor amputation (defined as amputation at the level of ankle joint and below) and major

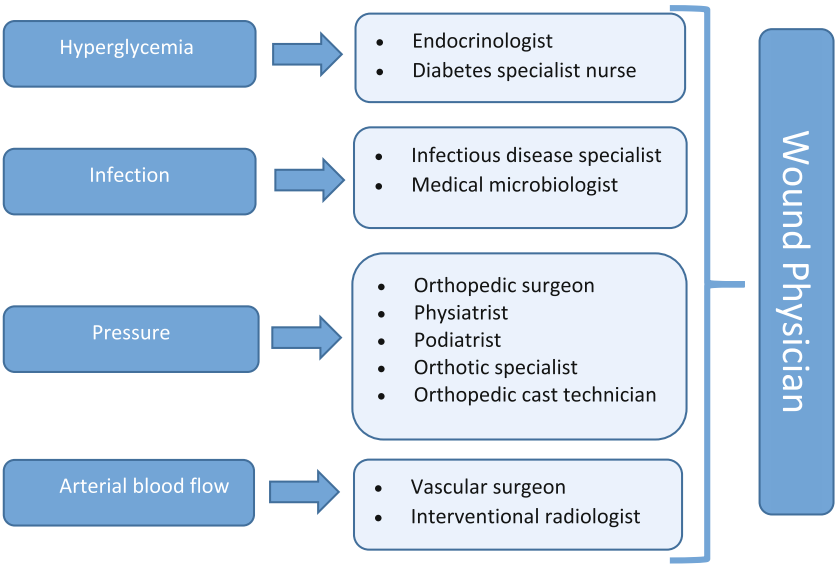

FIGURE 1 "HIPA" addressed by the Alrijne diabetic foot multidisciplinary team (DFMT)

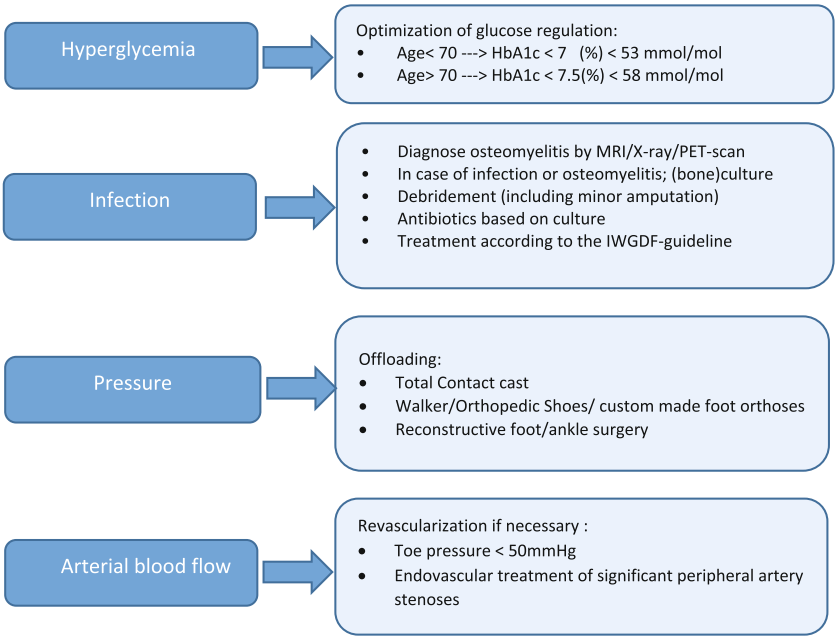

FIGURE 2 Basic protocol Alrijne Diabetic Foot Multidisciplinary Team (HIPA)

amputation, (defined as amputation above the ankle joint). The outcome was considered a success if the patient was mobile with an orthopaedic shoe, without having a recurrent ulcer or an amputation. Failure was registered when a recurrent ulcer occurred, if recurrent complaints were reported, such as pain or in case of failure of the reconstructive surgery.

2.1 | Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS®, Version 24, IBM Corporation, Armonk, New York).

This study was conducted under a protocol reviewed and approved by the Institutional Review Board and Medical Ethical Committee of Alrijne Hospital, the Netherlands (NWMO 21.289yw.tk). All patients consented to the use of their images for this publication.

3 | RESULTS

Between November 2019 and May 2021, 1475 unique patients were diagnosed and treated in the AWC. 29.2% (431/1475) of these patients were classified as having an DFU. In this period, 28.3% (122/431) of the patients were discussed by DFMT (Figure 3).

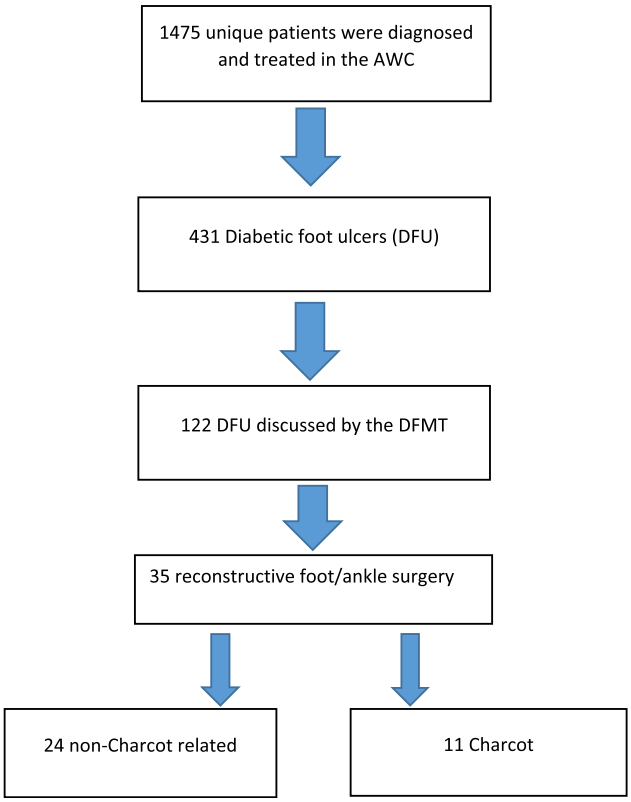

FIGURE 3 Patients treated in AWC between November 2019 and May 2021

In the study period, RFS was performed in 35 patients. The basic characteristics are shown in Table 1. This group had been diagnosed with DM for an average of 21 years. 28/35 (80%) of patients were male. 11/35 (31%) of patients were diagnosed with a Charcot foot, using x-ray, MRI-scan and, if needed, a PET-CT NaF scan.

Patients had an average duration of complaints of 877 days (DFU/unstable CN) before RFS was performed. The mean SINBAD score was 3.95 (range 1–6). 14/35 and 40% of patients had the highest TCS score (3D range 0A-3D). The estimated risk of amputation at 1 year (WIFI) was high (stage 4 on a scale of 1–4) in 20/35 (57%), and the mean WIFi-score was 2.94.

In total, 9 different types of RFS were identified in 35 patients of the 122 patients discussed by the DFMT.

Table 2 shows all interventions in this group of 35 patients, including the RFS. The mean number of interventions per patient was 6.7 (range 3–9). The minimum amount of interventions in one patient was three. The other 34 patients underwent at least five interventions (Table 2). Figure 4 shows the most notable interventions in a Venn diagram. Appendix S1 shows all indications per patient, as well as the basic characteristics per patient, including a more detailed description of the different types of RFS. The majority of the indications for

TABLE 1 (Mean) Basic characteristics

Total	***n* = 35**
Mean age (years)	67
Male	28 (80%)
DM II (vs DM I)	33 (94.3%)
PAOD (toe pressure <50 mmHg)	14 (40%)
Osteomyelitis	17 (49%)
Mean duration of complaints (days)	877 (range 70–4015)
Mean body mass index	30.2
Mean HbA1C (mmol/mol)	59.7
Mean duration of DM (years)	21
Mean SINBAD score	3.95
Texas classification system: score D3	14 (40%)
WIFI classification: High	20 (57%)
Charcot-pathology: yes	11 (31%)
No wound preoperatively (unstable Charcot)	6 (20)

Note: BMI, kg/m^2; SINBAD classification, site, ischemia, neuropathy, bacterial infection, and depth; Texas classification system, depth, infection, and ischemia to risk of amputation; WIFI, wound, ischemia, and wound infection.

TABLE 2 The reconstructive foot/ankle interventions and all basic interventions as discussed by the DFMT

Interventions	**N**	**Percentage**
• Reconstructive foot/ankle surgery	55/35	
• ATL/PMGR		23/35 (66%)
• Primary amputations		10/35 (29%)
• Foot corrections beside a primary amputation and ATL		22/35 (63%)
• Revascularisations	12	12/35 (34%)
• Glucose regulation optimisation	31	31/35 (89%)
• Antibiotics (Intravenous or Oral)	34	34/35 (97%)
• Total contact cast	33	33/35 (94%)
• Orthopaedic shoe (post-wound healing)	35	35/35 (100%)
• Hospitalisation	30	30/35 (86%)
• Hyperbaric oxygen therapy	5	5/35 (14%)
Total	235	
Mean number of interventions	6.7 (3–9)	

RFS were "Recurrent plantar ulcer at equinus after transmetatarsal (TMT) amputation" together with "Charcot arthropathy ankle or the midfoot," respectively, 10/35

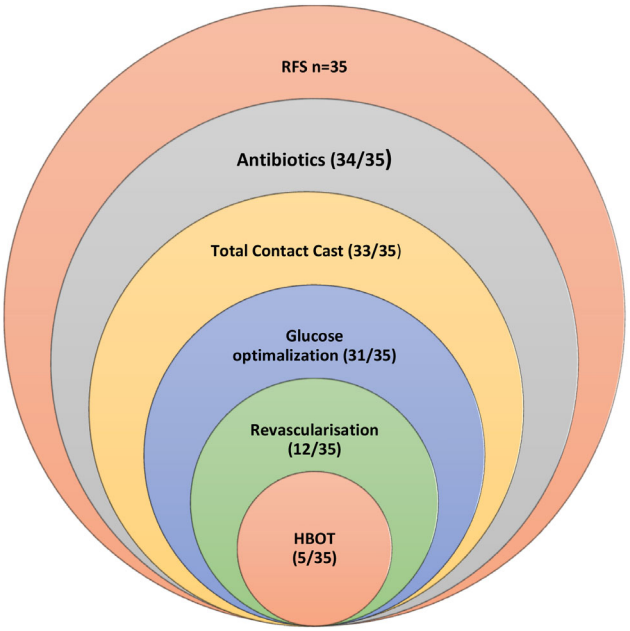

FIGURE 4 Diagram of the most notable interventions performed. RFS, reconstructive foot and ankle surgery

TABLE 3 Postoperative outcomes undergoing reconstructive foot/ankle surgery support with maximal multidisciplinary treatment

Total	$N = 35$	Range
Mean follow-up (days)	374 ($n = 35$)	136–1361
Time until closure (days)	75 ($n = 24$)	0–322
Mean ulcer-free days (days)	358 ($n = 30$)	44–1361
Recurrence	3/30 (10%)	
Amputation after correction	5/35 (14%)	
Success rate	27/35 (77%)	
30 day mortality	0	
Mortality in follow-up	4/35 (11%)	12–28 months

(29%) and 8/35 (23%). 23/35 (66%) of the RFS included a PMGR or ATL (Table 2, Appendix S2).

Table 3 shows the main outcomes. The overall success rate was 77% (27/35). 6/35 (20%) of the patients did not have an ulcer preoperatively, and their inclusion in this study was based on the presence of unstable Charcot pathology requiring RFS. In 24/29 (83%) of patients with a wound preoperatively, wound closure was achieved with a mean of 75 days after surgery (range 0–322 days). The mean ulcer-free period was 358 days (range 44–1361). 97% (34/35) had a minimal follow-up period of 120 days. The mean follow-up was 374 days (range 136–1361). 2/35 (5.7%) had minor amputation and 3/35 (8.6%) had a major amputation after reconstructive surgery. Of the five amputations after RFS, three were major amputations; the AKA was performed 3 months after an ATL in a patient with a CN, in which the Charcot instability could not be corrected. The initial advise was a BKA, but this was not accepted by the patient, after the complications of the Charcot reconstruction an AKA was inevitable. The first BKA was performed 3 weeks after the reconstructive foot/ankle interventions and revascularisation. The postoperative period was complicated by failure of the arterial intervention and subsequent critical ischemia. The second BKA was performed because of an osteosynthesis-associated infection, 4 months after panarthrodesis of the lower and upper tarsal joint (Charcot of the ankle). Two minor amputations were performed; one transmetatarsal amputation and one amputation of the second toe after hallux valgus correction, both followed by complete wound healing without recurrence. 3/30 (10%) patients experienced a recurrence of the ulcer or the ulcer persisted. In these patients, one did not use the orthopaedic shoes after intervention, the second refused to complete the treatment, including the planned second reconstructive intervention, the cause of the third recurrence remained undefined.

The mortality during or after the interventions was zero. During follow-up, 4/35 (11%) patients died between 12 and 28 months after the reconstructive surgery; these deaths were not related to the interventions.

In this study, 10 types of RFS were analysed (Appendix S2). In 23/35 (66%) of the patients, an ATL was performed. In addition to the ATL and the reconstruction of the metatarsals (primary amputations), a reconstructive intervention was also performed in 22/35 (63%). 14/35 (40%) of the patients were diagnosed with underlying arterial insufficiency. Revascularisation was attempted in all patients, which was successful in 12/14 (86%). 2/14 of the endovascular revascularisations were unsuccessful. These were patients with below the ankle arterial insufficiency. 31/35 (89%) of this group, glucose regulation was improved through either a change in medication or better monitoring. 34/35 (97%) of the patients received systemic antibiotic therapy of which 25/34 (74%) of patients were treated with intravenous antibiotics first. Orthopaedic footwear was custom made for each patient.

4 | DISCUSSION

This case series describes DFU and CN patients with extensive pathology. This population (with a mean WIFi-score of 2.9 and mean SINBAD score of 3.9) has a high risk of complications and amputation in the first year of having an ulcer.[29-31] Patients in clinical WIFi stages 3 and 4 have a significantly higher incidence of amputation, decreased amputation-free survival (AFS) and

delayed time to wound closure compared with those in WIFi stages 1 and 2.[32] Patients with moderate-grade ulcers SINBAD 3–4, or high-grade ulcers, SINBAD 5–6, are respectively 6.02- and 78.5-fold more likely to undergo an LEA compared to those with low-grade ulcers (SINBAD 1–2).[20] For patients with an unstable CN, the classification models such as SINBAD and WIFi do not always cover all the relevant facets of the diabetic foot. Treating this patient group is challenging even without the presence of wounds or arterial insufficiency. Patients with CN developing an ulcer have a 12 times higher risk of amputation.[33] 9/10 (90%) patients undergoing Charcot reconstructions eventually were able to mobilise on appropriate orthopaedic footwear during follow-up. This suggest that a reconstructive intervention in CN is indicated to prevent ulcers and eventually amputations.

The long duration of complaints (877 days) and the high number of interventions (mean 6.7) indicate the high complexity of this group. As compared to Guest et al where 130 patients were described with a newly diagnosed DFU, 35% healed within 12 months and the mean time to heal was 134 days (4.4 months),[34] and our data appears favourable. Although the follow-up is still short, the average ulcer-free period of 358 days, without recurrence, is interesting compared to the estimated 40% annual recurrence reported by Armstrong et al[3]

Only 3/35 patients underwent a major amputation, of which in one, the indication LEA was already advised by several DFMT meetings, before the RFS was performed. Due to the high complexity, and the high likelihood of an LEA according to the literature,[20,29-32] this is also a remarkable outcome.

The mean HbA1C was above 59 mmol/mol, and this is considerably higher than the reference value of 42 mmol/mol. Although there is still limited literature on the influence of dysregulated glucose levels on wound healing, this study suggests that optimisation of the glucose level is an important factor in the management of this population.[34-36] Armstrong et al described an odd-ratio of 4.1 related to a glycated haemoglobin >7.5 (HbA1C > 58 mmol/mol).[3,38] This emphasises the vital role of an endocrinologist as a member within the DFMT.

Our results support the importance of a multidisciplinary approach to treat the complex diabetic foot (HIPA). In addition to the participants of a multidisciplinary team advised in the IWGDF guideline[15] (endocrinologist, surgeon (general orthopaedic, or foot), vascular specialist (for endovascular and open revascularisation), infectious disease specialist or clinical microbiologist, podiatrist and diabetes nurse, in collaboration with orthoptist specialist), this study demonstrates the need for the presence of a specialist foot/ankle surgeon in the diabetic foot team, who is proficient in specific techniques regarding CN (super construct)[37] and DFU in addition to the standard techniques. Unfortunately, as described, there were also 8/35 (23%) failures (3 recurrences and 5 amputations). These failures have given us new insights. For example, in RFS and revascularisation, it is better to opt for the most optimal, maximal possible treatment to gain the best result.

One major limitation of the current analysis is the study design. This article describes case histories and has no statistical significant outcomes. The results cannot be compared with a control group. However, there is sufficient literature in which the results of this complex group can be compared, if not with scientific significance. Secondly, we are aware of a limited follow-up. This group is, therefore, being followed extensively and intensively in order to be able to say more about the results in the coming years. But although the follow-up is short, a positive trend is seen. In addition, this population has multiple underlying pathological factors, making interventions difficult to analyse. Thirdly, there is a selection bias; the 35 patients that have been analysed are the patients who have undergone reconstructive for/ankle surgery. These patients were deemed eligible candidates for RFS as others were not. There is little to no literature or consensus on the indication for RFS. The question of whether the risk of postoperative complication outweighs the benefit of the reduced risk of recurrence is still unanswered. Therefore, more research is needed to develop protocolled decision-making.

Despite the lack of statistical significance and the enormous workload because of the extensive multidisciplinary effort with a mean number of intervention of 6.7, the authors believe encouraged to continue the described approach.

Sharing our data may have a positive effect on the future treatment of the patients with a DFU and CN. Follow-up and cost-effectiveness research should be the next step.

5 | CONCLUSION

This case series shows that patients with recurrent DFU and CN, suffering of multiple underlying factors, can achieve wound closure and a long ulcer-free period, when treated in a multidisciplinary and a multi-interventional setting.

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DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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