



# A Randomized Trial Comparing Weekly With Every Second Week Sharp Debridement in People With Diabetes-Related Foot Ulcers Shows Similar Healing Outcomes: Potential Benefit to Resource Utilization

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Current guidelines strongly recommend regular, sharp debridement of diabetes-related foot ulcers (DFU) when blood flow is adequate (1). Sharp debridement disrupts biofilm and removes nonviable tissue, callus, and senescent cells, preparing the wound for endogenous healing (2) and advanced wound-healing therapies (3). Despite a reported association of more frequent debridement with improved healing outcomes (4), published prospective, randomized studies to inform optimal debridement frequency are absent, and existing evidence is rated as low (1).

A prospective, multicenter intervention study was conducted to determine the effect of sharp debridement frequency on healing outcomes in participants with DFU, randomized to weekly debridement or every second week debridement.

Adults with diabetes and a plantar neuropathic foot ulcer of  $\geq 2$  weeks' duration and  $\geq 0.5$ – $10$  cm<sup>2</sup> in size were included. Exclusion criteria were nonhealing despite  $\geq 6$  months of treatment, moderate or severe ischemia, moderate

or severe infection, nonplantar location, and/or inability to follow the protocol, including weekly visits.

Computer-generated, block randomization, 1:1 to either weekly or every second week debridement, with stratification factors of treatment center and DFU size ( $< 3$  cm<sup>2</sup> or  $\geq 3$  cm<sup>2</sup>), was used. A participant sample size of 120 was sought, with 85% power to detect a between-group 30% healing difference at 12 weeks, allowing for a 20% study dropout.

All study sites adhered to a state-approved model of care for interdisciplinary high-risk foot services (5) and documented treatment standards: pressure offloading using removable knee-high or ankle-high devices both with rocker soles and insoles (standardized), oral antibiotics when indicated, dressings (excluding those that debride), and systemic diabetes care. The debridement method was removal of nonviable tissue from the wound base and periphery using scalpel, curette, and forceps. Self-reported

adherence to wearing the offloading devices was recorded as the percentage of waking hours that the device was worn. All participants attended weekly.

Digital images were taken at baseline, 4 weeks, and 12 weeks or when the treating clinician deemed the ulcer had healed (whichever came first). Healing was defined as complete epithelialization of the wound with no exudate that would require dressing. All digital images were assessed by two independent wound experts, blinded to treatment allocation. Healing outcomes were recorded in the medical record by treating clinicians and reported as a site-assessed healing outcome. The predefined secondary outcome measures of percentage of wound area reduction at weeks 4 and 12 were calculated from real-time wound tracings.

A statistical analysis plan was developed prior to any data unblinding, and comparisons of primary and secondary outcomes between groups were analyzed according to the principle of intention to

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treat. All comparisons were two-sided together with corresponding 95% CI, and *P* values of <0.05 were considered statistically significant.

The study protocol was registered on the Australian New Zealand Clinical Trials Registry (<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=367998>) and approved by the Royal Prince Alfred Hospital ethics committee (X14-0184&HREC/14/RPAH/242) as the lead site, with local-site governance approval at each participating center.

In total, 122 participants (*n* = 61 per group) were recruited between October 2015 and September 2019 from seven treatment sites. Between-group participant and wound baseline characteristics were well matched (Table 1). Thirteen (11%) participants dropped out of the study with no outcome data for analysis (*n* = 3 in the weekly and *n* = 10 in the every second week debridement group). Overall, 75.4% (*n* = 92) completed each protocol. Digital images were available for assessment for only *n* = 78 participants.

Using a modified intent-to-treat analysis excluding participants whose healing outcome was not known, 53% (*n* = 24/45) in the weekly group and 52% (*n* = 17/33) in the every second week group healed by 12 weeks (mean difference 1.8%, 95% CI −16.3–20.0%, *P* = 0.84), according to assessment of digital images. Using clinician, site-assessed outcomes, 52% (*n* = 30/58) healed in the weekly and 45% (*n* = 23/51) in the every second week group (mean difference 6.6%, 95% CI −7.9–21.1%, *P* = 0.37). The secondary outcome of percentage of wound area reduction at week 12 showed a nonsignificant higher clinical closure rate (80.6% vs. 65.6%) in the more frequently debrided group (mean difference 15%, 95% CI −11.6–41.7%, *P* = 0.27). No on-study amputations occurred.

Study strengths include its pragmatic design with representative patients receiving contemporary management. Study limitations include use of removable pressure-offloading devices (Table 1); however, use of irremovable devices would have limited recruitment only to participants able to accept and use such methods.

Sharp debridement is optimally provided by skilled clinicians in the multidisciplinary setting, necessitating recurrent

**Table 1—Baseline characteristics by randomized treatment group to weekly or every second week debridement**

Parameter	Value by debridement frequency group	
	Weekly	Every second week
All randomized patients ( <i>n</i> )	61	61
Age in years, mean (SD)	59.4 (10.0)	60.1 (11.4)
Female, <i>n</i> (%)	12 (20)	7 (11)
Male, <i>n</i> (%)	49 (80)	54 (89)
Type 1 diabetes (%)	2	10
Type 2 diabetes (%)	98	90
Duration of diabetes in years (SD)	13.8 (8.8)	16.4 (10.4)
HbA <sub>1c</sub> % (NGSP units) (SD)	8.1 (2.2)	8.9 (2.0)
HbA <sub>1c</sub> (IFCC units) mmol/mol (SD)	65 (17.7)	74 (16.6)
Wound duration (months), % of patients		
<3	75	65
≥3 to 6	16	25
≥6 to 12	4	9
≥12	5	2
Wound size (cm <sup>2</sup> ), % of patients		
<3	82	77
≥3	18	23
PEDIS classification, % of patients		
1	63	70
2	35	30
3	2	0
WiFi classification, % of patients		
0	89	78
1	10	22
2	2	0
Wound location, % of patients		
Forefoot	56	69
Hallux	30	16
Heel	3	7
Midfoot	10	7
Toes	2	2
Pressure offloading, no./total no. (%)*		
Knee-high removable cast walker	32/61 (52)	29/61 (48)
Ankle-high offloading method	29/61 (48)	32/61 (52)
Adherence to offloading (≥10 h/day)	26/61 (43)	30/61 (49)

Group ulcer healing outcomes are provided in the text. IFCC, International Federation of Clinical Chemistry and Laboratory Medicine; PEDIS, perfusion, extent, depth, infection, and sensation; WiFi, wound, ischemia, and foot infection. \*This was the routine use of a knee-high prefabricated removable cast walker plus either an instant custom-molded total contact orthotic (iTCO) or self-molding prefabricated insole. If the participant was unable to mobilize safely or be accommodated in such a device, then a Darco post op shoe or a Darco cast shoe and iTCO were fitted.

presentation to a clinic. Consequently, debridement frequency and clinic presentation are closely aligned. Debridement frequency has substantial implications for patients, their families, and health care provider cost and workforce requirements. While weekly debridement may be of benefit if individual wound and patient factors warrant it, this study shows that weekly debridement is not superior to debridement every second

week. A good rate of ulcer healing is achieved with standardized care that includes both weekly and every second week debridement regimens.

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