



The Diabetes Debridement Study:

a randomised trial comparing conservative sharp wound debridement performed weekly or second weekly for diabetes-related foot ulcers

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Acknowledgements

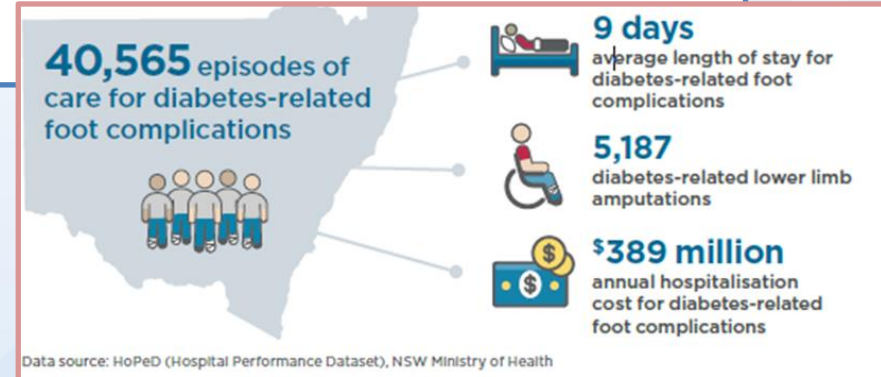
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- **Site Investigators:** Danielle Veldhoen, Cindy Meler, Ash Gargya, Georgina Frank, Jill Featherston and Joel Lasschuit, Jacqueline Batchelor and Catherine Stephens, Alan Kennedy.
- **High Risk Foot Service clinicians:** Anna Crawford, Jessica Kronenberg, Sarah Manewell, Purnima Rao & David Wong. PR collated and entered data.
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- **Patients** (and their families) who participated



Why does frequency of debridement matter?

- 74% Adults with Type 2 Diabetes > 10 years have DFU history ¹
- Australia's amputation rate is 28 per 100,000 ²
 - 3 x higher for regional and remote dwelling
 - 4.7 x higher for indigenous people
- High variation internationally, across Australian and NSW
 - 5 fold variation between LHD's ³



How big of a problem is diabetes foot ulceration?

- 74% Adults with Type 2 Diabetes > 10 years have DFU history¹

People living with diabetes-related foot ulceration

- require frequent and intensive treatment visits
- have high rates of co-morbidity; depression, cognitive dysfunction, cardiovascular and renal disease
- 5 year mortality rate 25-42%



Conservative Sharp Wound Debridement

Removal of non-viable tissue from the base and edges of an acute or chronic wound superficially, without general anaesthetic.

Routinely performed by podiatrists and some nurses.

Scalpel, forceps and curette are used.



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Pre and Post Debridement – Ulcer 1



Pre and Post Debridement – Ulcer 2



The literature

Conservative Sharp Wound Debridement

- Post hoc analysis of RCT (PDGF): 10 centres, 118 DFU. **Higher healing rate at 20 weeks in centres which debrided more often** ⁷
- Post hoc analysis of RCT (Bioengineered Dermal Replacement): 35 Centres, 310 **Higher rate of healing at 12 weeks (15 vs 29%) in centres which debrided weekly (75% of the time) (p=0.015) with “Minor evidence” benefit of serial debridement (patient level) (p=0.069)** ⁸
- Retrospective analysis in 59421 wounds showed **weekly debrided wounds healed faster** in 21days vs 64 (1-2 weeks) vs 76 days ≥ 2 weeks ⁹

7. Steed DL et al (1996) 8. Cardinal M et al (2009) 9. Wilcox JR et al (2013)

What is current practice ?

Aim: to document current practice with regards to the practice of conservative sharp wound debridement of diabetes-related foot ulcers by NSW Health employed podiatrists

- whether this is performed at every visit
- how often
- what factors determine debridement frequency

Method: Electronic survey managed in REDCap and distributed through clinical networks and managers. Survey was anonymous and consent was enacted when the participant chose to complete the survey.



What is current practice ?



Frequency of debridement	Respondents
More than once a week	5
Once a week	22
More than once a week / less than 2	7
Fortnightly	28
Every 3 weeks	5
Every 4 weeks or more	7

- 75 surveys completed
- 41% of the NSW Health Podiatrists
- Most (n=48) worked in metro versus regional/remote (n=27)
- Average 14.8 years of experience
- Podiatrists debride at every treatment visit
- Other modalities used infrequently
- Clinical indicators determined frequency
- Staffing resources are limiting factor in CSWD frequency

Rural podiatrists debride every 2 weeks or less often

(71% vs 45% $p=0.024$)

Aim

Primary outcome

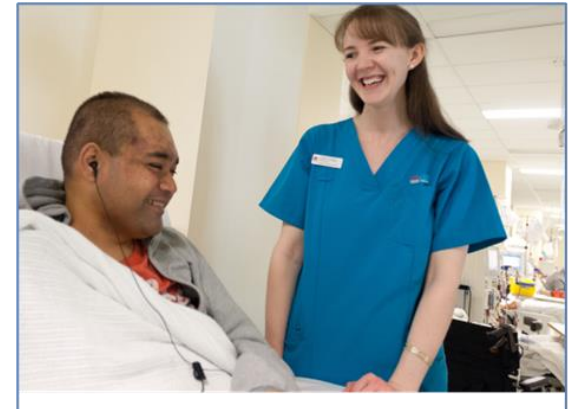
To determine the effect of sharp wound debridement performed at weekly versus second weekly intervals, on the percentage of Diabetes-related Foot ulcers healed at 12 weeks.

Secondary outcome measure

Percent wound reduction at 12 weeks

Method

The study design was developed to closely follow standard clinical care, provided by experienced clinicians working within interdisciplinary Diabetes High Risk Foot Services and with patients who are representative of the patient cohort to whom the treatment is applied.



Method

- **Included:** Adults with diabetes and chronic neuropathic foot ulcer 0.5 – 10cm²
- **Excluded:** Non-ambulant patients, non-healing wounds (>6 mo), moderate to severe infection or moderate to severe ischaemia or non-plantar wound location
- Ethics approved and trial registered with ANZCTR
- Computer generated, block randomisation (external) stratified by size.
- Primary outcome analyses performed according to SAP using Intention to Treat Principles, by statistician blind to group allocation
- Healing outcome determined by blind assessor using stored digital images

Method



- Standardised Care
- High Risk Foot Service
- Weekly for all participants



- Lower limb assessment
- Grading of wound, Ischaemia & infection



- Pressure offloading
- Wound care dressings

Results

7 Treatment Sites	Weekly	Second Weekly
Randomised patients	61	61
Age in years	59.4 (10.0)	60.1 (11.4)
Female (n)	12 (20%)	7 (11%)
Male (n)	49 (80%)	54 (89%)
Type 1 diabetes	1/61 (2%)	6/60 (10%)
Type 2 diabetes	60/61 (98%)	54/60 (90%)
Diabetes Duration (years)	13.8 (8.8)	16.4 (10.4)
HbA1c% (NGSP Units)& SD	(n= 58) 8.1 (2.2)	(n= 59) 8.9 (2.0)
Wound duration in months:		
<3	41/55 (75%)	37/57 (65%)
3-<6	9/55 (16%)	14/57 (25%)
6-<12	2/55 (4%)	5/57 (9%)
12+	3/55 (5%)	1/57 (2%)
Wound Size		
< 3cm ²	50/61 (82%)	47/61 (77%)
≥ 3cm ²	11/61 (18%)	14/61 (23%)

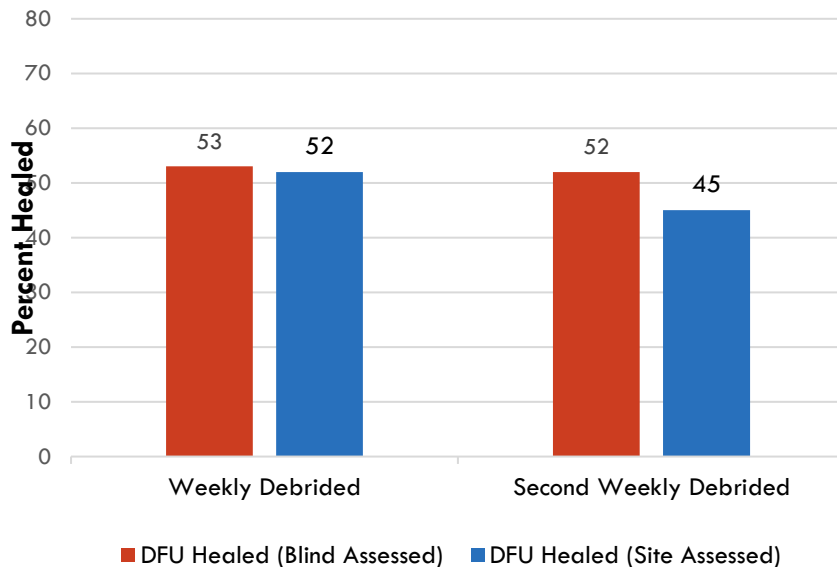
7 Treatment Sites	Weekly	Second Weekly
Randomised patients	61	61
PEDIS classification:		
1	38/60 (62%)	43/61 (70%)
2	21/60 (34%)	18/61 (30%)
3	1/60 (2%)	
Wifl classification:		
0	54/61 (89%)	47/60 (78%)
1	6/61 (10%)	13/60 (22%)
2	1/61 (2%)	0
Wound location:		
Forefoot	34/61 (56%)	42/61 (69%)
Hallux	18/61 (30%)	10/61 (16%)
Heel	2/61 (3%)	4/61 (7%)
Midfoot	6/61 (10%)	4/61 (7%)
Toes	1/61 (2%)	1/61 (2%)

Results

Primary outcome (n=78)
Mean diff 1.8 % (95% CI -16.3 to 20.0%, p= 0.84)

Sensitivity analysis / site assessed (n=109)
Mean diff 6.6% (95% CI -7.9 to 21.1% p=0.37)

Proportion (%) of diabetes-related ulcers healed by 12 weeks comparing weekly and second weekly (less frequent) debridement based on assessment blinded to treatment group and site assessment (clinician unblinded)

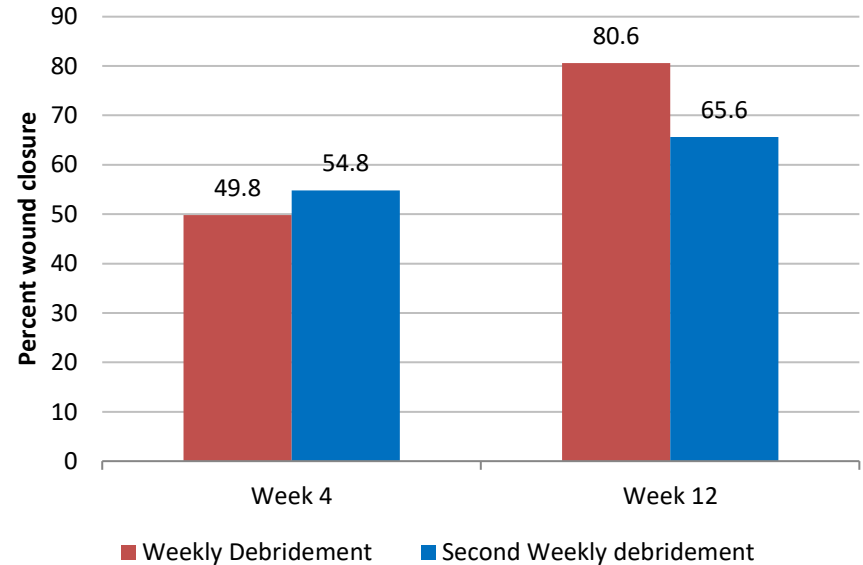


Results

Pre-defined secondary outcome Percent Wound Reduction at 4 & 12 weeks.

Non-significant 15% higher percent of wound closure at 12 weeks in the weekly debrided group (CI-11.62-41.74 p=0.27)

Percent wound closure of diabetes-related ulcers at 4 and 12 weeks comparing weekly and second weekly (less frequent) debridement



Discussion and conclusions

- First prospective, randomised study of CSWD
- Good healing rates (50%) achieved in both groups
- Results are generalisable across similar services
- Fewer than expected number of images available for blind assessment
- Clinician assessed outcomes confirmed primary outcome
- Drop-out rate, 25% suggests some patients (and their carers/families) found weekly visits a challenge.



What do the results mean for resource utilization?

Example 1: Appointments for 100 patients in 4 weeks of whom; 36% are seen weekly; 48% every 2 weeks; 16% every 4 weeks.

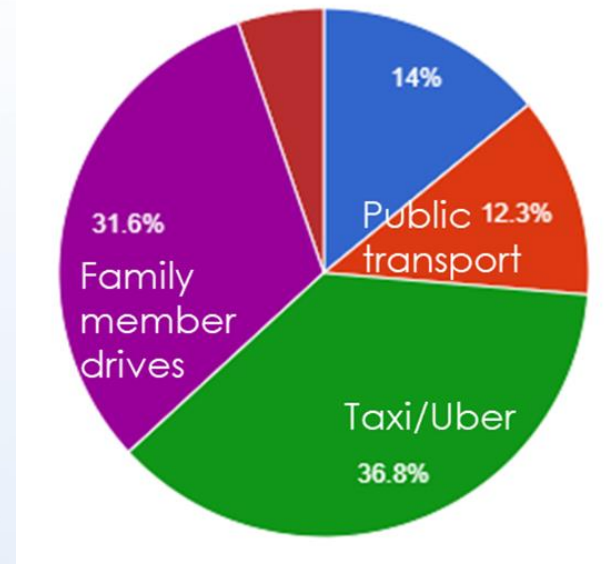
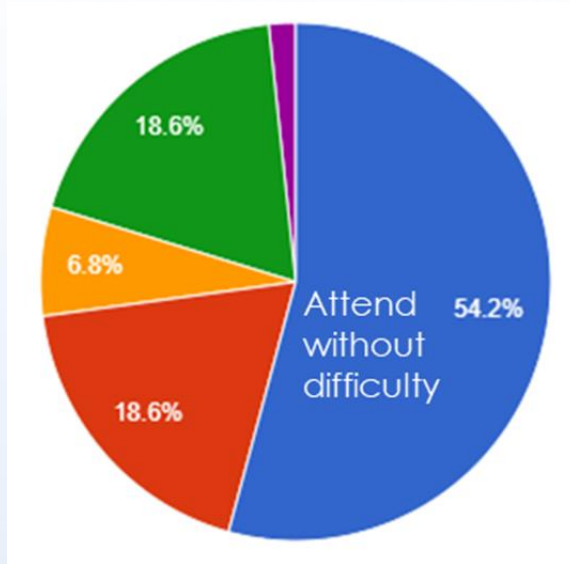
	Week 1	Week 2	Week 3	Week 4
# Pt appts for weekly attenders	36	36	36	36
# Pt appts for those attending every second week	24	24	24	24
# Pt appts for those attending every 4 weeks	4	4	4	4
Total appts/pts in 4 weeks for 100 patients	256			

**Example 2 where 20% of patient move to fortnightly visits:
Appointments for 100 patients in 4 weeks of whom; 16% are seen weekly; 68% every 2 weeks; 16% every 4 weeks.**

	Week 1	Week 2	Week 3	Week 4
# Pt appts for weekly attenders	16	16	16	16
# Pt appts for those attending every second week	34	34	34	34
# Pt appts for those attending every 4 weeks	4	4	4	4
Total appts/pts in 4 weeks for 100 patients	216			

40 additional consultations a month

What about the patient's perspective ?



Conclusions

Weekly debridement is not superior to debridement every second week.

Good healing achieved with standardised care weekly and every second week.

Weekly debridement (or more frequent) may be of benefit if individual patient and wound factors warrant.

We propose that where good healing trajectories are observed, and in the absence of visible, non-viable tissue or other indications for more frequent debridement that that second weekly debridement supports healing of chronic diabetes-related foot ulcers receiving standard care

There is potential for less frequent treatment and reduced patient & carer burden



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Thank you again to my Supervisors, colleagues and collaborators

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And my dear friend and inspiration Thyra Bolton



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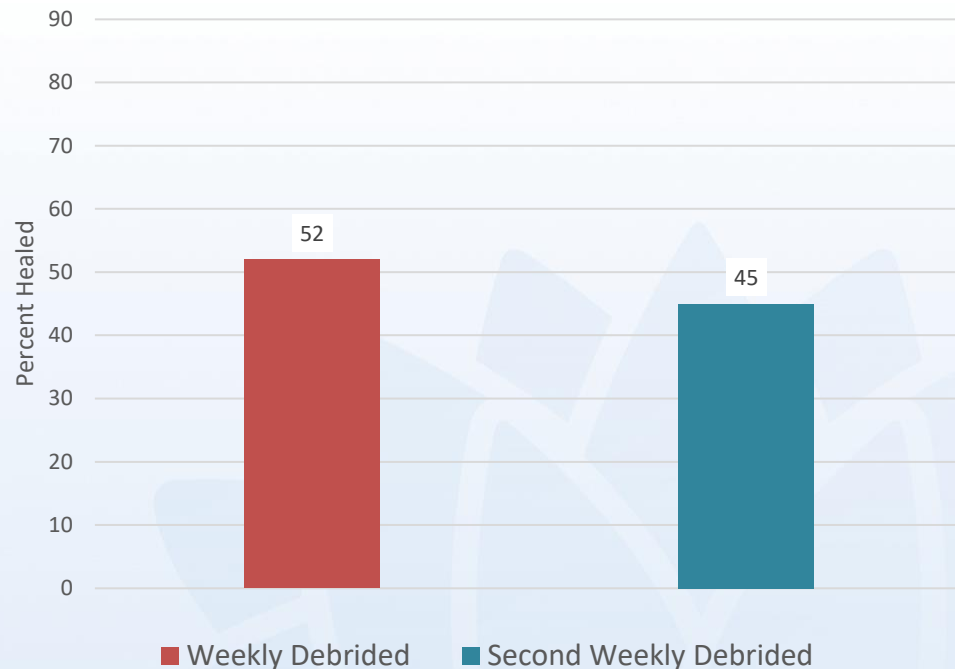


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Sensitivity Analysis

Based on clinician assessed outcome.
No difference between weekly and
second weekly debridement for healing
outcome at 12 weeks



Primary outcome

Applying intention to treat principles and blind assessment of healing outcome.

No difference between weekly and second weekly debridement for healing outcome at 12 weeks (CI -16.3 to 20%, $p = 0.84$).

