

Surgical techniques for treating diabetic foot ulcers: an evidence synthesis



Authors: Kaissar Yammine and Chahine Assi

There is an evidence gap with respect to the effectiveness of non-vascular surgeries over standard care for diabetic foot problems. Clinicians and researchers at the Lebanese American University Medical Centre decided to bridge this gap. The Evidence-based Diabetic Foot Research Centre was created, in order to conduct a series of evidence syntheses in the form of meta-analyses to evaluate the efficacy of available surgical procedures. The aim of this paper is to outline the evidence-based findings in relation to the outcomes of a number of surgical techniques in the treatment of diabetic foot disease, such as ulcers and ankle Charcot. The authors hope to encourage clinicians, particularly surgeons, to initiate primary and secondary research on the indications and usefulness of surgery when treating these difficult wounds.

Diabetic foot ulcers (DFUs) are serious complications that impose substantial morbidity, mortality and health costs (Boulton et al, 2005). Classically, diabetic wounds are initially managed by standard care, with methods including debridement, topical agents and non-surgical offloading (Everett et al, 2018).

Soft tissue and bone surgeries are usually reserved for difficult-to-treat wounds, such as infected, recalcitrant and recurrent wounds. However, a number of published articles reported better outcomes of different types of surgery over standard care, even when treating clean acute wounds (Frykberg et al, 2010).

Furthermore, contradictory outcomes have been reported from studies considering which type of surgery is better when treating some complications of the diabetic foot (Ettinger et al, 2016; ElAlfy et al, 2017).

An evidence gap exists with respect to the effectiveness of non-vascular surgeries. These surgical options have not been subjected to scrutinised investigation. No rigorous systematic approach has been used for evaluation; and the results of known and novel techniques used for DFUs have been reported in a scattered mode.

The question arises of how to make sense of the published data. A proven way to close this gap is to follow the principles of evidence-based medicine, mainly by conducting systematic reviews and meta-analyses.

Articles reporting surgically treated DFUs are searched for and the data collected in a systematic approach. Through this process, a more accurate way to evaluate these procedures could be offered and implications for clinical practice and future research could be proposed.

The authors' personal experience was in line with the good surgical outcomes reported in the literature. Therefore, the decision was taken by the clinicians and researchers of the Diabetic Foot Clinic at the Lebanese American University Medical Centre-Rizk Hospital to bridge the evidence gap. Initially, the Evidence-based Diabetic Foot Research Centre was created in order to conduct a series of meta-analyses to evaluate the efficacy of the available surgical procedures.

The aim of this article is to outline the evidence-based findings in relation to the outcomes of a number of surgical techniques in the treatment of diabetic foot disease. The authors hope to encourage clinicians, particularly surgeons, to initiate primary and secondary research on the indications and usefulness of surgery when treating these difficult wounds.

Examples of evidence synthesis on the outcomes of surgery in diabetic foot

The authors present their evidence-based findings from meta-analyses considering five surgical research questions.

Kaissar Yammine is Associate Professor of Orthopedic Surgery and Head of the Diabetic Foot Clinic and the Center for Evidence-based Diabetic Foot Research; Chahine Assi is Associate Professor of Orthopedic Surgery and Head of the Department of Orthopedic and Trauma Surgery. Both authors are at the Lebanese American University Medical center - Rizk Hospital, Lebanese American University School of Medicine, Beirut, Lebanon.

Disclosure statement: No competing financial interests exist.

1. Are intramedullary nails or external fixators better for unstable ankle Charcot with ulcers?

In ankle Charcot neuroarthropathy, conservative treatments usually yield poor results. Arthrodesis is considered the treatment of choice for the unstable Charcot ankle. The two methods used for ankle fusion are the retrograde intramedullary nail (IMN) and the external fixator (EF). However, the literature reports inconclusive results as to which method is better.

In four comparative studies of 117 patients (117 interventions), IMN was found to yield double the fusion rate of EF and the time to healing was 5 weeks less, but the results were not significant. EF significantly yielded higher rates of hardware removal and wound infection.

The authors concluded that in the clinical context of high-risk patients with diabetes, IMN could be a better option in the presence of medial or lateral ankle ulcers. However, when plantar ulcers are present, EF might be a better choice to avoid the plantar approach for nail insertion (Yammine and Assi, 2019a).

2. What is the efficacy of metatarsal osteotomies in treating neuropathic DFUs?

Metatarsal osteotomies have been used to treat recalcitrant or recurrent ulcers. The bone cut over the neck of the metatarsal aims at alleviating the pressure on the plantar ulcer induced by the metatarsal head.

The meta-analysis considered four studies that included 119 patients with 129 DFUs, refractory to conservative treatment, with a mean duration of 10.9 ± 4.2 months. The weighted healing rate was 98.7%, with a mean time to healing of 6.5 ± 1.2 weeks. Weighted rates for ulcer recurrence, ulcer transfer, infection and non-union were 4.3%, 10.3%, 3.7% and 3.4%, respectively. These results are noticeably better than those reported in the literature following non-surgical standard care (Yammine et al, 2018).

3. What are the types and outcomes of conservative excisional surgery for complicated diabetic toe ulcers?

Long-term antibiotics or toe amputation are the usual indications for complicated diabetic toe ulcers.

In seven studies comprising 290 patients with 317 ulcers, three types of conservative surgery were identified: resection arthroplasty of the interphalangeal joint, toe-sparing bone excision (internal pedal amputation), and distal Symes amputation. The meta-analysis showed a healing rate of 98.3%, a healing time of 6.8 ± 3.9 weeks, a recurrence rate of 2.3%, a wound

dehiscence/recurrent infection rate of 6.4%, a skin necrosis rate of 2.8%, and a revision surgery rate of 7.4%. Compared with the reported results of standard care coupled with antibiotics or toe amputation, conservative surgery seems to offer a better option for the treatment of recalcitrant or infected diabetic toe ulcers (Yammine and Assi, 2019b).

4. What are the outcomes of split-thickness skin graft on diabetic leg and foot ulcers?

The split-thickness skin graft had been proposed by some authors as an option to treat non-infected diabetic wounds of the leg and the dorsum of the foot. No evidence synthesis on its effectiveness was reported previously.

Based on 11 studies comprising 757 patients with 759 foot/leg ulcers, ulcers healed over a mean time of 5.35 ± 2.25 weeks, with a recurrence rate of 4.2%, an infection rate of 4.4%, and a re-grafting rate of 12.1%. Those results are better than those published following standard care when treating non-infected recurrent or recalcitrant ulcers of the leg and dorsal foot (Yammine and Assi, 2019c).

5. How often and when to propose surgical offloading for the treatment of forefoot diabetic ulcers?

Based on the highest level of evidence available, metatarsal head resection, resection arthroplasty, metatarsal osteotomy, Achilles tendon lengthening, gastrocnemius recession, and flexor tenotomy were found to generate better values than standard non-surgical conservative care for all outcomes except for the transfer rate. Moreover, 96% of DFUs healed in <1 month following surgical bony offloading, whereas 68% of ulcers healed within 3 months after standard care.

There is enough evidence to challenge the classical guidelines of DFU management. Surgical offloading could be used more often and be proposed earlier; a period of 12 weeks could be considered a reasonable cut-off value to consider surgical treatment for patients with non-healing DFUs (Yammine and Assi, 2019d).

Specificities of the evidence-based approach for surgical DFUs

The small number of included studies sometimes encountered in a systematic review should not be a hindrance. When compared to the non-surgical standard of care, publications on the surgical treatment of the diabetic foot ulcers are substantially fewer. Nevertheless, the authors' experience showed that even with a

small number of included studies, quantitative analysis yielding meta-analytical results could be very informative.

For instance, in treating the unstable ankle Charcot, the meta-analysis located one study in favour of the EF technique and three favouring the IMN method. When combining the data, the IMN was the favourable option in terms of healing rate, although significance was not reached. When looking at other outcomes such as hardware removal and infection rates, the IMN did significantly better. Only when all outcome values were appraised via quantitative weighted analyses, evidence-based information could be emitted.

In addition, the level of evidence of the included studies should not discourage researchers. Many relevant studies are observational, some are retrospective comparative and very few are controlled prospective trials (Yamine and Assi, 2019d). The situation is not different from the status of surgical research in general (Yamine, 2015); surgical randomised clinical trials are often more challenging to perform (Adie et al, 2016).

Implications for clinical practice and research

This approach has the ability to inform healthcare professionals and decision makers on the value of these surgeries. Many types of surgeries not only generated excellent healing rates, but the time to heal was also substantially, and in some cases significantly, less than those reported following non-surgical treatment.

Pooled data analysis of published comparative studies comparing metatarsal head resection or resection arthroplasty to non-surgical standard of care yielded a cut-off value of 12 weeks for forefoot diabetic ulcers. Therefore, in the case of an ulcer which did not heal after 3 months of standard non-surgical treatment, the evidence suggests proposing surgery to achieve wound healing.

The evidence-based approach demonstrated that many types of surgery should be indicated more often and earlier. The authors' centre has already completed four meta-analyses on other types of surgeries and found similar good to excellent outcomes. Moreover, the cost of long-term conservative treatment can be higher than that of surgery. Wieman et al (1998) showed a 16% cost difference in favour of metatarsal head resection when compared to standard care for uncomplicated ulcers.

This approach would also encourage clinicians and researchers to make the effort to conduct high-quality prospective controlled trials in order to evaluate the available surgical techniques.

The burden and cost of the treatment of diabetic foot complications are very high and every effort should be sought to enhance the quality of life of these patients. The worthy results obtained from the available studies with low levels of evidence should incite healthcare professionals to conduct trials with better study design. WME

References

- Adie S, Harris IA, Naylor JM et al (2016) The quality of surgical versus non-surgical randomized controlled trials. *Contemp Clin Trials Commun* 10(5): 63–6
- Boulton AJ, Vileikyte L, Ragnarson-Tennvall G et al (2005) The global burden of diabetic foot disease. *Lancet* 366(9498): 1719–24
- ElAlfy B, Ali AM, Fawzy SI (2017) Ilizarov external fixator versus retrograde intramedullary nailing for ankle joint arthrodesis in diabetic Charcot neuroarthropathy. *J Foot Ankle Surg* 56(2): 309–13
- Ettinger S, Plaass C, Claassen L et al (2016) Surgical management of Charcot deformity for the foot and ankle—radiologic outcome after internal/external fixation. *J Foot Ankle Surg* 55(3): 522–8
- Everett E, Mathioudakis N (2018) Update on management of diabetic foot ulcers. *Ann NY Acad Sci* 1411(1): 153–65
- Frykberg RG, Bevilacqua NJ, Habershaw G (2010) Surgical off-loading of the diabetic foot. *J Am Podiatr Med Assoc* 100(5): 369–84
- Wieman TJ, Mercke YK, Cerrito PB et al (1998) Resection of the metatarsal head for diabetic foot ulcers. *Am J Surg* 176: 436–41
- Yamine K (2015) Open access of evidence-based publications: the case of the orthopedic and musculoskeletal literature. *J Evid Based Med* 8(4): 181–4
- Yamine K, Assi C (2019a) Intramedullary nail versus external fixator for ankle arthrodesis in Charcot neuroarthropathy: a meta-analysis of comparative studies. *J Orthop Surg (Hong Kong)* 27(2): 2309499019836012
- Yamine K, Assi C (2019b) A meta-analysis of the types and outcomes of conservative excisional surgery for recalcitrant or infected diabetic toe ulcers. *Foot Ankle Spec* 19 June. Epub ahead of print
- Yamine K, Assi C (2019c) A meta-analysis of the outcomes of split-thickness skin graft on diabetic leg and foot ulcers. *Int J Low Extrem Wounds* 18(1): 23–30
- Yamine K, Assi C (2019d) Surgical offloading techniques should be used more often and earlier in treating forefoot diabetic ulcers: an evidence-based review. *Int J Low Extrem Wounds* 20 Nov. Epub ahead of print
- Yamine K, Nahed M, Assi C (2018) Metatarsal osteotomies for treating neuropathic diabetic foot ulcers: a meta-analysis. *Foot Ankle Spec* 12(6): 555–62