

Sharp debridement of diabetic foot ulcers and the importance of meaningful informed consent

There is minimal evidence to support the use of sharp debridement in clinical practice even though it is an accepted part of the management of diabetic foot ulceration (DFU). It is not common practice within podiatry departments to gain written, informed consent for this invasive procedure. However, in today's more litigious environment, the North West Podiatry Clinical Effectiveness Group decided to develop an information leaflet to identify the risks and benefits of sharp debridement in order to gain written, informed consent. This article looks at the evidence for sharp debridement of DFU and the process of developing the patient leaflet.

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KEY WORDS

Consent
Informed consent
Patient information leaflet
Sharp debridement

Debridement has been defined by a Cochrane review as the removal of devitalised or contaminated tissue from within or adjacent to a wound until surrounding healthy tissue is exposed (Smith, 2002) (Figure 1).

Although it is widely accepted that wound debridement may be necessary for optimal wound healing for diabetic foot ulcers, evidence from randomised trials relating to the effectiveness of its different methods is lacking, and methods of measuring its effectiveness are poorly developed. One assessment concluded that there is little or no evidence to suggest that one debridement method is more effective than another (Bradley et al, 1999).

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The Cochrane review (Smith, 2002) systematically reviewed five randomised controlled trials. Three assessed the effectiveness of hydrogels, one surgical/sharp debridement and one larval therapy. The authors concluded that hydrogels increased the healing rate of diabetic foot ulcers compared with dry gauze and that there was no significant benefit from larval or surgical debridement.

However, Steed et al (1996) evaluated the use of debridement in a study comparing healing rates after debridement plus treatment with

human platelet-derived growth factor and healing rates after debridement plus placebo treatment. The authors concluded that those subjects with diabetic foot ulcers in the study who had more frequent sharp debridements, healed faster.

There are many methods of debridement used in the management of diabetic foot ulcers. These methods include surgical/sharp, autolytic, biosurgical, wet to dry and, more recently, hydrotherapy. Autolytic debridement is the process the body undertakes to remove dead tissue and is enhanced by products such



Figure 1. A diabetic foot ulcer before and after debridement.

as hydrocolloids and hydrogels. The biosurgical method uses sterile larvae to debride diabetic foot ulcers which produce proteolytic enzymes. The wet to dry method is used infrequently in clinical practice in the UK but involves the application of a moistened gauze swab to a wound allowing the swab to dry out then removing it rapidly to effect a debridement. Hydrotherapy is the use of a high speed stream of saline to remove tissue from a diabetic foot ulcer.

In diabetic foot ulcer management, sharp debridement is, at present, the gold standard (Edmonds and Foster, 2005). Edmonds and Foster (2005) describe debridement as the most important part of wound control and give rationale for debridement of diabetic foot ulcers including:

- ▶▶ It removes pressure from the edge of an ulcer providing an optimal opportunity for wound healing
- ▶▶ It exposes the full extent of the wound allowing a more detailed review of the size and depth and anatomical structures involved in the ulceration
- ▶▶ It enables a deep wound swab to be taken which is a more accurate

method of determining the causative agent of any infection than the use of a superficial wound swab

- ▶▶ It converts a chronic wound back to an acute wound, recreating an optimal wound healing environment.

Sharp debridement and informed consent

Despite the fact that the practice of sharp debridement has minimal supportive evidence and involves an invasive procedure, it is not common practice within podiatry departments to gain written, informed consent for the procedure (Chadwick et al, 2007).

Within the nursing profession conservative sharp debridement, defined as the removal of dead tissue with a scalpel above the level of viable tissue, has been identified as a high clinical risk procedure (Fairbairn et al, 2002; O'Brien, 2003; Bentley, 2005). The clinical risks are damaging viable structures such as tendons, nerves and arteries. However, it is advocated that, if conservative sharp debridement is performed correctly and viable tissue is not exposed, there should be no danger to viable tissue (O'Brien, 2003).

The Nursing and Midwifery Council's (NMC's) Code of Professional Conduct (NMC, 2004) paved the way for extending the boundaries and development of safe nursing practice. The code states that a registered nurse is personally accountable for their practice by:

- ▶▶ Obtaining consent before any treatment or care is provided
- ▶▶ Protecting confidential information
- ▶▶ Updating professional knowledge and competence
- ▶▶ Acting to identify and minimise risk to patients and clients
- ▶▶ Practising competently and possessing the knowledge, skills and abilities required for lawful, safe and effective practice without direct supervision
- ▶▶ Acknowledging the limits of professional competence and only undertake practice and accept responsibility for those activities at which you are competent.

Before the implementation of conservative sharp debridement and during the procedure, attention should be paid by the practitioner to this code of practice.



Figure 2. Radical debridement of a foot ulcer with gentamycin beads in situ. Gentamycin beads were packed into the wound following sharp debridement as part of the wound management.

While the debridement of calluses — diffuse areas of relatively even thickness of skin that occurs in response to excessive pressure (Neale, 1989) — and wound edge debridement has been common practice within the field of podiatry for many years, more extensive and radical debridement, particularly involving diabetic foot ulceration, is a fairly recent development. *Figure 2* illustrates radical debridement of the foot where the bone and tendon have been removed and the wound packed with gentamycin beads.

The Society of Chiropractors and Podiatrists' (2005) consent guidelines state that the patient's cooperation will be sufficient to indicate that they have given consent. Written consent for the debridement of diabetic ulcers is not recommended and verbal consent is considered sufficient. The society does state that if the patient does give consent, it is important that they have sufficient information to make an informed decision. Often it will be sufficient for this information to be given verbally, but there are times when it is best to provide clear, simple written information.

Department of Health (2001) good practice guidelines in relation to consent state that the provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensive information about their condition, possible treatments and investigations and the risks and benefits of these treatments.

Litigation is a potential problem when patients are not informed of the risks and benefits of debridement and hence may have a case should something go wrong. In these increasingly litigious times, the North West Podiatry Clinical Effectiveness Group (CEG) felt it was vital to develop a process whereby patients would be able to give written, informed consent for sharp debridement of the foot and that this would become standard practice within the north-west of England. This idea follows the advice given by Bridgit

Dimond (2005), an expert in the law regarding healthcare, who states that consent by word of mouth is valid, but its existence may be difficult to establish in court, since it might be one person's word against another.

Giving informed consent

When the issue of informed consent arises, many healthcare professionals think of a signed form giving permission for a specific medical intervention. In good practice, informed consent encompasses a process by which qualified individuals discuss the nature, indications, benefits and risks of treatment with patients, who may then decide how they want their care or treatment to proceed (Herringer, 2005). Herringer states that there is a difference between having a document signed and witnessed, and explaining the situation, having patients understand and then giving their informed consent. The American Medical Association (AMA) concurs, stating that informed consent is a process of communication between a patient and clinician (American Medical Association, 2007).

Method of gaining informed consent

Informed consent is a legal requirement whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implications of any actions. To help people achieve this level of understanding, a sub-group of the CEG developed a patient information leaflet which described the process of debridement and identified the risks and benefits of debridement using pictorial representation where possible. The document was proof-read by the clinical governance department of one of the representatives of one of the trusts of the North West Podiatry CEG. It was then tested on a small group of five existing patients. Subjects for the pilot were recruited using convenience sampling. Many of the subjects had previously had a number of debridements. The subjects were all interviewed individually by the same practitioner, who subsequently undertook the debridement.

Debridement was described to the patient as removal of hard skin or dead or infected tissue. The benefits of debridement described in the patient information leaflet were that:

- ▶▶ It reveals the full size of the ulcer, enabling full assessment of the wound
- ▶▶ It reduces pressure on the edge of the ulcer
- ▶▶ It reduces the risk of trapped infection.

It was explained in the document that dead tissue provides an ideal growth place for bacteria which if left could develop into a severe infection that could put the foot and limb at risk of gangrene or amputation so therefore it is important to remove all dead tissue from the ulcer to prevent infection. The leaflet also explains that although the ulcer may appear bigger or even bleed after debridement it will be a healthier wound because all the dead tissue has been removed.

While the leaflet does not cover the risks of more radical debridements, it is good practice to inform patients undergoing normal sharp debridement of their ulcer, the process, and the rationale for that debridement.

The leaflet also informed patients that podiatrists performing debridement are trained to carry out the procedure.

Results of the pilot

Patients were asked if they understood the leaflet and whether it provided them with a deeper insight into the debridement procedure. The patients' comments were as follows:

- ▶▶ 'A clear and informative leaflet. I understand now why it is important to remove the dead tissue'
- ▶▶ 'Excellent! I haven't really thought about why, before reading this, it is important to have my ulcer debrided'
- ▶▶ 'A good clear explanation. I feel happier about having my ulcer debrided now I have had the reasons explained'
- ▶▶ 'I liked the leaflet. I knew that removing the dead skin was

important, but I didn't really understand why until I read this'

- ▶ 'Very good leaflet. Clear and easy to understand. I liked the pictures also which show how much cleaner the ulcer looks after removal of the dead skin.'

Although the sample was a small convenience sample (n=5) and the results cannot be generalised to the whole population it is still thought that this leaflet could benefit the targeted audience.

The information leaflet will be further piloted in one other PCT before implementation.

Discussion

Sharp debridement is an integral aspect of diabetic foot ulcer care. The risks and benefits of undertaking debridement and the process involved need to be explained fully in order for the patient to give informed consent. The small study of the piloting of an information leaflet demonstrated that many patients lacked understanding about debridement despite the fact that they may have undergone ulcer debridement on numerous occasions before the study.

It is the legal responsibility of medical practitioners to ensure patients have an understanding of the facts and implications of any medical interventions. The common method of verbal description, or no description of the procedure at all, is clearly insufficient.

The process of gaining written consent can be a contentious issue. Indeed The Society of Chiropractors and Podiatrists still recommend only the use of verbal consent. Yet the use of more radical debridement including the removal of necrotic tissue and structures such as bone requires that patients have an understanding of the risks of such management. Further in these increasingly litigious times, the practitioner who debrides an extravasated callus and discovers ulceration in a neuropathic foot

may be accused of causing it. It has, therefore, become even more important to ensure that consent is fully documented.

All the subjects in the pilot study had a good understanding of the English language and had good vision. Future versions of the leaflet may need to be developed in different languages and a different font size for patients with visual impairment associated with conditions such as retinopathy which may also be secondary to diabetes.

Conclusion

The CEG has developed a patient information leaflet, the aim of which is to give patients a better understanding of the process of wound debridement. The leaflet describes the risks and benefits of debridement with a secondary aim to reduce the number of complaints due to lack of understanding and poor communication. The subsequent work of the CEG involving a larger pilot and final roll-out will establish the leaflet and the gaining of written consent into normal clinical practice. **WUK**

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Key Points

- ▶ Sharp debridement is an invasive procedure. However, it is not common practice within podiatry to gain written, informed consent before it is performed.
- ▶ A patient information leaflet was developed to help people understand what debridement involves and the risks and benefits of the procedure.
- ▶ Informed consent encompasses a process in which qualified individuals discuss the nature, indications, benefits and risks of treatment.