

# The more things change, the more they stay the same

## KEY WORDS

- ▶ Foot care
- ▶ Diabetes
- ▶ Multidisciplinary teams
- ▶ Dressings

**Over the past 30 years, there have been various trends in diabetes foot care, but the overall aims and outcomes remain fundamentally unchanged. Diabetes patient numbers are increasing, and many of the new methods and products that have been developed in recent years have not proved effective enough to change regimens of care to any great extent. While new technologies are also important, working in a multidisciplinary way is crucial and needs to be a priority for practitioners. Although some progress has been made, this needs to continue and increase to meet the old and new challenges being faced.**

This year I will complete my 30th year as a doctor. I have been a consultant for over 20 years and have over 26 years' experience of looking after diabetic feet. If I had written this article 20 years ago, the names of the NHS structures would have been different but the aims — and indeed many of the conclusions — would have remained unchanged. In the time I have worked with diabetes foot care I have seen fashions come and go, but the overall outcomes have hardly altered. Local, regional and international amputation rates still show variations of more than twofold between the lowest and the highest rates, and fully-integrated multidisciplinary care remains a minority. Some progress has been made over the past couple of decades, but not nearly enough.

## INTEGRATED FOOT CARE

The principles of multidisciplinary foot care have their roots in American leprosy clinics and, in particular, the Hansen's Disease Center in Carville. In the United Kingdom and Europe, however, the first paper to demonstrate that an integrated multidisciplinary foot care team (MDFCT) could reduce major amputations in diabetic foot ulcer patients was published in 1986 (Edmonds et al). The King's College Hospital group demonstrated that a specialist foot clinic for patients with diabetes could halve major amputations. This has led to many similar publications over the years with similar results.

The simple measure of coordinating the specialties of diabetes, podiatry, orthotics and relevant surgical specialties into a single team has a major impact on amputations and outcomes for patients with diabetes (SIGN, 2010). More than half of all directly diabetes-related admissions are due to active foot disease (National Diabetes In-patient Audit, 2012). Without a team to manage them, foot patients stay in hospital longer and hospitals incur greater costs. Usually all of the required staff members are already employed by a Trust, but often in different departments. Although the improvements in lengths of stay and long-term cost savings should make creating such teams an easy choice for management, it typically requires an interested diabetologist to bring it all together. Therefore, to end the cycle of on-going variable outcomes for diabetic foot disease, we need to train more diabetes consultants with an interest in foot problems and set up a MDFCT in every NHS Trust in England, every health board in Scotland and Wales, and in the five Northern Ireland Health and Social Care Trusts (Young, 2013). I believe this is achievable, but clearly obstacles remain, and even today the National Diabetes In-patient Audit (2012) reports that at least 30% of England and Wales NHS Trusts do not have a MDFCT.

## FASHIONS IN WOUND CARE

Wound care has trends and fashionable movements. I wonder if in the future we will look

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upon silver dressings in a similar way to flares from the 1970s and leg warmers and pastels from the 80s, or if biofilms are the critical colonisation of the 21st century. Bioengineering, wound bed preparation, moist wound healing and now oxygen are other concepts that have produced a flurry of articles and hype, but to what lasting effect?

The problem, with a few notable exceptions, is that none of these developments were underpinned with the evidence required by modern health care to truly establish their place in regimens of care. Evidence-based practice itself is a relatively recent concept; before it, there was a greater ability to do what an individual practitioner felt was right or what worked for him or her without having to justify what he or she did to others. Wound care is a prime example of this. Within the multiple variables that affect healing of the diabetic foot, off-loading, infection and vascular insufficiency are likely to have a greater impact on healing than changing the dressing. Therefore, unless the dressing is truly magical, it requires 100s and possibly 1,000s of patients to demonstrate a significant difference in efficacy and healing. For this reason, most companies have relied upon case reports and anecdotal evidence to promote their products. This has led Cochrane reviews and a study from the Nottingham group to conclude that there is not enough evidence to recommend newer and more expensive dressings over their older, simpler predecessors for foot or leg ulceration (Cullum et al, 2001; Game et al, 2012; Jeffcoate et al, 2009; O'Meara et al, 2000; Storm-Versloot, 2010).

The message that newer dressings are not proven to be better does not mean that they are not an improvement over older dressings. In the end it will come down to individual experience and local mini-trials to determine whether a new product does what the practitioner wants it to achieve. It does not, however, explain the wholesale adoption and dropping of product types that has occurred over the past two decades. There are two significant examples of this with bioengineered products and silver dressings.

#### **BIOENGINEERED DRESSINGS**

The microenvironment of the chronic diabetic wound was starting to be understood in the early 1990s, with science about to end chronic wounds

— or so we thought. Becaplermin, platelet-derived growth factor-BB gel, was the first (and so far the only) commercial growth factor for healing foot ulcers. Promising to 'heal more wounds more quickly', the trial results were not impressive enough to encourage widespread use and, often used in the toughest, most chronic wounds, the trial results were never reproduced. Similarly, Dermagraft®, Apligraf®, Graftjacket® and patient-derived cell culture synthetic skin substitutes were produced to aid healing. All came and largely went, particularly in Europe where nationalised health systems could not afford them. As an early user of Dermagraft, patient selection was vital and results could be good, but ultimately the outcomes rarely justified the cost, despite any number of cost-effectiveness models.

In the NHS, spending money on expensive interventions rarely makes the projected savings expected from these models. Models therefore concentrate more on efficiency savings, treating more patients for the same money, though this rarely happens where demand is almost infinite and resources are very finite. It is a model that other treatment modalities, including Versajet® and topical negative pressure wound-closure systems, have tried to copy. It seems to cloud the picture rather than clarify the use of such systems in my mind. Individual benefit, patient selection and clinical effectiveness make more sense to me as a clinician, if only more managers and companies would see this.

All of these products have essentially fallen out of fashion in the United Kingdom. Indeed, some concerns about cancers with the use of three or more tubes of becaplermin will make the return of such products difficult in the future.

Similarly the rise, fall, and rise and fall again of silver-containing dressings is an interesting development. In the early 20th century, silver was known to inhibit bacterial growth and, in the late 60s, silver salazine dressings came into use. They were not in vogue in diabetes wound care, but in the late 90s and early 2000s, the concept of critical colonisation – with bacterial levels inhibiting healing, but not high enough to cause invasive infection – began to be described. This resulted in the emergence of silver-containing versions of established dressings and new silver-based dressings to treat this 'new' phenomenon. Soon every company and most products had a silver version. Practitioners were tempted to

use them, on the basis that they might reduce infection rates, and the money spent on silver products rose exponentially. However, two systematic reviews reported that there was a lack of evidence for efficacy for topical antimicrobials and the inevitable backlash began (O'Meara et al, 2000; Storm-Versloot, 2010). Pharmacists and formulary committees stripped silver-containing dressings from their formularies, but has this made a difference to outcomes? Sadly no one can tell, as there are no nationally-coordinated databases to record the results, and one unit is unlikely to have enough patients to see a trend unless the effect is huge. As outlined in the introduction, however, it is unlikely that outcomes have changed in a measurable way.

### FASHIONS IN DEBRIDEMENT

Sharp scalpel debridement is regarded as a cornerstone of diabetic foot care. This has not changed over the years, although a number of innovations have been tried. The most notable of these was the Versajet system. This hydro-scalpel uses a thin but powerful jet of water to remove tissue from the area being treated. Our unit bought the system and had excellent results but, in keeping with the original paper (Caputo et al, 2008) that demonstrated only marginal improvements in debridement time compared to the amount of time needed to set the unit up, we only use it rarely now and stick to scalpels or larvae, which are perhaps even less evidence-based.

### DEATH IS NOT THE END

The mortality rate from diabetic foot ulceration has always been high and is actually higher than many cancers. There are now two case-controlled studies that have demonstrated that appropriate cardiovascular risk reduction strategies can reduce mortality, at least in the first 5 years after the ulcer develops (Faglia et al, 2014; Young et al, 2008). It is this realisation and translation into practice that has been one of the major changes in diabetic foot care. Along with the general improvement in diabetes outcomes due to better glucose and blood pressure care, diabetic foot ulcer patients are living longer in many centres, although that brings its own problems.

### STUBBORN AMPUTATION NUMBERS

In 1989, the first year I started working with foot ulcer patients, the St Vincent declaration (published 1990) called for a 50% reduction in

amputations for diabetic foot ulceration, and recently this aim was re-affirmed as part of the Putting Feet First campaign (Diabetes UK, 2013). As I have already described, local improvements of this degree are made possible by setting up MDFCTs but have never been achieved on a national scale. The closest is the reduction in amputation rates seen in Scotland. However, due to the rise in diabetes patient numbers, the fact they are living longer, and the increase being principally in type 2 patients who have more arterial disease, there are consequences for amputation. The total number of amputations is not going down, even if the number per 1,000 patients with diabetes might be. This remains a challenge for tomorrow just as much as it was a quarter of a century ago. WUK

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