

INTERNATIONAL
CASE STUDIES

USING ASKINA® CALGITROL® PASTE FOR THE TREATMENT OF DIABETIC FOOT INFECTION: **CASE STUDIES**

CASE STUDIES SERIES 2013



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About this document

This document contains a series of case reports describing the use of Askina® Calgitrol® Paste (B Braun) in patients with infected diabetic foot wounds. All patients were treated for a minimum of two weeks and the decision to continue treatment was based on assessment and the 'two-week challenge' (see page 2). A formal assessment was performed weekly, although dressing changes were carried out more frequently.

Photographs were taken to document wound progression. Relevant additional wound treatments, eg antibiotic therapy etc, were reported.

Askina® Calgitrol® Paste for the treatment of diabetic foot infection

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INTRODUCTION

The risk of lower extremity amputation for people with diabetes is more than 20 times that of people without diabetes¹. In the UK, around 6,000 people with diabetes undergo leg, foot or toe amputation each year. Many of these amputations are avoidable and significant variations in the incidence of lower extremity amputations, both globally and within the same country, suggest the need for improved data collection and standardisation of care².

Foot complications may present clinically as infection, neuropathy, peripheral arterial disease and Charcot neuroarthropathy³. Urgent referral and assessment is vital as a delay in diagnosis and management increases morbidity and mortality and can contribute to a higher amputation rate³. In addition, ulceration and amputation substantially reduce the quality of life in patients with diabetes; treatment often involves frequent clinic visits and/or hospitalisation resulting in loss of earnings and reduced independence¹.

Treatment of diabetic foot ulcers is aimed at preventing infection and providing an optimal wound healing environment. Vascular control of the disease (eg regulation of serum glucose levels and arterial risk factors such as hypertension and dyslipidaemia), combined with debridement, pressure offloading, treatment of infection and the effective use of wound dressings are important factors in the care of patients with diabetes⁴. Patients with infected wounds require early treatment with systemic antibiotics⁴. For ulcers that are critically colonised or show signs of local infection, topical antimicrobials can be used to control bacterial load and protect the wound from further damage or contamination.

This document looks at the use of a novel formulation of an established topical antimicrobial, Askina® Calgitrol® Paste (B Braun), in the management of diabetic foot ulcers and presents a series of case studies.

DIABETIC FOOT INFECTION

Diabetic foot ulcers are usually the result of some minor trauma that may occur as a result of decreased sensation due to neuropathy⁵ or poor tissue viability as a result of a reduced vascular supply. Many patients have a combination of both neuropathy and poor vascular supply. Ulceration in areas of increased pressure is also common. Offloading, debridement, effective wound care and close follow-up are recommended for these wounds³.

A large proportion of patients with diabetic foot ulceration will develop infection. This can spread rapidly and, when care is not taken to manage infection effectively, the wounds can become deep, and osteomyelitis and serious soft tissue infection may occur⁶. Early identification and prompt management of infection is crucial to prevent limb loss. In addition, infection in the feet can spread elsewhere through the blood, leading to potentially life-threatening complications¹.

However, recognising infection in the diabetic foot is often difficult; up to 50% of patients with infected diabetic foot ulcers will not present with the classical signs of redness, heat and swelling⁷. This can be due to a poor blood supply that reduces the classical signs of infection, an immunocompromised host and neuropathy, which can mask pain. In the absence of pain, or altered sensation, other, often more subtle, signs of infection may be visible and should not be ignored⁸ (Box 1).

Clinicians should consider the possibility of infection occurring in any foot wound in a patient with diabetes and be aware of factors that increase the risk of infection⁴.

Box 1: Indicators of infection in diabetic foot ulcers (adapted from⁸)

- Ulcer base yellowish grey
- Blue discolouration of surrounding tissues
- Fluctuance (softness) or crepitus (crackling, grating) on palpation
- Purulent exudate
- Sloughing of ulcer and surrounding tissue
- Sinuses with undermined or exposed bone
- Abscess formation
- Odour
- Wound breakdown
- Delayed healing

STRATEGIES TO MANAGE DIABETIC FOOT INFECTION

Mild to moderate infection can be managed on an outpatient basis with broad spectrum antibiotics for 1–2 weeks⁴. If a longer course is required, the choice of antibiotic can be narrowed following a wound swab. This swab should be taken after debridement of the wound and on initiation of the antibiotics. The decision to continue antibiotic therapy will be based on the severity of the infection and response to the antibiotics. Deeper wounds with exposed or palpable bone and in wounds with residual signs and symptoms of infection usually require antibiotic therapy for much longer than 1–2 weeks. Individuals with severe infection require hospital admission for intravenous antibiotic therapy⁹. Wounds without evidence of soft tissue or bone infection do not require antibiotic therapy⁴.

Topical antimicrobial cleansing agents and dressings are having an increasing role in the management of diabetic foot infections due to problems such as antimicrobial resistance (eg methicillin-resistant *Staphylococcus aureus* [MRSA]) or other adverse effects (*C. difficile*). They do not replace antibiotic use when there are frank signs of infection, but can be used as an adjunctive therapy. As an adjunctive therapy they provide antimicrobial treatment directly at the wound dressing interface. This may be important where there are concerns regarding reduced antibiotic tissue penetration — for example, where the patient has a poor vascular supply. In addition, topical antimicrobials are often used in cases where the classical signs and symptoms of infection may be absent, but where there is a clinical suspicion of increased bioburden. This may present as increasing exudate, darkened granulation tissue, odour and a non-healing wound⁸.

Topical antimicrobials have a broad spectrum of activity and can help to manage the local wound environment by reducing exudate and promoting re-epithelialisation¹⁰. Treating these wounds effectively at this early stage may prevent any localised infection spreading to the deeper tissues and all the possible devastating complications that ensue¹¹.

The role of silver in diabetic foot infection

The topical antimicrobial agent silver has been used for hundreds of years in wound care¹². In recent years, a wide range of wound dressings that contain elemental silver or a silver-releasing compound have been developed. Silver ions are active against a broad range of bacteria, fungi and viruses¹³, including antibiotic resistant bacteria, such as MRSA and vancomycin-resistant *Enterococci* (VRE). In addition, studies using experimental models of biofilms suggest that silver may help to reduce bacterial adhesion and destabilise the matrix¹⁴.

Silver-containing wound dressings provide sustained availability of silver and may have additional benefits such as management of excessive exudate, maintenance of a moist wound environment, or facilitation of autolytic debridement¹⁵. While flat dressings may be more suitable for superficial wounds¹⁶, deeper wounds may require treatment with more malleable dressings that can conform to the ulcer and provide more intimate contact with the wound bed.

The two-week challenge

A recent international consensus document recommends that silver dressings be used initially for a 'two-week challenge' period. At the end of the two weeks, the wound, the patient and the management approach should be re-evaluated¹⁵. If after two weeks, the wound has:

- improved, but there are continuing signs of infection, it may be clinically justifiable to continue use of silver dressings with regular review
- improved and there are no longer signs or symptoms of infection, the silver dressing should be discontinued
- not improved, the silver dressing should be discontinued and the patient reviewed and a dressing containing a different antimicrobial agent initiated, with or without systemic antibiotics.

Other wound management issues

Diabetic patients with a foot wound should receive appropriate wound care⁴, which usually consists of the following:

- Debridement, aimed at removing debris, necrotic tissue and surrounding callus. It is important to achieve the right balance in the amount of tissue removed — too much will prolong the healing process, while if too little is removed, the wound's chronic status will continue⁸
- Redistribution of pressure off the wound to the entire weight-bearing surface of the foot. This is particularly important for plantar wounds¹⁷
- Selection of dressings that allow for moist wound healing. The choice of dressing should be based on the size, depth, and characteristics of the ulcer. Dressings can also help to protect the wound from further mechanical trauma¹⁸.

Applying dressings to the foot is not easy due to its shape, three-dimensional contouring and intrinsic variance in size. The toes and heel are most difficult to dress and dressings may be too tightly applied or bulky, leading to discomfort and points of increased tissue pressure. Anecdotally it is acknowledged that the contours and structure of feet provide a particular challenge. Further considerations with feet are that they are walked on and have to be accommodated in foot wear¹⁹. The act of walking creates stresses and pressures²⁰ on the feet and subsequently the dressings, which can impede their ability to remain *in situ*.

Problems of dressing application and the difficulty of having an intimate contact between the dressing and the wound have led to the development of a new topical antimicrobial product that can be applied as a paste.

WHAT IS ASKINA® CALGITROL® PASTE?

Askina® Calgitrol® Paste is the first silver alginate dressing in the form of a paste. It is available as a 15g tube and can be used to facilitate the control of infection in the management of diabetic foot ulcers. It is an amorphous and homogeneous paste that conforms closely to the wound bed, helping to prevent any 'dead spaces' where bacteria may flourish²¹.

It comprises the same ionic silver alginate matrix used in the Askina® Calgitrol® Ag flat dressings, which has demonstrated antimicrobial efficacy in a randomised clinical trial in patients with infected acute and chronic wounds²².

Askina® Calgitrol® Paste contains an average ionic silver concentration of 180mg/15g tube application. Its high water content (43%) offers additional moisturising features, which may provide a soothing effect. As with the flat dressings, the paste does not require any activation by water prior to use.

How does it work?

When the paste comes into contact with wound exudate, the fluid is absorbed into the alginate matrix, leading to swelling of the alginate and causing the silver and calcium alginate bonds to release the silver ions into the wound. As the silver ions are gradually depleted at the wound surface, further silver ions are drawn from within the paste leading to a controlled and steady state release of silver into the wound without losing the structural integrity of the matrix itself²¹.

In vitro studies have shown that the antimicrobial effect of Calgitrol® Paste commences within the first hour of application²³. It has been shown to be effective against multiple Gram-positive and Gram-negative bacterial strains including MRSA, *Pseudomonas aeruginosa* and *E. coli*²⁴.

Systemic absorption of silver from Calgitrol® Paste has been shown to be insignificant in a pre-clinical model²⁵ and it is not associated with significant risk of sensitisation and no staining of the surrounding skin has been reported post-application²⁵.

Indications for use

Askina® Calgitrol® Paste is indicated for use in the management of partial to full thickness wounds, pressure ulcers, venous and arterial leg ulcers, diabetic foot ulcers and second-degree burns. It may also be used for infected wounds.



Acknowledgement: Photo taken in the clinic of Katharine Speak, Centre for Diabetes and Endocrinology, York Hospital, UK

Useful links

- **Askina® Calgitrol® Paste Product information**
from: <http://www.bbraun.com/cps/rde/xchg/bbraun-com/hs.xsl/products>
- **Askina® Calgitrol® Made Easy** from: http://www.woundsinternational.com/pdf/content_10266.pdf
- **International Consensus. Appropriate use of silver dressings in wounds**
from: http://www.woundsinternational.com/pdf/content_10381.pdf



Acknowledgement: Photo taken in the clinic of Dr Paul Chadwick, Dept of Podiatry and Foot Health, Salford Royal Hospital, UK

APPLICATION GUIDE

- Debride and cleanse the wound according to local protocols
- Shake the tube prior to use
- Apply a thick layer of the paste to the entire wound surface
- Use the cannula to apply paste to wound tunnels and small sinuses
- For larger wounds spread the paste with gloved hands
- Cover with a secondary dressing and secure as appropriate. For most wounds, a low-adherent dressing may be used. A more absorbent foam dressing may be required for heavily exuding wounds.

The frequency of dressing changes will depend on the level of exudate. Daily dressing changes may be required initially for infected wounds if exudate levels are high.

Due to its ease of use and high conformability, Calgitrol® Paste is ideally suited to the management of difficult to manage wound shapes, tunnel wounds and small sinuses found in diabetic foot ulcers. It can be used with a variety of secondary dressings, including a low-adherent wound contact layer or low-adherent absorbent dressing.

CLINICAL EXPERIENCE USING ASKINA® CALGITROL® PASTE

The following case study presentations evaluate the use of Calgitrol® Paste in the management of infected diabetic foot ulcers. These show that Calgitrol® Paste:

- Reduced clinical signs of infection
- Improved wound progression
- Was easy to apply and remove with no discolouration
- Stayed *in-situ* during wear time
- Effectively managed exudate with improvement in the condition of the periwound skin
- Improved patient comfort/quality of life
- Offered a cost-effective dressing regimen.

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CASE 1: PARTIAL FOOT AMPUTATION WOUND

Samantha Haycocks/Paul Chadwick, Department of Podiatry and Foot Health, Salford Royal Hospital, UK

BACKGROUND

This patient was a 45-year-old gentleman with long-standing type 2 diabetes, hypertension and on dialysis due to Stage 5 chronic kidney disease. He was a non-smoker and had a history of ulceration and osteomyelitis. He presented to the acute outpatient clinic with a non-healing amputation of the right 5th ray.

On presentation, the wound measured 62mm x 35mm and had been present for two weeks following surgery (Fig 1). The wound bed contained 40% slough and 60% granulation tissue, and the surrounding skin appeared macerated and swollen with local cellulitis. Exudate levels were moderate. The wound had been previously treated with negative pressure wound therapy (NPWT).

TREATMENT

It was decided to treat the wound locally with Askina® Calgitrol® Paste to prevent infection in this high-risk patient. The paste was easy to apply and adhered to the wound bed. This was covered using a low-adherent absorbent dressing (Melolin®, Smith & Nephew) as a secondary dressing. Dressing changes were carried out every two days by the district nurse. The patient was also given a course of antibiotics (co-amoxiclav) three times a day due to the high risk of osteomyelitis and recurrence.

Week 1: At follow-up the condition of the wound had improved. The wound bed contained less slough, was clean and granulating well. There was less maceration of the surrounding skin and exudate levels were reduced slightly (Fig 2). There was some slight staining of the surrounding skin. However, the paste was easy to remove and reapply. Calgitrol® Paste was continued for a further week with dressing changes carried out every two days by the district nurse. The patient continued his course of antibiotics.

Week 2: Further improvement was seen at follow-up one week later. Exudate levels were low and the wound bed was clean and granulating. The wound had decreased in size and now measured 60mm x 27mm. As the wound was healing well, the decision was made to continue Calgitrol® Paste for a further 10 days (Fig 3). At follow-up the wound showed no evidence of infection (Fig 4).

OUTCOME

Askina® Calgitrol® Paste was able to manage the local wound environment effectively using a simple cost-effective secondary dressing. Our usual practice would have been to apply a superabsorbent dressing or silver-containing foam/Hydrofiber®. The paste was easy to apply and the patient found it comfortable during wear and on removal.



Figure 1: At the start of treatment with Calgitrol® Paste.



Figure 2: At week one the wound contained less slough and was granulating well.



Figure 3: As the wound was progressing well at week 2, treatment was continued for a further 10 days.



Figure 4: At follow-up, one month after the end of treatment with Calgitrol® Paste. There was no recurrence of infection and the wound continued to progress towards healing.

CASE2: PARTIAL FOOT AMPUTATION WOUND

Samantha Haycocks/Paul Chadwick, Department of Podiatry and Foot Health, Salford Royal Hospital, UK

BACKGROUND

The patient was a 42-year-old man with type 2 diabetes since 2000, chronic venous hypertension, diabetic retinopathy and hypertension. He presented to the acute outpatient clinic following a 1st ray amputation of the right foot six weeks previously. He had a history of ulceration and osteomyelitis, which had not responded to treatment. Following surgery, the wound was treated with NPWT and a superabsorbent dressing.

On presentation, the wound measured 62mm x 51mm and had 50% granulation tissue and 50% slough with low levels of exudate. The surrounding skin was healthy and intact, with no maceration or localised erythema at the wound edge (Fig 1). A wound swab revealed group B *Streptococcus*, mixed skin flora and yeast.

TREATMENT

It was decided to treat the wound locally with Askina® Calgitrol® Paste to reduce the wound bioburden. This was covered using a low-adherent absorbent dressing (Melolin®, Smith & Nephew) and a type 1 conforming and retention bandage (KSoft®/KBand®, Urgo Medical). In addition, the patient was started on a course of systemic antibiotics (co-amoxiclav and ciprofloxacin) due to the high risk of osteomyelitis. The dressings were changed every two days by the district nurses.

Week 1: The condition of the wound bed had improved with 60% granulation tissue coverage and 40% slough. The level of exudate had decreased (Fig 2). It was decided to continue the dressing regimen for a further week together with the antibiotics.

Week 2: At a review one week later there was an increase in the granulation tissue in the wound bed and the wound was progressing towards healing. The wound had decreased in size slightly to 62mm x 50mm. Calgitrol® Paste was continued for a further three weeks as the wound continued to improve (Fig 3).

OUTCOME

A further wound swab post-treatment showed no bacterial growth and signs of infection had resolved (Fig 4). Askina® Calgitrol® Paste was found to be easy to use and offered an effective alternative product to other silver-containing dressings or topical antimicrobial treatments. The clinical staff rated the overall performance of the paste as very good and the patient was very satisfied with the outcome.



Figure 1: At the start of treatment with Calgitrol® Paste



Figure 2: At one week there were signs of improvement and reduced exudate.



Figure 3: At four weeks, the wound had continued to improve.



Figure 4: At the end of treatment with Calgitrol® Paste signs of infection had resolved.

CASE 3: PARTIAL FOOT AMPUTATION WOUND

Frans Meuleneire, Wound Centre, AZ St-Elisabeth - Zottegem, Private Wound Centre Hillegem, Belgium

BACKGROUND

The patient was a 72-year-old gentleman with type 1 diabetes, polyneuropathy and hypertension. He underwent amputation of the second metatarsal on the right foot in July. He subsequently developed osteomyelitis and was admitted to hospital.

He presented with an infected metatarsal wound on the right foot, which was resected (Fig 1). It appeared inflamed but there were no signs of pus. The wound measured 8cm x 2.5cm and 1.5cm deep. A wound swab revealed *Pseudomonas aeruginosa*. He was started on systemic antibiotics (ciprofloxacin and clindamycin).

TREATMENT

Negative pressure wound therapy was applied for four weeks following surgery at which time the wound measured 6.5cm x 0.9cm and 0.8 cm deep. It was decided to apply Askina® Calgitrol® Paste to avoid possible infection due to the patient's poorly controlled diabetes. This was able to conform to the wound bed easily (Fig 2). The paste was covered with a cotton gauze dressing and retention bandage.

The dressing was changed every two days to allow the nursing staff to monitor the wound. After two weeks the wound was granulating well with a significant reduction in the wound depth (6cm x 0.7cm x 0.3cm) (Fig 3).

OUTCOME

The nurses found the paste easy to apply and it could be removed by cleansing with saline and a sterile gauze. The patient did not report any pain or discomfort on dressing removal and the paste was found to be comfortable when *in-situ*. There was a significant improvement in the wound bed with almost complete re-epithelialisation at 8 weeks' follow-up (Fig 4). The wound went on to heal.



Figure 1: Day 7 following resection of the infected metatarsal.



Figure 2: Four weeks post-surgery at the start of treatment with Calgitrol® Paste.



Figure 3: Two weeks after the start of treatment with Calgitrol® Paste.



Figure 4: The wound eight weeks post-surgery.

CASE 4: ISCHAEMIC TOE ULCER

Katharine Speak, Clinical Lead Podiatrist – Diabetes, Centre for Diabetes and Endocrinology, York Hospital, Wiggington Road, York, UK

BACKGROUND

The patient was a 93-year-old lady who had been referred to the multi-disciplinary foot clinic by the vascular surgeon. Her past medical history included peripheral arterial disease, right-sided heart failure, atrial fibrillation, valvular heart disease and the patient had difficulty hearing. She lived independently with help from her daughters and her ability to self-care was good.

The patient was first admitted with an ischaemic great toe and a subungual ulcer, which had been present for approximately one month. A superior femoral artery angioplasty was carried out at this time and was deemed successful, resulting in in-line flow. When she subsequently presented in the podiatry clinic, one month following angioplasty, the nail had avulsed. The wound, which was approximately 15mm x 20mm and probed to bone, was malodorous and covered with 100% heavy sloughy tissue, which was difficult to sharp debride using forceps. Exudate levels were high with strikethrough to the dressing. The wound had been previously treated with an iodine dressing, which had irritated the skin and caused the patient discomfort at night. The dressing had been applied tightly, which had led to constriction of the base of the toe and the development of a second ulcer (Fig 1).

TREATMENT

The wound bed was cleaned with saline and Askina® Calgitrol® Paste was applied. A secondary foam dressing was used to manage the exudate. The dressing was changed every three days by the district nurse in the patient's home.

Week 1: At review one week later, the level of exudate had decreased. The slough had lifted with granulation tissue showing in small areas of the wound, although bone was still visible (Fig 2). There was still some erythema but the patient reported greater comfort and undisturbed sleep. The wound was cleaned and debrided of slough using a scalpel. The paste was continued for a further week, with twice weekly dressing changes performed by the district nurse. The paste was also applied to the ulcer at the base of the toe.

Week 2: At the next dressing review, the nail bed was clean and granulating well with new fragile tissue covering the bone. The exudate level had decreased further with less periwound maceration. Swelling and erythema were much reduced. The ulcer at the base of the toe was virtually healed (Fig 3). The patient continued to report no discomfort. It was decided to discontinue Calgitrol® Paste as it was considered safe to switch to a silicone-backed foam dressing (Mepilex®, Mölnlycke Health Care).

OUTCOME

Calgitrol® Paste contributed to successful wound progression by managing the wound effectively. The surrounding skin improved and the dressing was found to be comfortable by the patient, improving her quality of life. The nurses found it easy to apply. The paste stayed in place during wear time and could be removed easily at dressing changes using saline solution. Due to the efficacy of the dressing, the patient did not require systemic antibiotic therapy. The patient was very pleased with the outcome.



Figure 1: The wound on presentation. The wound bed was 100% sloughy with erythema and maceration of the surrounding skin.



Figure 2: At week one the wound was progressing well with a reduction in the signs of infection.



Figure 3: Significant progress was noted after two weeks. Calgitrol® Paste was discontinued and a silicone-backed foam was applied.

CASE 5: METATARSO-PHALANGEAL JOINT

Kerry Collins, Podiatry Diabetes and Foot Ulcer Clinic, Paulsgrove Healthy Living Centre, Paulsgrove, UK

BACKGROUND

The patient was a 70-year-old gentleman with type 2 diabetes, a long-standing wound to the plantar aspect of the left foot and 2nd metatarso-phalangeal joint, and a history of recurrent infection. He had recently sustained a traumatic injury to the foot, which necessitated emergency hospital admission to suture the wound. The patient was also placed on a course of intravenous antibiotics.

The wound was slow to improve and the patient was seen in clinic three weeks following the accident. The wound was slightly inflamed, but there was no evidence of infection and the suture area had healed. However, the patient was admitted as an emergency admission two weeks later and underwent surgery to amputate his toe due to underlying osteomyelitis. The metatarsal head was removed.

TREATMENT

The decision was made to start Askina® Calgitrol® Paste four days post-surgery to treat any infection present. Systemic antibiotics were not considered necessary.

Prior to application, the wound was cleansed with a wound irrigation solution (Prontosan®, B Braun). Calgitrol® Paste was applied to the cavity and covered with a secondary dressing to manage the exudate and protect the wound from bacterial contamination.

The dressings were changed by the patient's wife every two days. Dressing change frequency was reduced as exudate levels decreased.

The patient was reviewed in the podiatry outpatient clinic on a weekly basis. At week 1 there was a noticeable improvement in the wound with a reduction in the depth of the cavity and formation of normal healthy granulation tissue.

At week 2, Calgitrol Paste was discontinued as there was no longer a cavity to fill. The dressing was changed to Askina® Calgitrol® THIN for one week and then to a non-adherent dressing and gauze.

OUTCOME

The wound healed better than expected: the patient had previously had a 5th toe amputated on his right foot and this had taken several months to heal. The patient's wife found the paste simple and easy to apply compared with other dressings used in the past. She liked the fact that there was no cutting of the dressing involved, which she had previously found difficult. Unlike conventional dressings, which require pushing into the cavity, she felt reassured that dispensing the paste from a tube allowed a no-touch technique and meant she was not contaminating the wound during dressing changes.



Figure 1: Four days post-surgery prior to application of Askina® Calgitrol® Paste. The cavity depth was >12mm.



Figure 2: One week post-surgery.



Figure 3: Two weeks post-surgery.



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