

Evaluating the effectiveness of KerraContact Ag dressings in the treatment of infected leg ulcers

KEY WORDS

- ▶ Exudate
- ▶ Pain reduction
- ▶ Silver oxysalts
- ▶ Wound infection

Background: Recent evidence suggests that dressings containing silver oxysalts, that is silver in its most active state (Ag^+ , Ag^{2+} , Ag^{3+}), are more efficient at killing bacteria than dressings containing commercially available silver (Ag^+), thereby making them more cost efficient as fewer dressings are required to eliminate infection. This UK product evaluation which sought to determine the effectiveness of a novel dressing, KerraContact™ Ag with Ag Oxysalt technology, on infected leg ulcers. **Method:** Patients with infected leg ulceration were recruited from 10 tissue viability clinics across the UK. Parameters evaluated included clinical signs and symptoms of infection — pain, exudate, odour and swelling/heat/redness. Background information and patient experience were also recorded. **Results:** Thirty-one patients were included. Pain levels reduced significantly or completely in 43% of patients; exudate levels reduced in 83%; wound odour reduced in 77%; swelling/heat/redness reduced in 75%. Two wounds (9.5%) healed by week four; the remaining 90% ($n=19$) had improved. **Conclusion:** The KerraContact Ag dressings had high levels of acceptability by the clinicians and patients who participated in the evaluation and could be to be an effective dressing of choice for managing infected chronic leg ulceration.

A plethora of evidence demonstrates that chronic leg ulceration has a profound negative impact on the quality of life of patients (Douglas, 2010; Isaac, 2016; Lerneval et al, 2017) and that the treatment and management of ulcers are costly (Guest et al, 2016; Guest et al, 2017). Infected wounds cause further distress to the patient due to the presence of exudate, odour and pain. Infection can delay healing, thus incurring extra management costs. It has been suggested that the majority of leg ulcers are colonised with bacteria (Harker, 2001); therefore, one aim of management is to prevent the wound moving from colonised to localised infection (critical colonisation) or systemic infection (Schultz et al, 2003; Gray et al, 2010). A baseline of the wound should be recorded during the first holistic assessment and at each dressing change thereafter, documenting changes in the wound bed and peri-wound area including changes in pain, redness, odour and exudate (Ousey and Cook, 2012).

While silver has been used for centuries to manage infected wounds, it is only in recent

years that its action has become more widely understood; silver ions either bind to the cell membrane and disrupt the cell wall causing it to leak, or bind to proteins, interfering with energy production, enzyme function and cell replication. In order to kill bacteria, a silver atom (Ag or Ag^0) has to lose electrons to be ionic (positively charged Ag^+); the fewer the electrons remaining, the more reactive the silver. A 2010 *in vitro* study suggests that in addition to being active against a broad range of bacteria, fungi and viruses, silver may reduce bacterial adhesion, destabilise a biofilm matrix, and kill bacteria within the matrix (Kostenko et al, 2010).

In wound care, silver and other antibacterial dressings are indicated to:

- ▶ To reduce bioburden in acute or chronic wounds that are infected or are being prevented from healing by microorganisms
- ▶ To act as an antimicrobial barrier for acute or chronic wounds at high risk of infection or re-infection (Expert Working Group, 2012).

DONNA
WOOLSTENCROFT
Community Staff Nurse,
District Nursing Service,
Tameside and Glossop
Integrated Care NHS
Foundation Trust

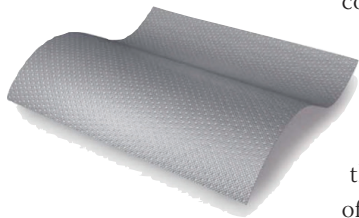


Figure 1.
KerraContact Ag Dressing

Currently, the majority of these dressings contain elemental silver (silver metal, nanocrystalline silver) — as an inorganic compound (silver oxide, silver sulphadiazine) or silver as an organic complex (silver-zinc, allantoinate, silver alginate) — which can coat the dressing, be incorporated into the structure of the dressing, or both (Expert Working Group, 2012).

Ag dressing in the management of infected venous, arterial or mixed aetiology leg ulcers. KerraContact™ Ag dressing with Ag Oxysalts™ is an advanced silver wound contact layer dressing. It is comprised of two non-adherent polyethene mesh wound contact layers and a polyester core (Figure 1). The Ag Oxysalts technology is effective in reducing bacterial and biofilms within one week (White and Parker, 2015), and is suitable for locally infected or critically colonised wounds.

HIGHER OXIDATION STATE SILVER

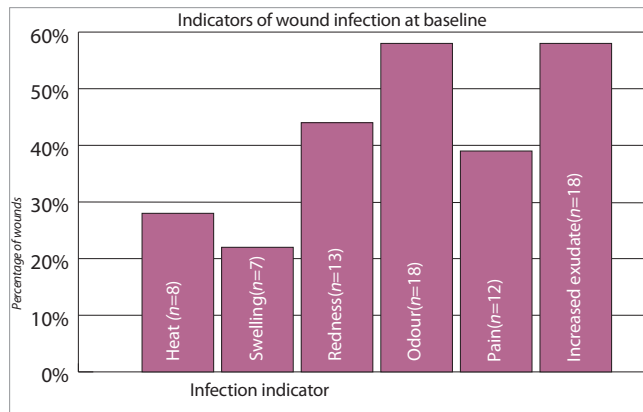


Figure 2. KerraContact Ag Dressing

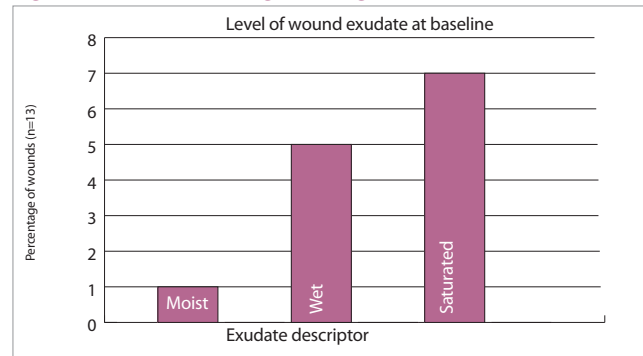


Figure 3. KerraContact Ag Dressing

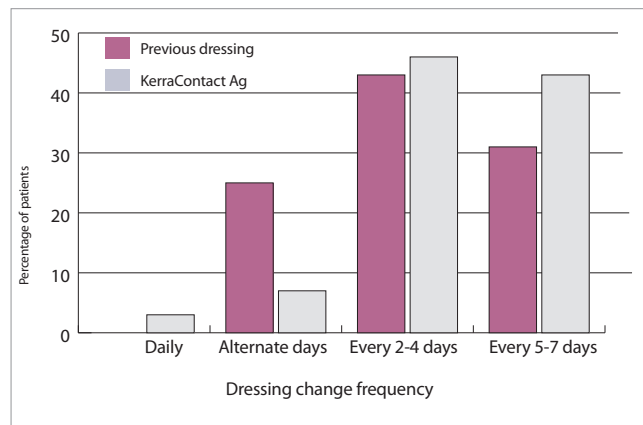


Figure 4. KerraContact Ag Dressing

The concept of ‘supercharged’ silver added to dressings is gaining momentum and evidence is supporting its effectiveness for infected leg ulceration, where the objective is to reduce the signs and symptoms of infection and allow compression to treat the underlying cause (Sibbald et al, 2012; Lemire et al, 2015; Beasley, 2016; Young et al, 2016). Higher oxidation states of silver (Ag⁺, Ag²⁺, Ag³⁺) known as silver oxysalts, are being incorporated into dressings based on the notion that the higher the positive charge, the more effective the action of silver (Spina, 2012).

DRESSING EVALUATION

The primary aim of this UK-wide evaluation was to demonstrate the clinical effectiveness of KerraContact™

METHOD

The study took place between February and July 2017 in 10 clinics across the UK. Inclusion criteria included the presence of wound infection identified through clinical diagnosis and the ability to give informed written consent. Four patients, two of whom were diabetic and two had rheumatoid arthritis, whose wounds were not demonstrating the clinical signs and symptoms of infection were also included as due to their comorbidities, they were at high-risk of infection. The study dressings were used as replacements for the silver dressings they were currently using.

For each patient, clinicians completed an evaluation form designed to collect data relating to the clinical signs and symptoms of infection — pain, exudate, odour and swelling/heat/redness. Background information and patient experience was also recorded. For the purposes of this evaluation, wound size was not assessed as the aim was purely to evaluate the ability of the dressing to reduce the signs and symptoms of infection; once the infection was cleared, a different dressing would be required to continue to healing.

RESULTS

A total of 31 evaluations were completed from a number of Trusts across the UK. Each evaluation lasted four weeks. Patient demographics and wound assessment at baseline are as follows:

Of the 31 included in the evaluation, 52.9% (n=9) were male, 47% (n=8) were female (17 responses), whose ages ranged from 30 (13.3%, n=2) to over 90 (13.3%, n=2) (15 responses). Wound duration ranged between 1 and 3 months (6.6%, n=1) and over 3 years (46.6%, n=7) (15 responses). Twenty-six wounds (80.6%) were venous (30 responses).

The clinical indicators of infection; heat, swelling,

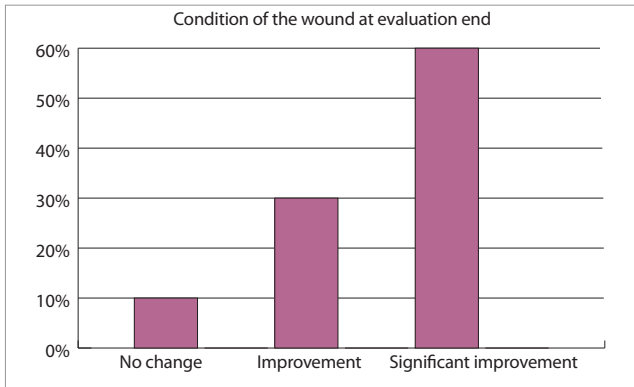


Figure 5. KerraContact Ag Dressing

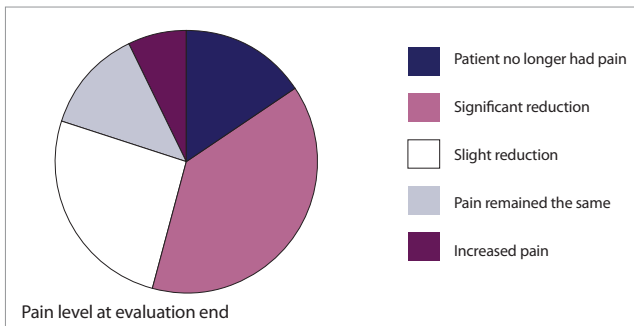


Figure 6. KerraContact Ag Dressing

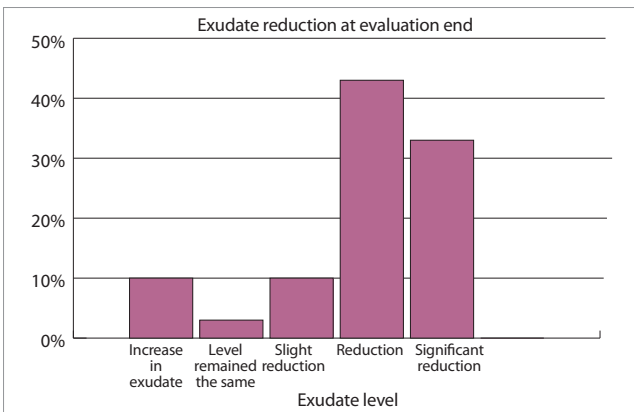


Figure 7. KerraContact Ag Dressing

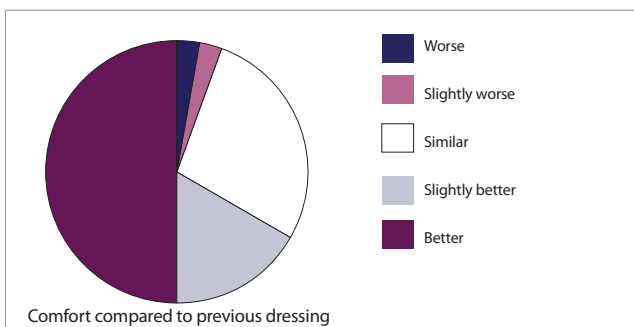


Figure 8. KerraContact Ag Dressing

redness, odour, pain and increased exudate, are shown in *Figure 2*. A solution of sterile normal saline was used to cleanse wounds in 53.8% ($n=7$) of patients (13 responses). Eight patients (36.3%) were taking antibiotics (22 responses); of these, 60% ($n=6$) had been taking them for up to a week, 20% ($n=2$) for between 1 and 2 weeks, and 20% ($n=2$) for over 2 weeks (10 responses).

Exudate was reported as low (moist) in 7.6% ($n=1$), moderate (wet) in 38.4% ($n=5$) and high (saturated) in 53.8% ($n=7$) (*Figure 3*). Peri-wound maceration was present in 69.2% ($n=9$) of wounds (13 responses). All patients had been assessed previously using a holistic approach to rule out any underlying causes of leg ulceration, and ABPI was recorded, those patients diagnosed as having venous aetiology were treated in the therapeutic amount of compression, i.e. 40mmhg. Of the four patients who were diagnosed as having mixed aetiology ulcers, two were diabetic and two had rheumatoid disease.

Fifteen patients (48%) had been using

a silver-containing dressing before entering the study, the most common being Aquacel Ag Extra ($n=7$, 46.6%). Two patients (6.4%) had Flaminal and Silvercel applied. Wounds had been assessed at each dressing change and fully reassessed at two weeks of using silver; those wounds which had shown progression of healing but increase in infection continued to receive a silver regime as stated by Carter et al (2010).

The evaluation dressing was used for an average of 19 days (range 7–28 days [22 recorded]). The frequency of dressing change was reduced compared to previous dressing used; the number of dressings remaining in place for 5–7 days increased from 31.2% ($n=5$) (16 responses) to 42.8% ($n=12$) (28 responses) (*Figure 4*).

Thirty clinicians reported that the dressing reduced the signs and symptoms of wound infection. Analysis of the results indicated that 2 (7%) wounds healed by week four. Improvements were seen in the remaining 93% ($n=28$) (*Figure 5*).

Wound odour was reduced in 77% of wounds; in 64.4% ($n=20$) of these, odour reduced or significantly reduced (31 responses). Of the 25 (80.6%) sets of data recorded pertaining to pain, it was noted that 52% ($n=13$) of patients reported a significant or complete reduction in pain (*Figure 6*).

Figure 7 shows the reduction in exudate levels. Overall, levels were reduced in 83% of patients, of which, 77% ($n=23$) indicated exudate reduced or significantly reduced (30 responses).

Patient feedback

Fifty-six percent ($n=17$) of patients indicated that the dressing was slightly better or better than their previous dressing in terms of comfort (*Figure 8*).

Clinician feedback

Of the thirty-one clinicians, 80.6% ($n=25$) reported that the dressing was easy to apply, with 77.4% ($n=24$) stating that removal was also easy (31 responses). In 50% ($n=15$) of cases, clinicians indicated that the dressings exceeded their expectations, 46.6% ($n=14$) indicated that it met expectations (30 responses), and 90% stated that they would be happy to continue using the KerraContact Ag dressing. Clinicians were asked to report their views of the dressing. These are outlined in *Box 1*.

Box 1. Clinician views of dressing

- ▶▶ Easy to apply; doesn't require wetting
- ▶▶ Easy to cut ... pain-free removal ... doesn't stick
- ▶▶ Good 'kick-start' to the wound
- ▶▶ Significant improvement noted after 1 week. Patient reported dressing was comfortable. Patient initially distressed at malodour was pleased with final results
- ▶▶ Product has cleaned all sloughy areas ... it is left on for 7 days – less stress on dressing change weekly
- ▶▶ Easy to apply and patients pain was controlled
- ▶▶ Exudate management. Noticeable reduction in wound size
- ▶▶ Patient reluctant at first as has multiple sensitivities but was impressed with comfort and results
- ▶▶ Patient was non-concordant so wound did deteriorate without KerraContact Ag for almost 2 weeks but was more than happy to continue once he returned to clinic
- ▶▶ Patient redresses between appointments and feels there has been an improvement in the wound
- ▶▶ Patient is happy with improvement. Has changed from wet and malodorous to practically slough free and smaller.

DISCUSSION

The management of infected chronic leg ulceration can be challenging to clinicians. When the signs and symptoms of infection are detected it is important that they are managed rapidly to help reduce the risk of further complications (Posnett and Franks, 2008; Guest et al, 2017).

In relation to decreasing the signs and symptoms of infection, the results of this small evaluation are similar to others. Sibbald et al (2012) undertook a 20 patient case series to explore the use of KerraContact Ag for the treatment of critically colonised, stalled chronic leg and foot ulcers and results showed that mean pain scores reduced over an 8 week period ($n=20$). KerraContact Ag was also clinically effective in reducing wound size in 16 out of 20 stalled chronic wounds with critical colonisation. A further study by Lemire et al (2015) showed that KerraContact Ag was fast and powerful ($4 \times \log_{10}$ reduction in ≤ 4 hours) against all tested wound pathogens in planktonic cultures *in vitro* and demonstrated sustained activity against common wound pathogens in simulated wound fluid over 7 days, demonstrating superior performance compared with competitor dressings.

A case study report by Beasley (2016) aimed to assess the effectiveness of KerraContact Ag in treating wound infection when used for 7 days. Reduction in signs and symptoms of infection and any changes in the wound appearance were noted. Patient 1 demonstrated a 60% reduction in thick, green slough, a reduction in wound size, and an

increase in epithelial tissue. Patient 2's wound had a suspected biofilm, yet after seven days wear, most sloughy tissue had been removed and granulation tissue was present. While this study, as with the present evaluation, investigated the effect of KerraContact Ag on infection indicators, the data also showed that the wounds were on a healing trajectory after 4 weeks (Kimmel, 2013), suggesting that they would go on to heal. This small evaluation showed similar results in reducing the signs and symptoms of infection.

Young et al (2016) in a study of 15 patients receiving KerraContact Ag for infected venous leg ulcers showed a 52% mean healing rate after 4 weeks; predictors of healing state that if they reduce in area by 40% in 4 weeks the wound will track to healing (Kimmel, 2013). In addition, moderate to high levels of wound exudate reduced from 94% to 47%, a 79.5% reduction in purulent exudate from week 1 to week 4. Pain also decreased at all time-points assessed (upon application, during wear and upon removal). This reduction in pain is indicative of a decrease in infection (Cutting, 2008)

The assessment of the cost effectiveness of wound treatments is not straightforward; direct and indirect costs such as the inability to work and social isolation, and consequent reduction in quality of life can be difficult to measure (Expert Working Group, 2012) and more recently the personal and financial implications of sub-optimal and optimal care are compared in Betty's Story (NHS England, 2017). However, several studies have demonstrated beneficial effects of using silver dressings for the management of infected wounds on the overall cost and quality of life parameters. In this evaluation, 47% ($n=7$) of participants' wound duration was greater than three years. Ashby et al (2014) postulate that the annual cost of treating a leg ulcer is £1,700; extrapolating from this figure, the cost of treating their ulcer would be approximately £35,700 ($\text{£}1,700 \times 7 \times 3$). In addition, eight patients (36.3%) were taking antibiotics at baseline (22 responses); of these, 60% ($n=6$) had been taking them for up to a week, 20% ($n=2$) for between 1 and 2 weeks, and 20% ($n=2$) for over 2 weeks (10 responses), an additional cost and against National Institute for Health and Care Excellence (NICE) guidance, which suggest that 'The use of a clinically effective antimicrobial dressing to treat the infection would reduce the

need for prolonged use of antibiotics' (NICE, 2016).

The evaluation dressing can further save resources; reducing the number of dressing changes minimises wound bed disturbance and/or damage and reduces the time required at clinic for both healthcare professionals and patients. These benefits, in addition to the rapid clearance of the signs and symptoms of infection and faster wound healing can improve patient's quality of life.

LIMITATIONS

It should be acknowledged that the reduction in signs and symptoms of infection were to a degree, subjective as wound swabs were not sent for culture during or after the study. In addition, this was a small evaluation due in part to the limited time-period and because in some cases, clinicians were reluctant to try a dressing which was not on their local formulary.

It is assumed that those patients who were receiving compression at entry into the study remained in compression as this was not recorded.

CONCLUSION

This summary of evaluations clearly demonstrates the positive impact of KerraContact Ag dressings for managing the signs and symptoms of infected wounds. KerraContact Ag dressings were verified to have high levels of acceptability by the clinicians and patients who participated in the evaluation, could be to be an effective dressing of choice for managing infected chronic leg ulceration. WUK

CONCLUSION

Ashby RL, Gabe R, Ali S, Adderly U et al (2014) Clinical and cost-effectiveness of compression hosiery versus compression bandages in treatment of venous leg ulcers (Venous leg Ulcer Study IV, VenUS IV): a randomised controlled trial. *Lancet* 383(9920):871–9

Beasley A (2015) *A Clinical Case Study Of The Effective Treatment Of Wound Infection With KerraContact Ag*. Poster available at: <http://www.epostersonline.com/wnds2015/node/588> (accessed 12.04.2018)

Carter MJ, Tingley-Kelly K, Warriner RA (2010) Silver treatments and silver-impregnated dressings for the healing of leg wounds and ulcers: a systematic review and meta-analysis. *J Am Acad Dermatol* 63(4):668–79

Cutting KF (2008) Should evidence dictate clinical practice, or support it? *J Wound Care* 17(5): 216

Douglas V (2010) Living with a chronic leg ulcer: an insight into patients' experiences and feelings. *J Wound Care* 10(9):355–60

Expert Working Group (2012) *International Consensus: Appropriate use of Silver Dressings in Wounds*. Available at: <http://www.woundsinternational.com/consensus-documents/view/international-consensus-appropriate-use-of-silver-dressings-in-wounds> (accessed 12.04.2014)

Gray D, White R, Cooper P, Kingsley A (2010) Applied wound management and using the wound healing continuum in practice. *Wound Essentials* 5:131–9

Guest JF, Ayoub N, McIlwraith T, Ucheqbu et al (2016) Health Economic burden that different wound types impose on the UK's National Health Service. *Int Wound Jnl* 14(2): 322–30

Guest JF, Vowden K, Vowden P (2017) The health economic burden that acute and chronic wounds impose on an average Clinical Commissioning Group/Health Board in the UK. *J Wound Care*. 26(6):292–303

Harker J (2001) The effect of bacteria on leg ulcer healing. *BBr J Community Nurs* 6(3):126–34

Isaac A (2016) How venous leg ulcers affect quality of life. *Primary Health Care* 26(3):18–23

Kimmel HM (2013) An evidence-based algorithm for treating venous leg ulcers utilizing the Cochrane database of systematic reviews. *Wounds*. 25(9):242–50

Kostenko V, Lyczak J, Turner K, Martinuzzi RJ (2010) Impact of silver-containing wound dressings on bacterial biofilm viability and susceptibility to antibiotics during prolonged treatment. *Antimicrob Agents Chemoth*. 54(12):5120–31

Lemire JA, Kalan L, Bradu A, Turner RJ (2015) Silver oxynitrate, an unexplored silver compound with antimicrobial and antibiofilm activity. *Antimicrob Agents Chemother* 59(7):4031–9

Lerneval LSD, Fogh K, Nielsen CB et al (2017) Lived experiences of life with a leg ulcer - a life in hell. *EWMA Journal*. 17(1):15–21

NHS England (2017) *NHS RightCare Scenario: The variation between Sub-Optimal and Optimal Pathways; Betty's story: Leg Ulcer Wound Care*. Available at: <https://www.england.nhs.uk/rightcare/wp-content/uploads/sites/40/2017/01/nhs-rightcare-bettys-story-narrative-full.pdf> (accessed 12.04.2018)

National Institute for Health and Care Excellence (2016) *Evidence Summary. Chronic Wounds: Advanced Wound Dressings and Antimicrobial Dressings*. Available at: <https://www.nice.org.uk/advice/esmpb2/chapter/Key-points-from-the-evidence> (accessed 12.04.2018)

Posnett J, Franks PJ (2008) The burden of chronic wounds in the UK. *Nurs Times* 104(3):44–45

Schultz GS, Sibbald RG, Falanga V et al (2003) Wound bed preparation: a systematic approach to wound management. *Wound Repair Regen* 11 (Suppl 1):S1–28

Sibbald RG, Goodman L, Woo KY, Smart H, et al (2012) *A 20 Patient Case Series to Explore New Ionized Silver Dressing for Critically Colonized, Stalled Chronic Leg & Foot Ulcers*. Available at: http://usdev.crawfordhealthcare.com/images/docs/Coutts_20_patient_case_series_to_explore_ionized_silver_dressing.pdf (accessed 12.04.2018)

Spina C (2012) *Silver I, II, III: Chemical Characteristics, Properties, and Antimicrobial Activity*. Crawford Healthcare Ltd. Data on File.

Vermeulen H, van Hattem JM, Storm-Versloot MN, Ubbink DT (2007) Topical silver for treating infected wounds. *Cochrane Database Syst Rev*. (1):CD005486

White R, Parker J (2015) *Ag Oxysalts Made Easy*. Wounds UK. Available at: https://www.crawfordhealthcare.com/images/docs/KerraContact_Ag_web.pdf (accessed 12.04.2018)

Young S, Collarte A, Kincaid I, Lara L (2016) 'Super' silver: the answer to wound infection and biofilm management in venous leg ulcers? *Wounds UK* 13(3):63–7