20 years of innovation driven by Hydrofiber™

- Exudate management
- Silver for infection management
- Ag+ Technology for biofilm management
- Beyond conventional dressings – *Avelle* NPWT

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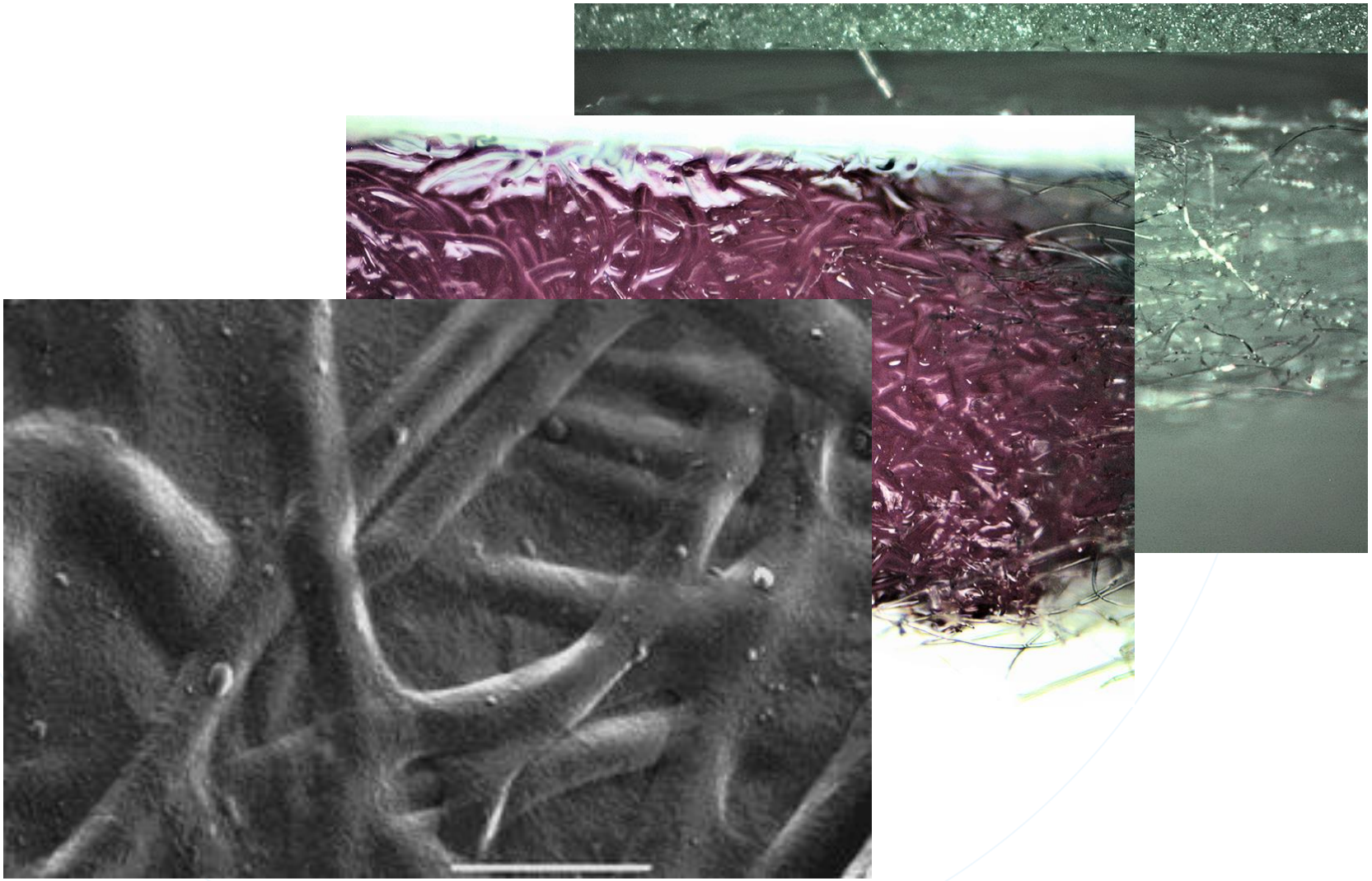
ConvaTec

Hydrofiber™ is the foundation

Hydrofiber™ absorbs & traps wound fluid & its components by rapidly gelling



Exudate management

- **20+ year** leader in absorbent fibre technology – Hydrofiber™ (**AQUACEL®**)
  - Absorption and retention of exudate, microbes, slough, enzymes…
  - Conformability and comfort

  - Additional absorption and strength (**AQUACEL® Extra**)

AQUACEL® Extra™
A heritage you can believe in

Look deeper into the unrivalled history and efficacy of the AQUACEL® family – you'll see it has been constantly evolving, answering wound care needs since 1996.

AQUACEL® Extra™ dressings, helping you to meet your day-to-day challenges safe in the knowledge there's the evidence.

20+ years of global clinical heritage

AQUACEL® family of dressings are the only CMC dressings powered by Hydrofiber® Technology

400 Million+ dressings sold

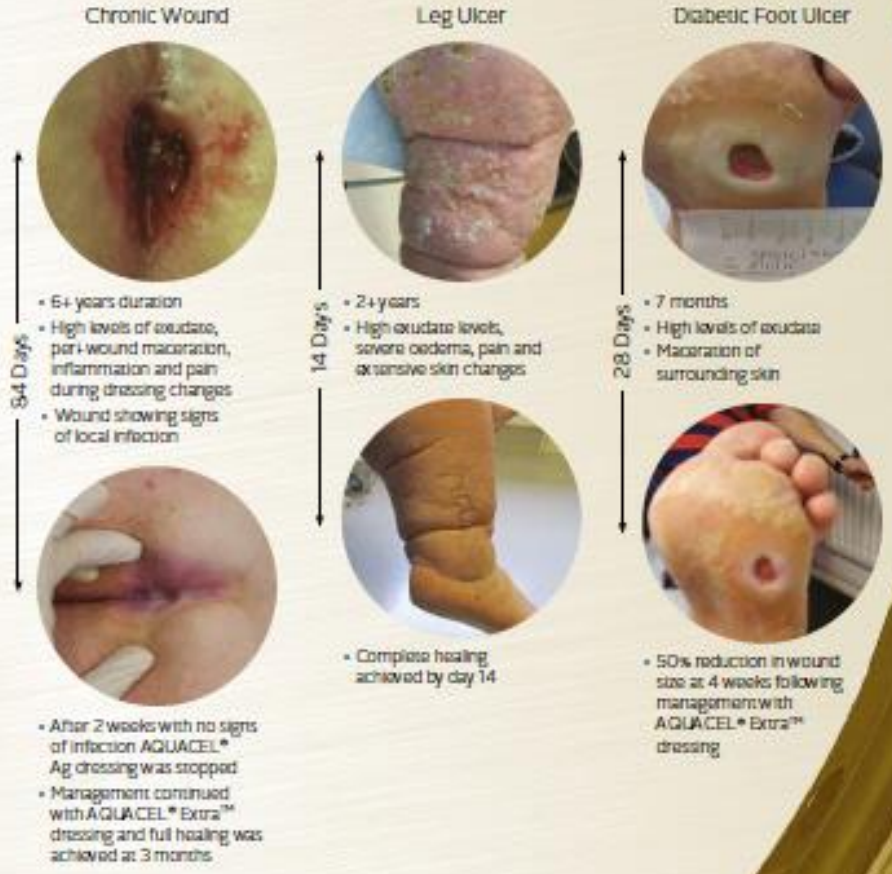
30 randomised controlled trials

More than **365** pieces of evidence

AQUACEL® Extra™
Proving itself on the wounds you treat every day

Designed for optimised healing

AQUACEL® Extra™ dressings are suitable for moderately to heavily exuding chronic and acute wounds.



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Exudate Management

- **20+ year** leader in absorbent fibre technology – Hydrofiber™ (**AQUACEL®**)
  - Absorption and retention of exudate, microbes, slough, enzymes…
  - Conformability, comfort and strength (**AQUACEL® Extra**)

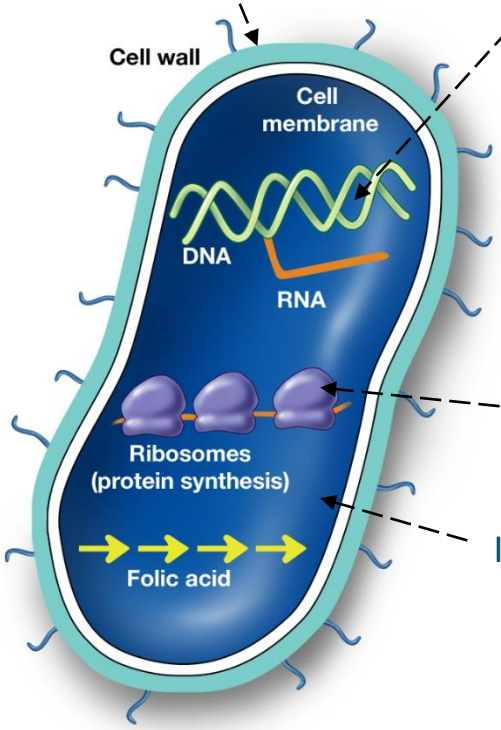
Infection Management

- **15 year** leader in ionic silver containing absorbent fibre technology (**AQUACEL® Ag… AQUACEL® Ag Extra™**)
  - Broad spectrum antimicrobial coverage
  - Enduring protection against microorganisms

Multiple modes of action of ionic silver (& other antiseptics)

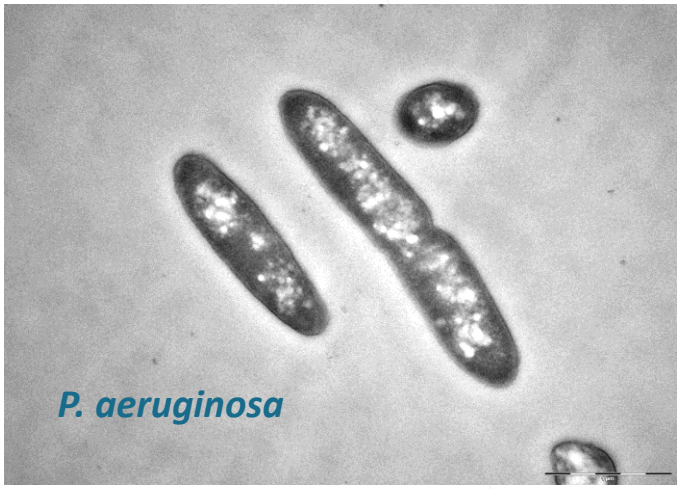
Damages the cell wall[1]

Interferes with DNA synthesis[1]

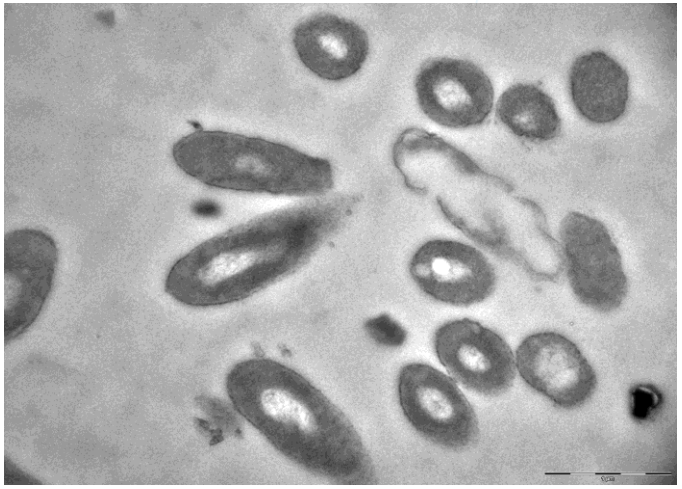


Denatures proteins & enzymes[1]

Inhibits protein synthesis[1]



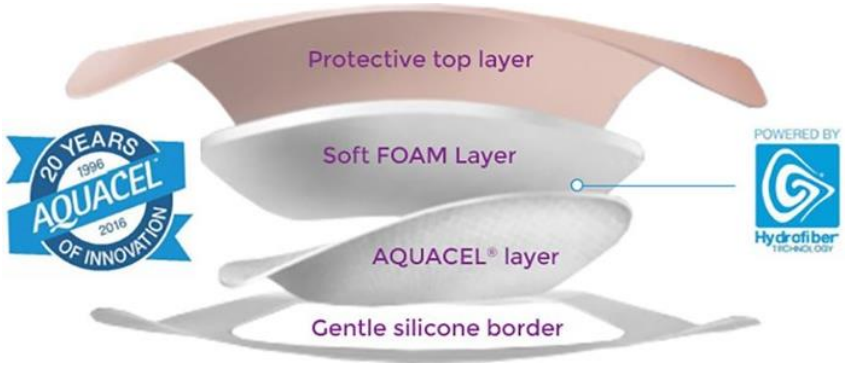
+ silver Hydrofiber™ dressing[2]



1. Castellano et al. Comparative evaluation of silver-containing antimicrobial dressings and drugs. Int Wound J 2007; 4: 114-122
2. Hobot et al. Effect of Hydrofiber Dressings on Bacterial Ultrastructure. J Electron Micro 2008; 57: 67-75

Core Hydrofiber™ & silver technology – Foam

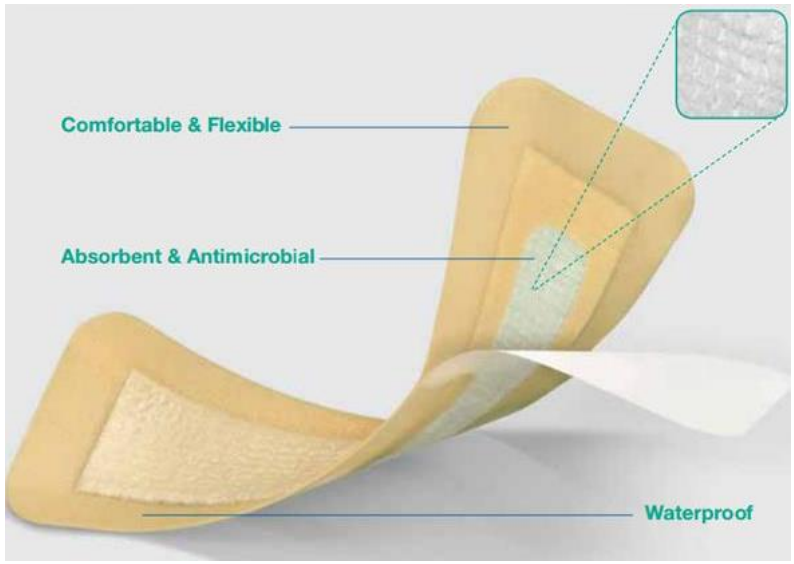
- **AQUACEL® Foam** and **AQUACEL® Ag Foam** dressings
- Differentiated from standard foam dressings:
  - Powered by Hydrofiber™ wound contact layer
  - Silver-containing versions for infection prevention and management



- **AQUACEL® Burn** and **AQUACEL® Ag Burn** dressings

Core Hydrofiber™ & silver technology – Surgical

- **AQUACEL® Surgical** and **AQUACEL® Ag Surgical** dressings
  - Powered by Hydrofiber™ wound contact layer
  - Silver-containing versions for infection prevention and management



- Now also in **AQUACEL® Surgical SP** and **AQUACEL® Ag Surgical SP** (slim profile) options

AQUACEL® Ag Surgical – latest evidence

- AQUACEL® Ag Surgical vs. gauze in **breast cancer surgery** (N=230)[3]
- SSI in AQUACEL® Ag Surgical group = 6.6%

  Gauze = 12.9%
- Breast salvage sub-set:
- AQUACEL® Ag Surgical group = 1.8% (n=1)

  Gauze = 10.8% (p=0.047)

LB04

A Randomized Controlled Trial on the Effect of a Silver Carboxymethylcellulose Dressing on Surgical Site Infections after Breast Cancer Surgery

G.M. Struik, W.W. Vrijland, E. Birnie, T.M.A.L. Klem

Franciscus Gasthuis en Vlietland, Surgery, Rotterdam, Netherlands

- Patient satisfaction; fewer dressing changes; lower wound management costs

- AQUACEL® Ag Surgical vs. antimicrobial gauze in **total knee arthroplasty** (N=240)[4]
- SSI in AQUACEL® Ag Surgical group = 0.8%

  Antimicrobial gauze = 8.3% (p=0.01)
- Longer wear time (5.2 days vs. 1.7 days), fewer dressing changes (1.0 vs 3.6)

3. Struik et al. A A Randomized Controlled Trial on the Effect of a Silver Carboxymethylcellulose Dressing on Surgical Site Infections after Breast Cancer Surgery. Eur Surg Res 2017; 58 (suppl 2):1-69.

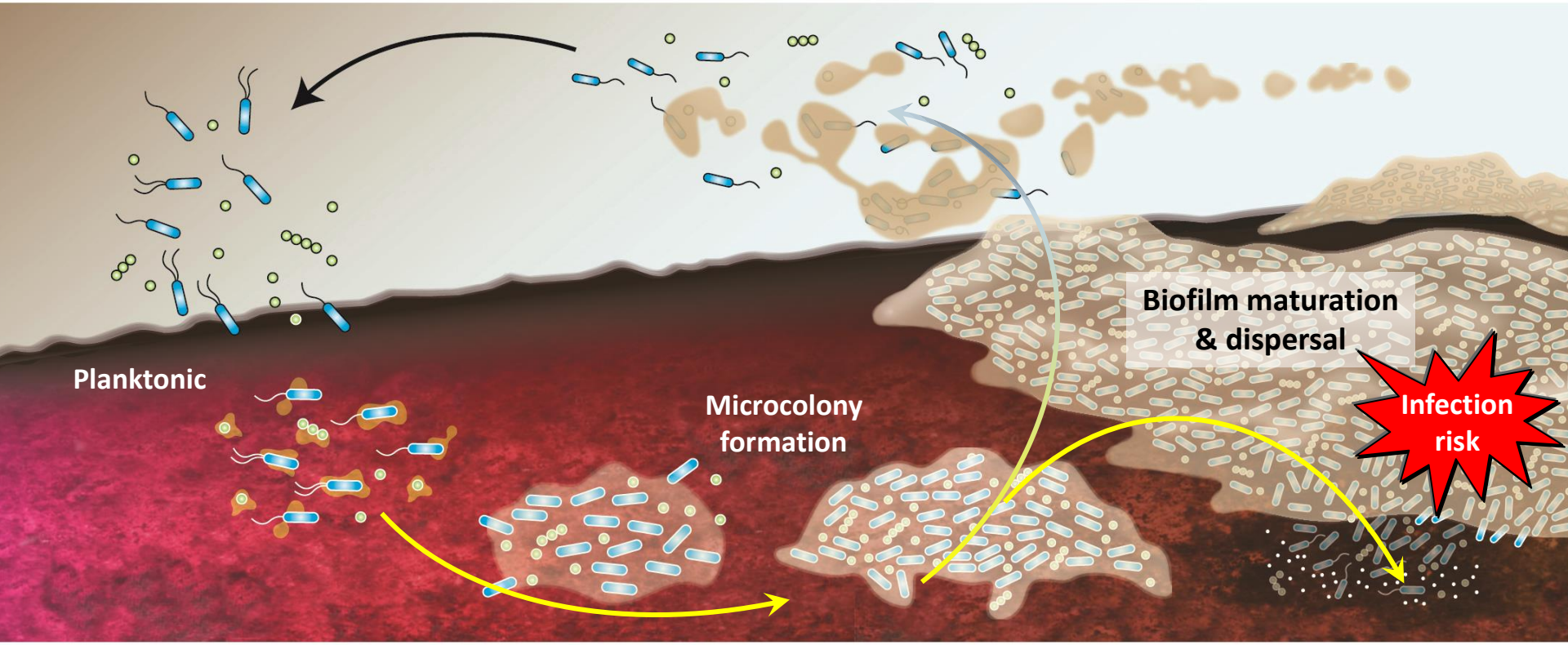
4. Kuo et al. AQUACEL Ag Surgical Dressing Reduces Surgical Site Infection and Improves Patient Satisfaction in Minimally Invasive Total Knee Arthroplasty: A Prospective, Randomized, Controlled Study. BioMed Res Int 2017, 1262108

Infection, delayed healing & biofilm

- **INFECTION** is well known to delay wound healing
  - Acute, inflammatory, immune response to the invasion of healthy tissue by pathogens, and toxins they produce
  - Infection results in the classic clinical signs and symptoms:
    - Redness, heat, swelling, pain, odour, etc.
  - Wounds become stuck in the inflammatory phase of the healing process

- 2010s: **BIOFILM** is now recognised as a precursor to **wound infection** and **delayed healing**
  - Elicits low-grade chronic inflammation
    - *"Critical colonisation"* or *"biofilm infections"*
  - This can lead to full-on clinical **wound infection**
  - Presence of biofilm itself is a physical barrier that can **delay wound healing**

Wound biofilm formation increases infection risk and delays healing



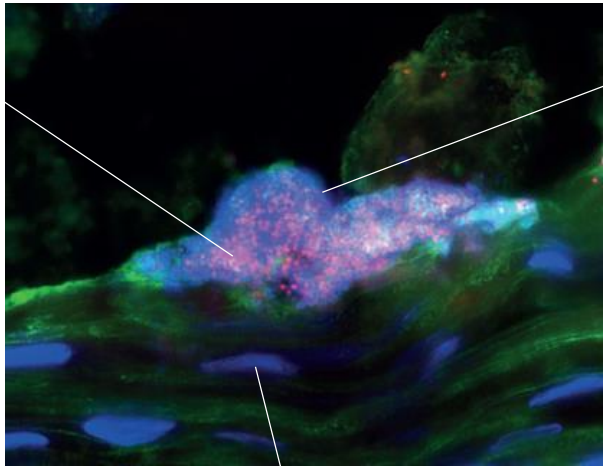
Clean wound → Contamination → Colonisation → Biofilm development
Inflammatory host response → Possible infection
Local → Spreading

Increasing risk of infection & delayed healing

Biofilm in wounds – meta-analysis[7]

- Analysis of the prevalence of biofilm in chronic wounds was conducted by a panel of international expert clinicians and scientists
- 9 published studies involving 185 chronic wounds were identified
- Biofilm was reported in **78%** of chronic wounds by microscopy

Biofilm microbes[8]



EPS ('slime')[8]

Epithelial cells[8]

7. Malone et al. *The prevalence of biofilms in chronic wounds: a systematic review and meta-analysis of published data*. J Wound Care 2017; 26: 20-25.
8. Oates et al. The visualization of biofilms in chronic diabetic foot wounds using routine diagnostic microscopy methods. J Diabetes Res 2014; 2014: 153586.

A dressing designed to manage biofilm

- Our challenge was to make **AQUACEL® Ag** more effective against biofilm
- Adding more silver was not the answer:
  - Could comprise patient safety & alter physical properties of the Hydrofiber™
  - *Not necessary* (more than enough bio-available silver in AQUACEL® Ag: 1.2%)
- Following 3 years of research, and testing 70,000 combinations, the optimum, synergistic combination of anti-biofilm agents was discovered:
  - **Biofilm-disrupting agent (metal chelator; EDTA)** – weaken biofilm structure; expose microorganisms to **silver**
  - **Surfactant (BEC)** – loosen biofilm; lift it off the wound bed; allow **silver** to move freely
  - **pH control** – pH 5.5 is optimum for **silver** efficacy, microbial suppression and wound healing

A dressing designed to manage biofilm

→ **Hydrofiber™ is <u>the same</u>** (AQUACEL)

→ **Silver content is <u>the same</u>** (Ag ions, 1.2%)

→ **Ag+ Technology™ is <u>new</u>**

→ **Exudate**

→ **Infection**

→ **Biofilm**

Biofilm-disrupting agent (EDTA)

Surfactant (BEC)

pH control **+ 1.2% ionic silver**

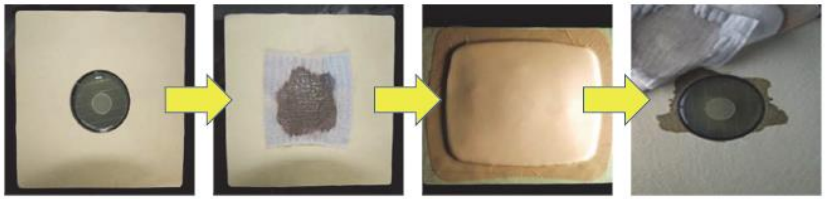
Locks in, contours, responds

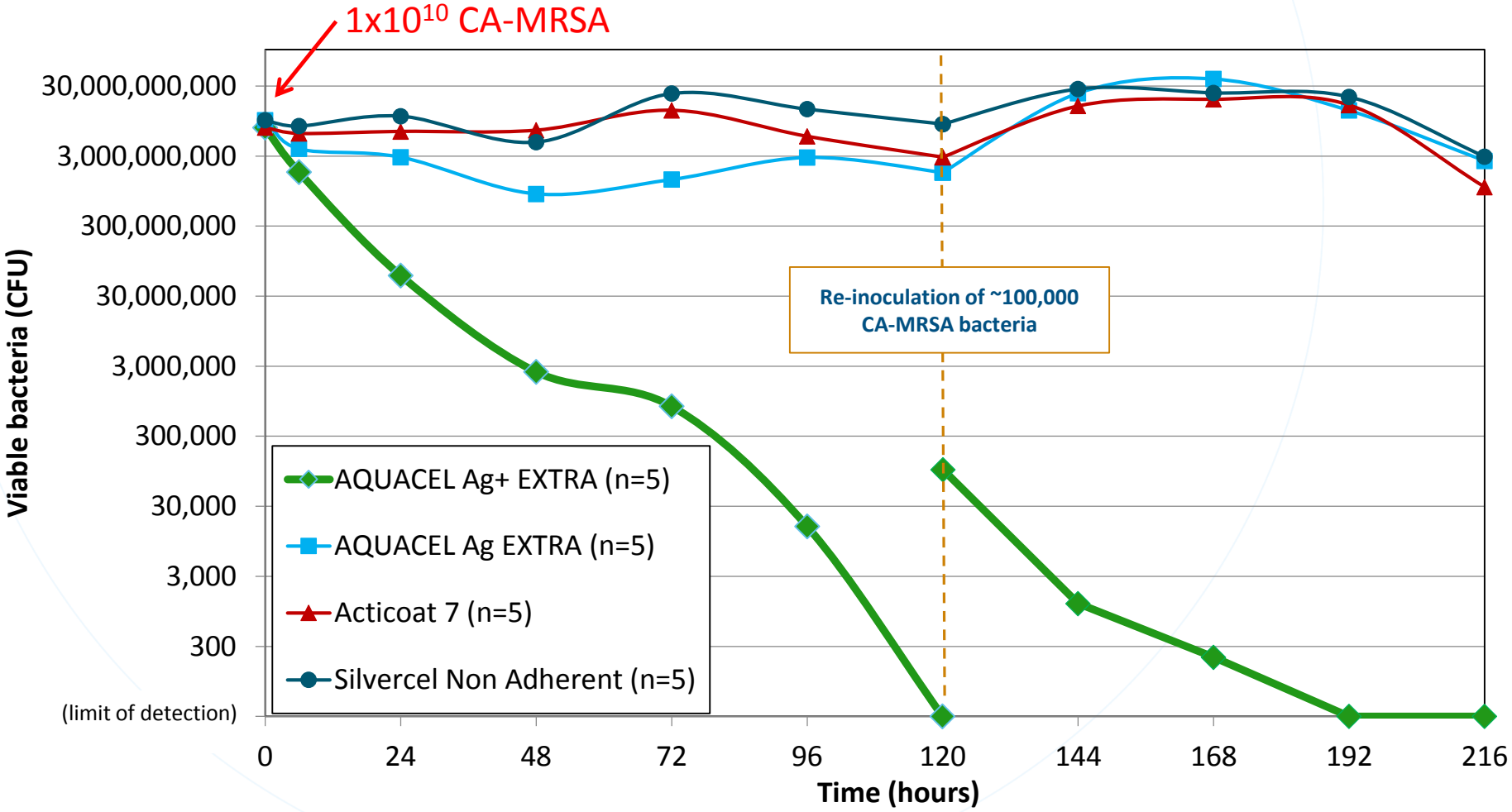
Disrupts, kills, prevents biofilm

AQUACEL® Ag+ Extra™

Laboratory anti-biofilm testing

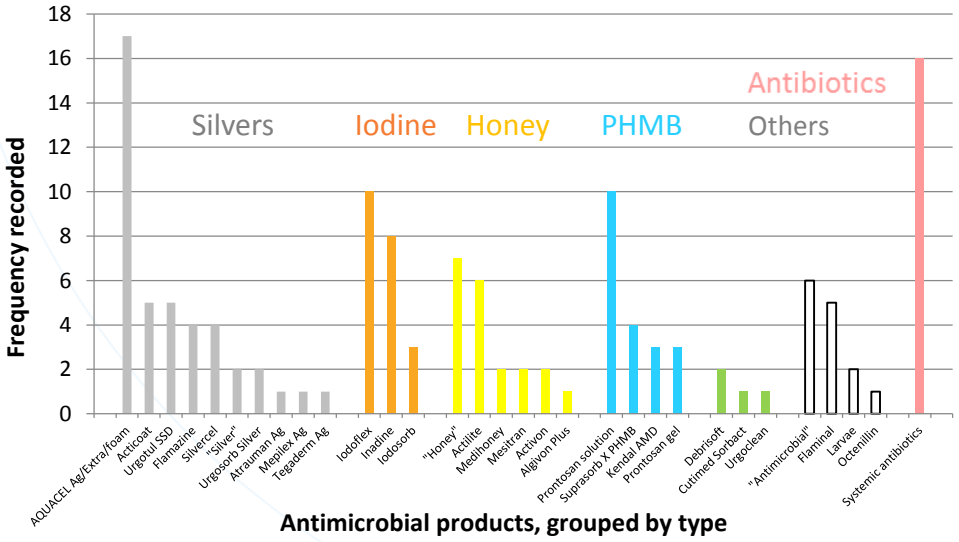
- Challenging *in vitro* wound biofilm model:

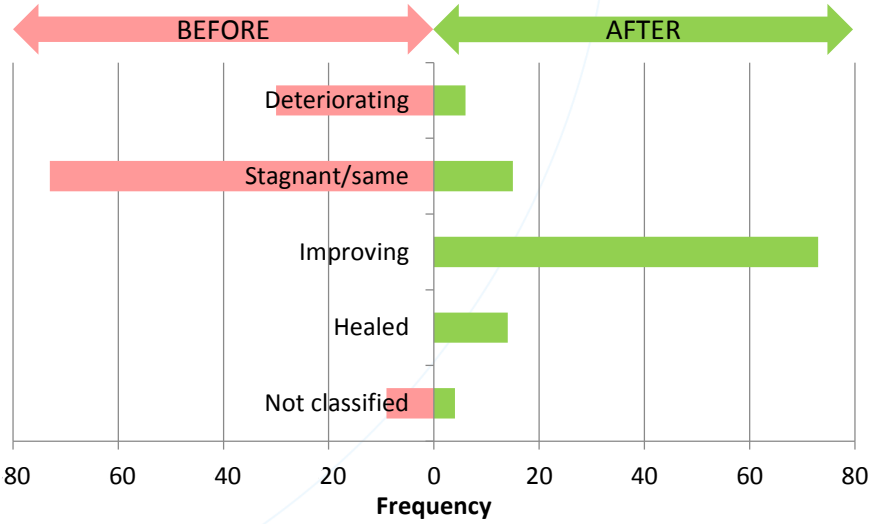




Safety and effectiveness clinical evaluation[9]

- 112 wounds (30% VLU); median duration 12 months (1 wk-30 yrs)
- 65% stagnant, 27% deteriorating; 31% judged infected, high biofilm suspicion (54%)
- Silver, iodine, honey, PHMB dressings & antibiotics, previously used:
- After switching to AQUACEL® Ag+ Extra™, in an average of 3.9 weeks:
  - **73 wounds improved**; **14 healed**, associated improvement in exudate & tissues
  - No more/fewer dressings were used than previously
  - Only 3 dressing-related adverse events

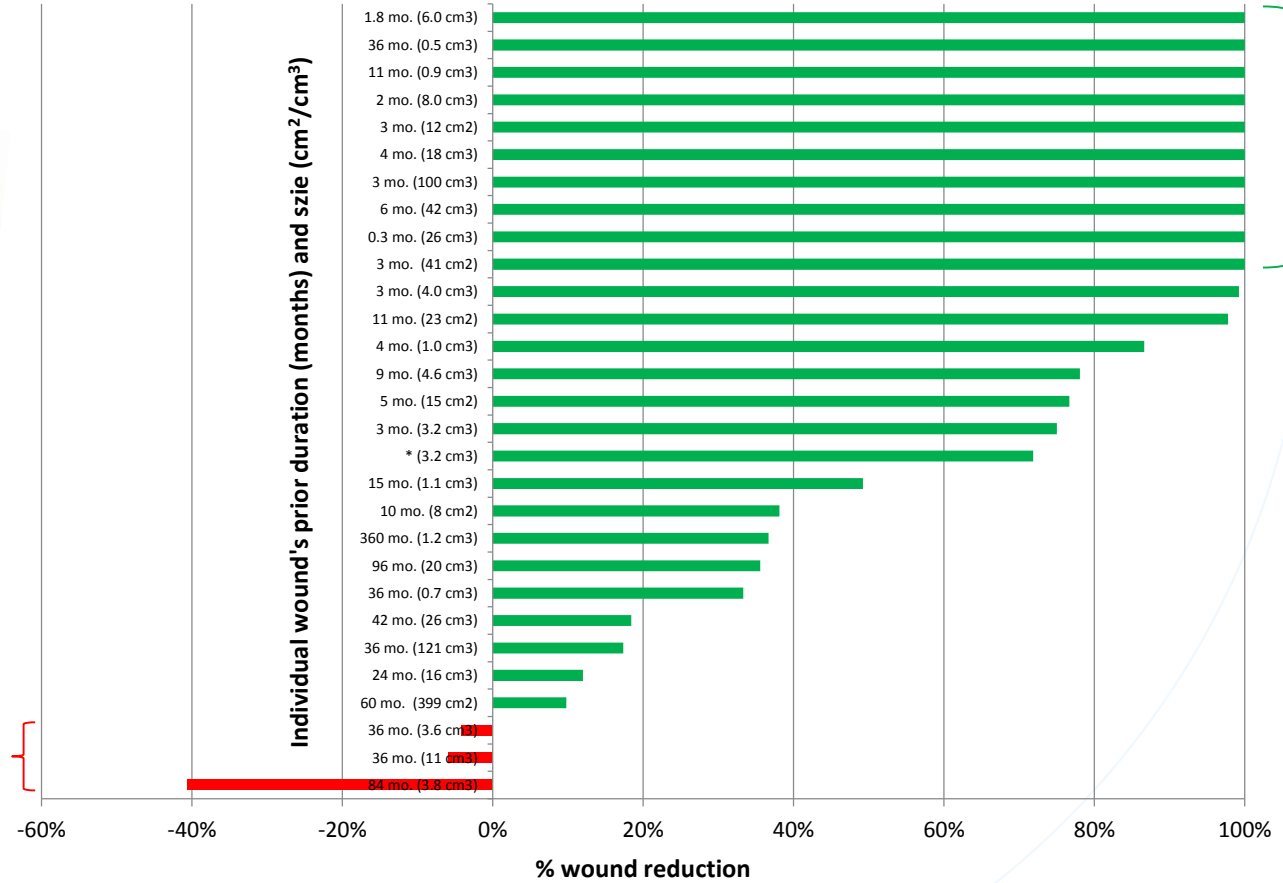




9. Metcalf et al. *Clinical safety and effectiveness evaluation of a new antimicrobial wound dressing designed to manage exudate, infection and biofilm.* Int Wound J 2017; 14; 203-213.

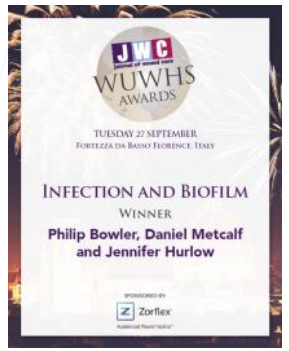
Wound closure clinical evaluation[10]

- Of 29 wounds, **10 healed** in average of 6.7 weeks of AQUACEL® Ag+ Extra™



Avg. 7 months old wounds; healed in 6.7 weeks

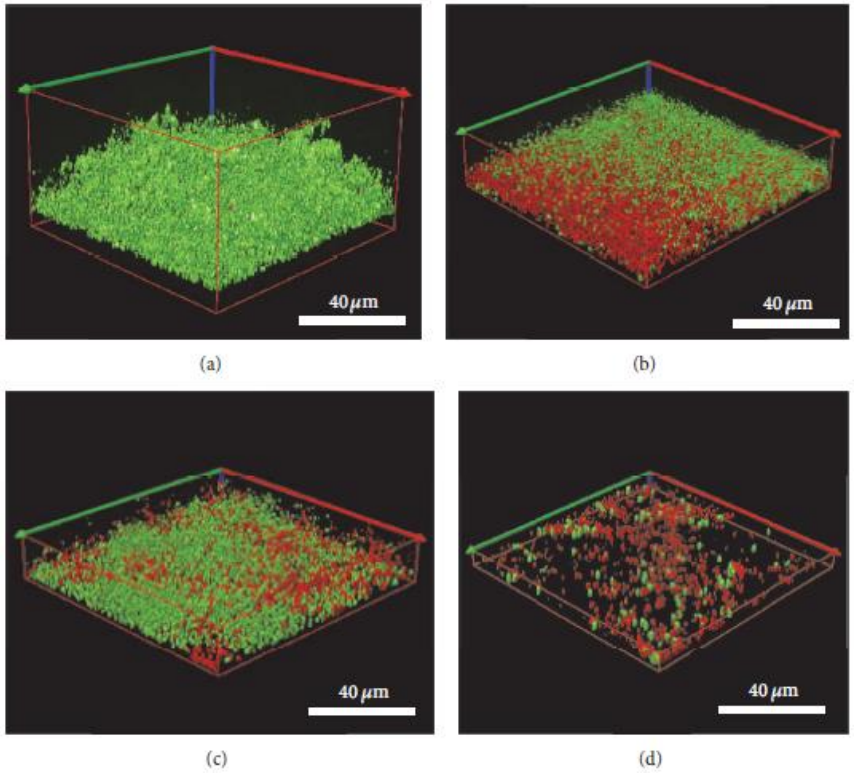
2 wounds from same patient on flucoxacillin; other a 7-yr old wound in a PAD patient

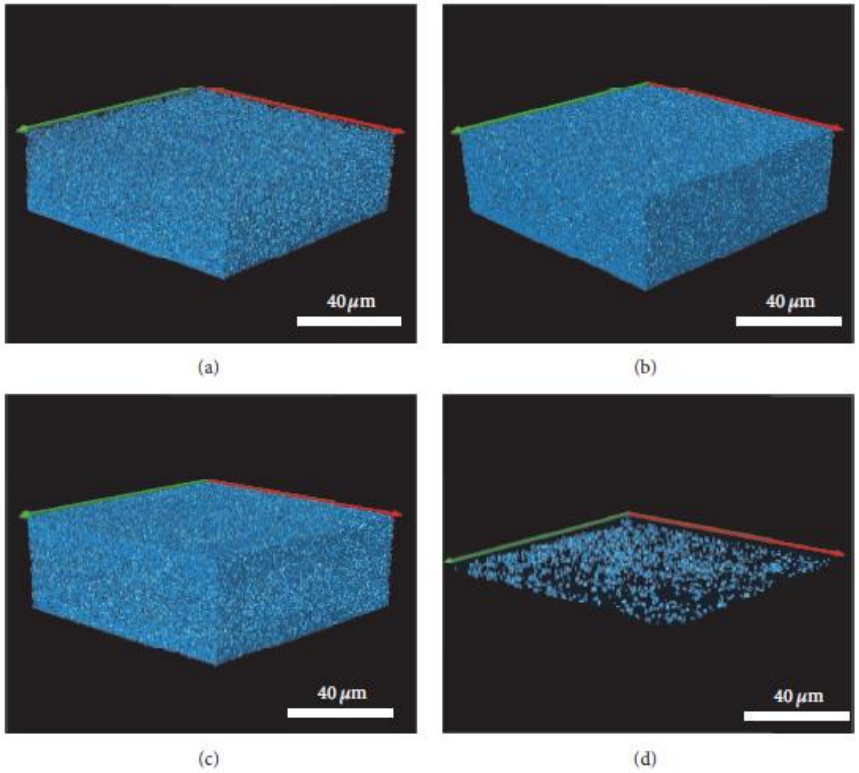


10. Metcalf et al. *A next-generation antimicrobial wound dressing: a real-life clinical evaluation in the UK and Ireland*. J Wound Care 2016; 25: 132-138.

Understanding why and how it works[11]

- AQUACEL® Ag+ Extra™ (d) **kills** more biofilm bacteria, & **removes** more biofilm cells than standard silver dressings (b, c)
- AQUACEL® Ag+ Extra™ (d) **disrupts** and **removes** biofilm slime (EPS)

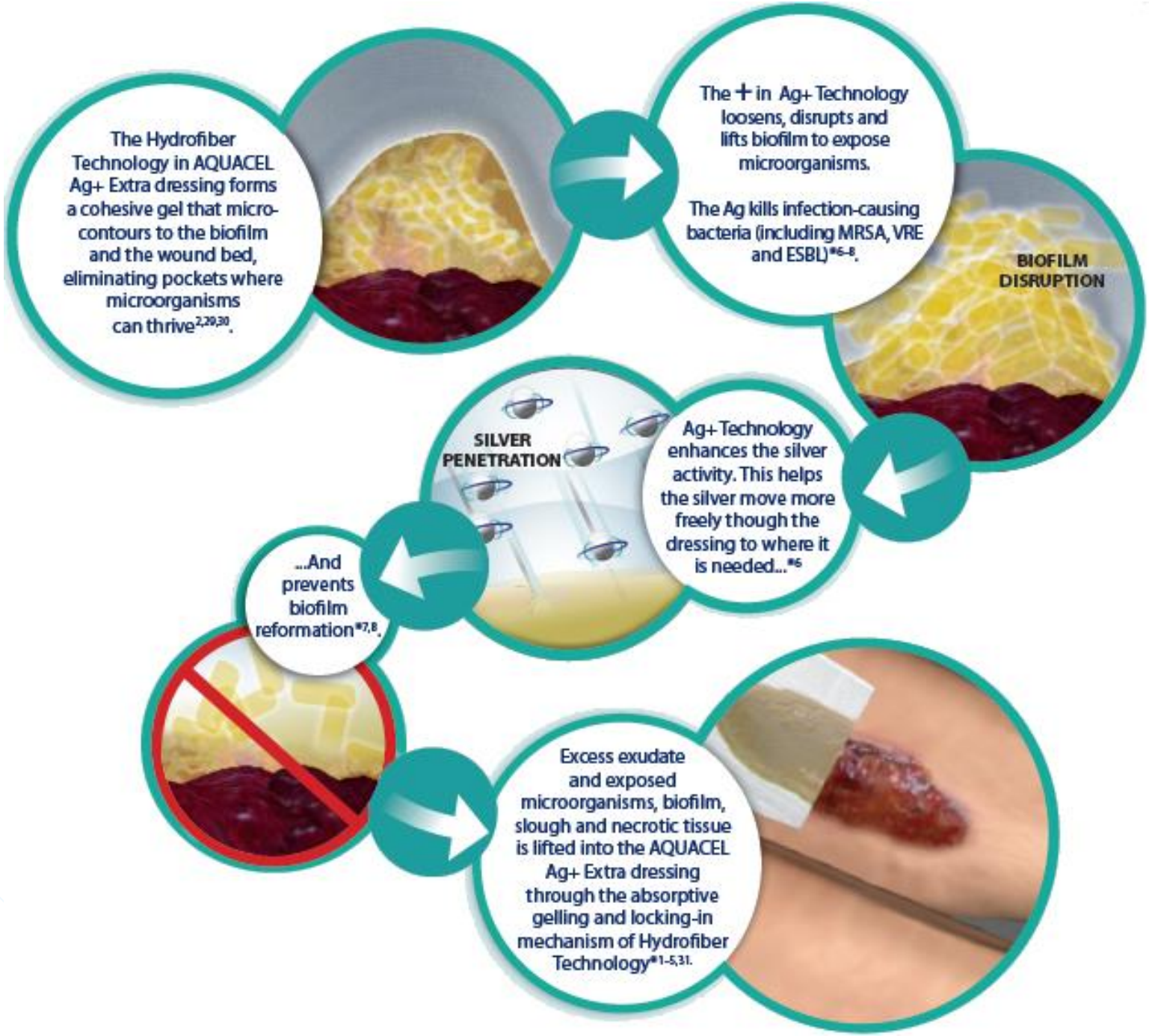




Green = live **Red = dead**

Blue = biofilm slime (EPS)

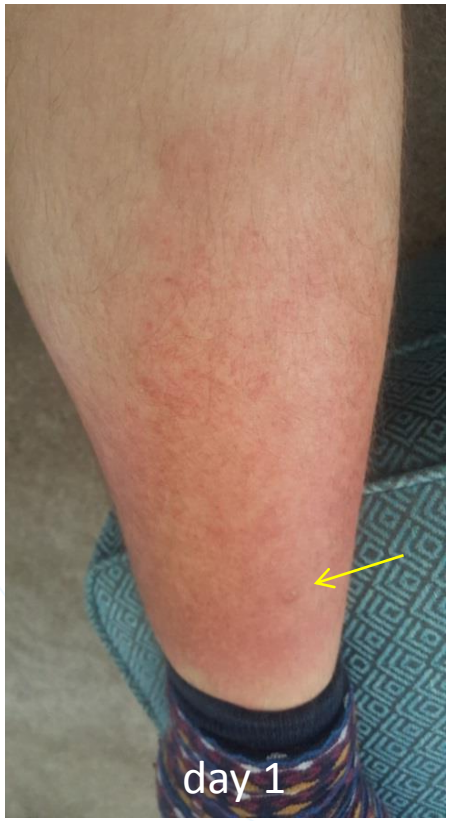
11. Parsons et al. *Enhanced Performance and Mode of Action of a Novel Antibiofilm Hydrofiber Wound Dressing*. BioMed Res Int 2016; 7616471.

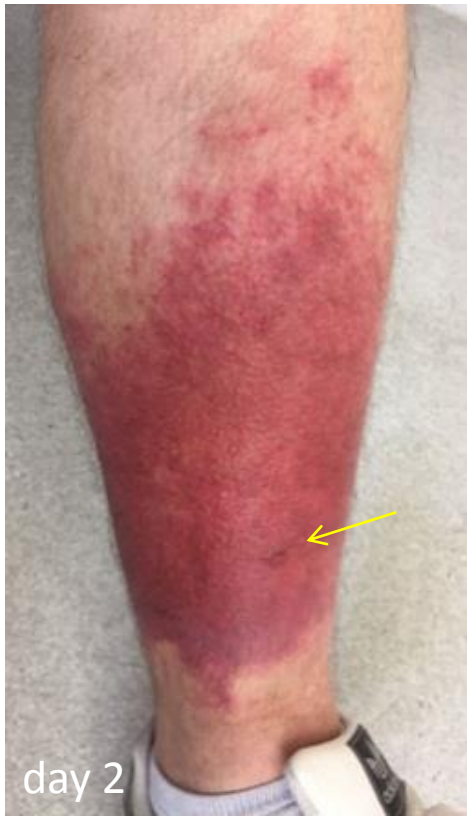


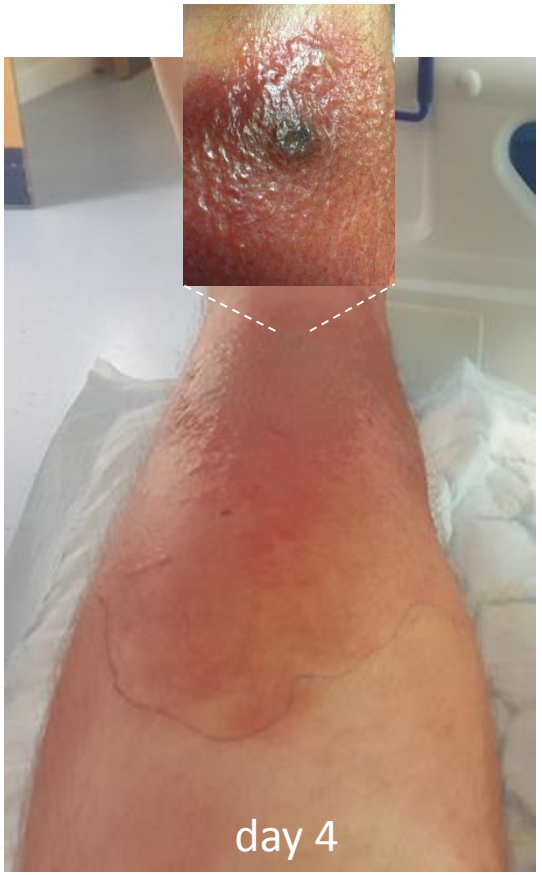
12. *AQUACEL Ag+ Extra dressings Made Easy.* Wounds Int 2017; May.

Cellulitis case

- Insect bite after a countryside walk, followed by redness
- Cellulitis diagnosed; oral flucloxacillin (day 2)
- Admitted to hospital with systemic symptoms; CRP level 187 mg/ml (day 4)



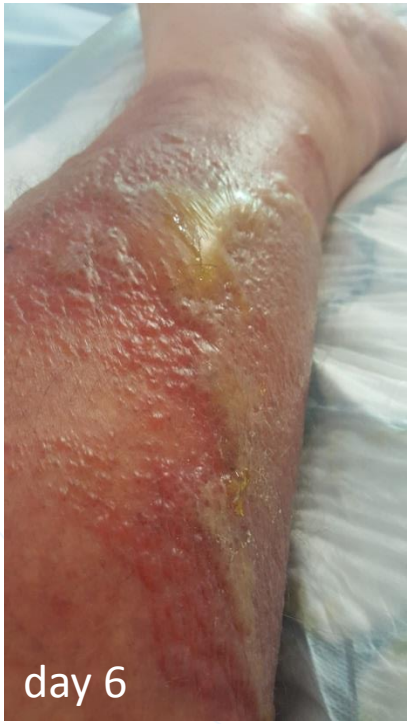


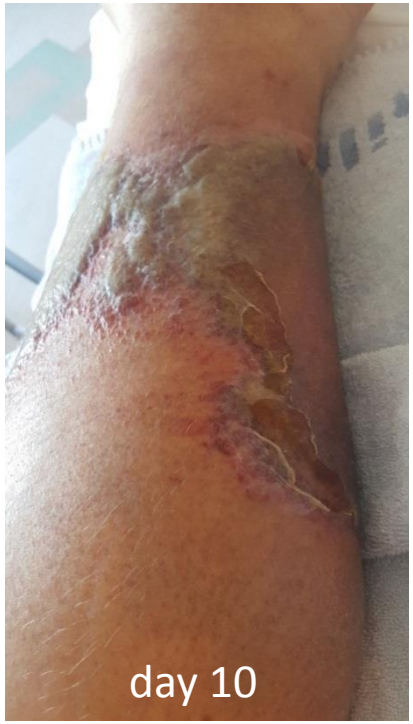


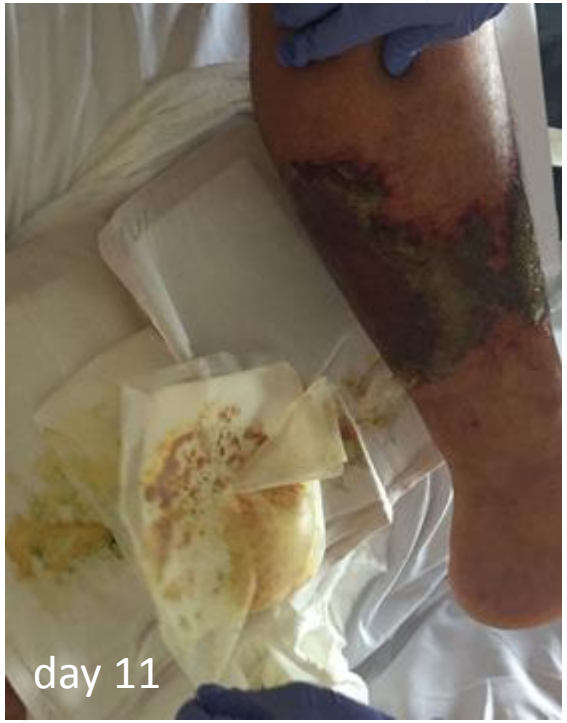
Hospital care

- IV clindamycin; arterial & venous assessment, ultrasound & diabetes tests OK
- Antibiotics dealt with infection (blood CRP 16 mg/ml), swelling down (day 10)
- Blisters allowed to leak and air-dry, then dressed with gauze (day 11)
- Dark devitalised tissue, yellow/green exudate, characteristic *Pseud* smell

→ **heavy colonisation (biofilm likely)**, patient discharged

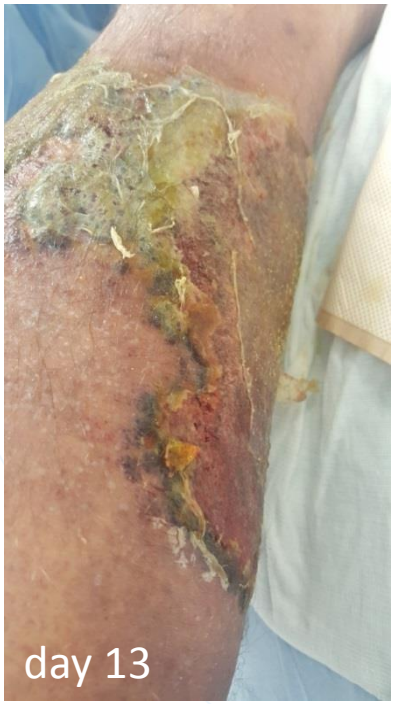


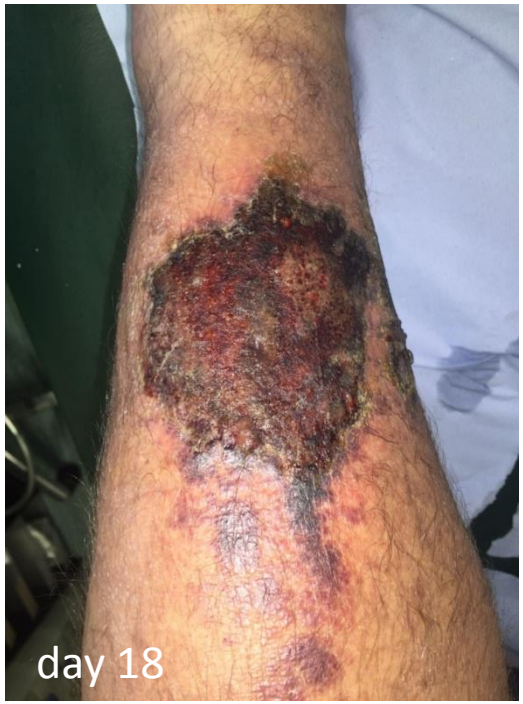


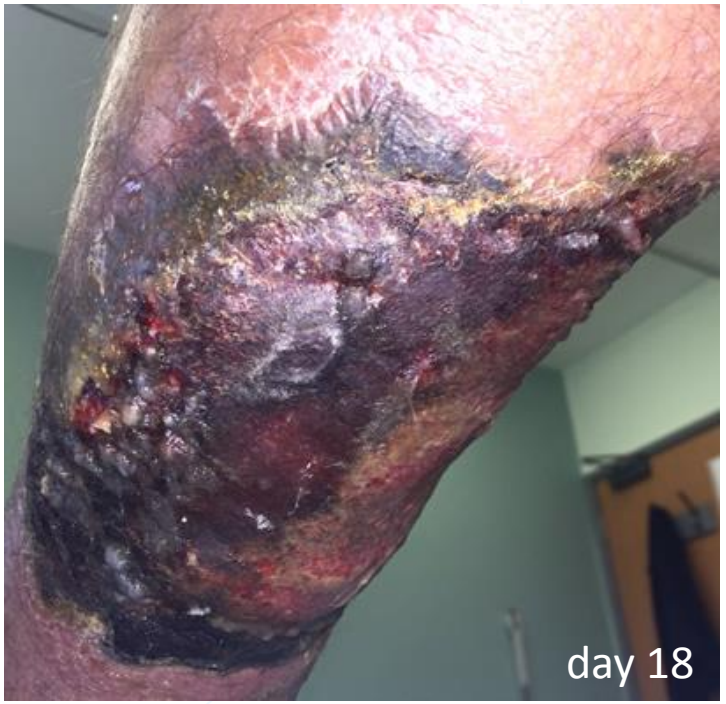


Community care

- Silver gauze; necrosis, poor granulation, slough, fibrin, possible biofilm (day 13)
- Still no **TVN assessment** or **debridement** possible in the community
- Non-antimicrobial foam; after 3 days, wound dressings were saturated, unpleasant smell

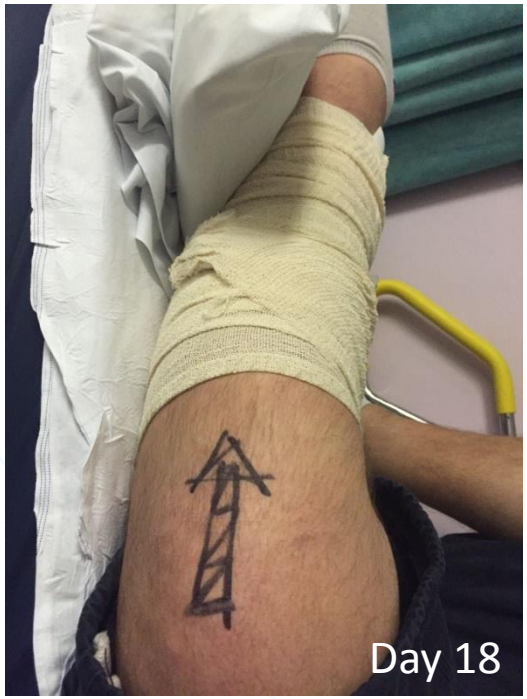


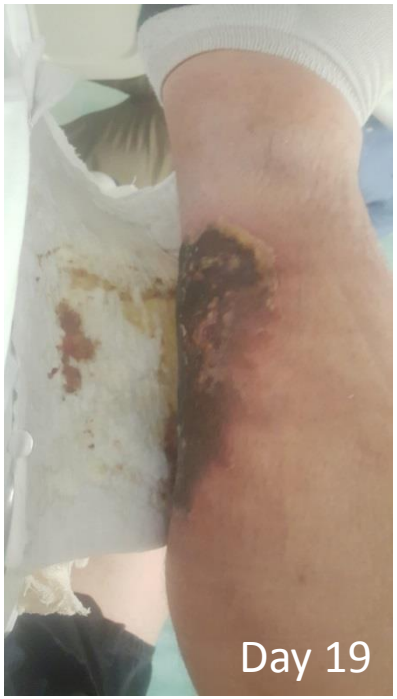


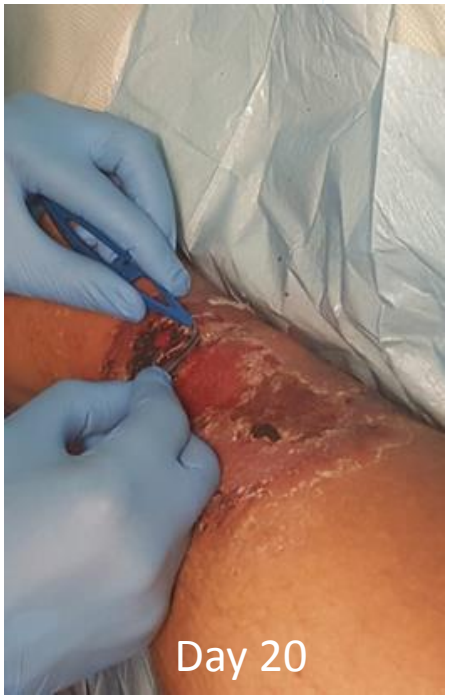


Surgery planned

- Admitted to Orthopaedic Surgical Unit, excision and large skin graft planned
- Dressed with **AQUACEL® Ag+ Extra™** for first time (Day 18)
  - The dressing (moistened) appeared to shift the wound in patient's favour
  - Synergy of anti-biofilm agents (**disrupt**), silver (**kill**) & Hydrofiber™ (**absorb**)
- Tissue Viability Nurse assessment (Day 20)
  - Debridement by TVN revealed some healing tissue beneath







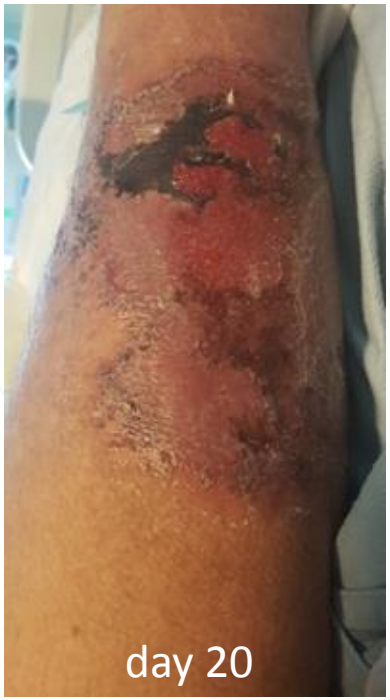
Surgery avoided, wound healed

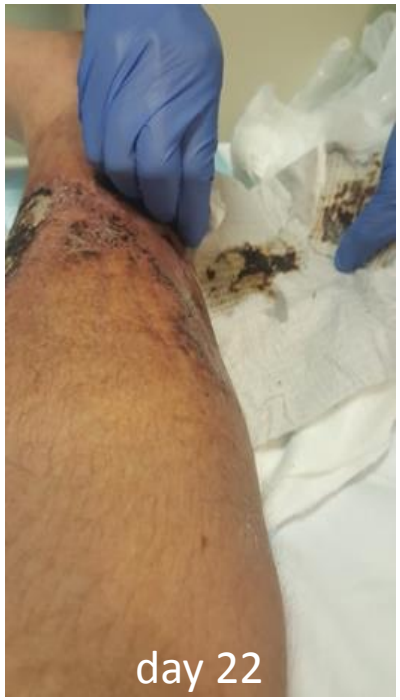
- Further use of moistened AQUACEL® Ag+ Extra™ on broken or tougher areas (dressing facilitating debridement); more sharp debridement (Day 22)

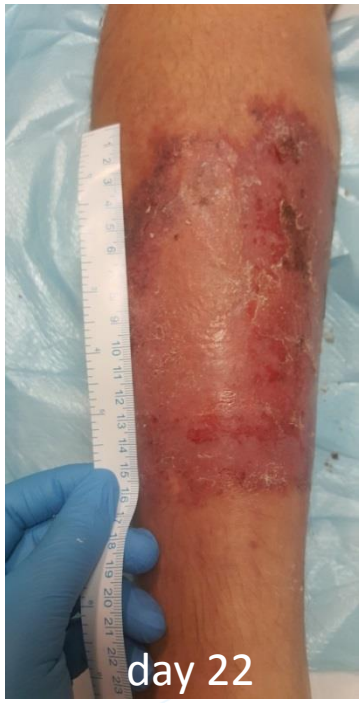
→ Patient was home within 4 days of starting an appropriate **protocol-of-care**… **debride, cleanse, anti-biofilm Hydrofiber™ dressing**

→ **Surgery avoided, cost savings** (surgical costs, bed days, nurse time, overheads)

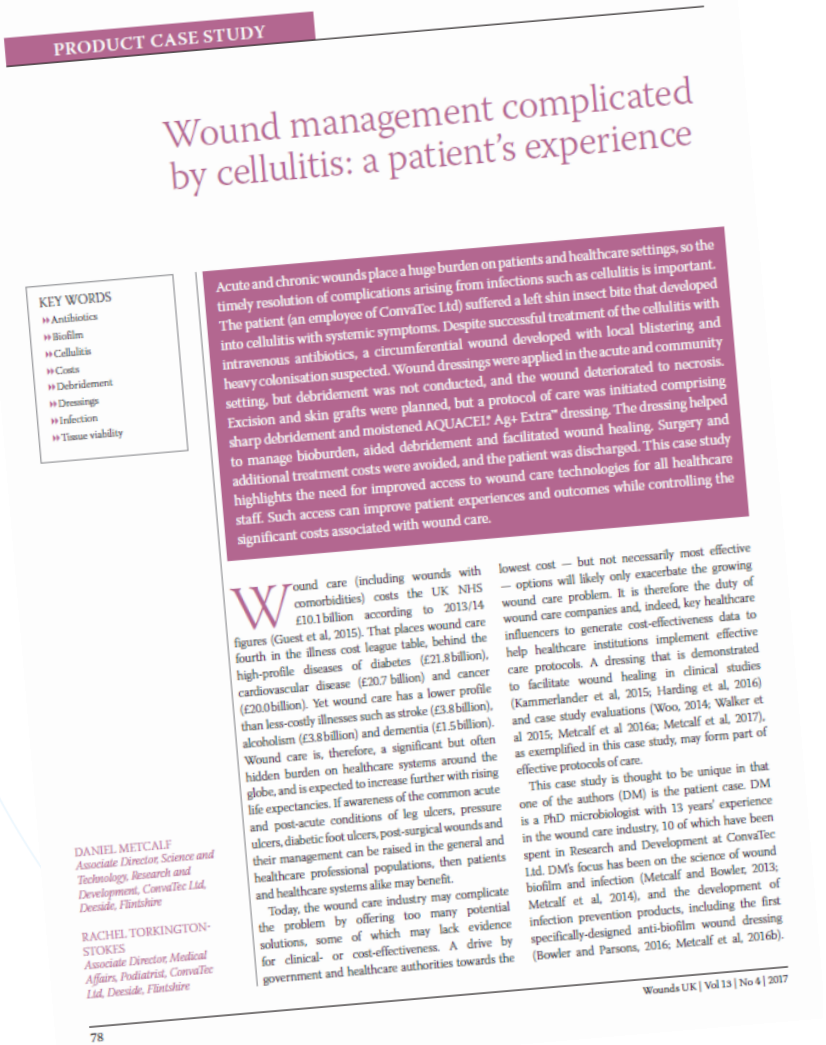
→ Leg healed, and patient back to work (Day 34)







Cellulitis case study: patient experience[13]



PRODUCT CASE STUDY

Wound management complicated by cellulitis: a patient's experience

KEY WORDS
- Antibiotics
- Biofilm
- Cellulitis
- Costs
- Debridement
- Dressings
- Infection
- Tissue viability

Acute and chronic wounds place a huge burden on patients and healthcare settings, so the timely resolution of complications arising from infections such as cellulitis is important. The patient (an employee of ConvaTec Ltd) suffered a left shin insect bite that developed into cellulitis with systemic symptoms. Despite successful treatment of the cellulitis with intravenous antibiotics, a circumferential wound developed with local blistering and heavy colonisation suspected. Wound dressings were applied in the acute and community setting, but debridement was not conducted, and the wound deteriorated to necrosis. Excision and skin grafts were planned, but a protocol of care was initiated comprising sharp debridement and moistened AQUACEL® Ag+ Extra™ dressing. The dressing helped to manage biobunden, aided debridement and facilitated wound healing. Surgery and additional treatment costs were avoided, and the patient was discharged. This case study highlights the need for improved access to wound care technologies for all healthcare staff. Such access can improve patient experiences and outcomes while controlling the significant costs associated with wound care.

Wound care (including wounds with comorbidities) costs the UK NHS £10.1 billion according to 2013/14 figures (Guest et al, 2015). That places wound care fourth in the illness cost league table, behind the high-profile diseases of diabetes (£21.8 billion), cardiovascular disease (£20.7 billion) and cancer (£20.0 billion). Yet wound care has a lower profile than less-costly illnesses such as stroke (£3.8 billion), alcoholism (£3.8 billion) and dementia (£1.5 billion). Wound care is, therefore, a significant but often hidden burden on healthcare systems around the globe, and is expected to increase further with rising life expectancies. If awareness of the common acute and post-acute conditions of leg ulcers, pressure ulcers, diabetic foot ulcers, post-surgical wounds and their management can be raised in the general and healthcare professional populations, then patients and healthcare systems alike may benefit.

Today, the wound care industry may complicate the problem by offering too many potential solutions, some of which may lack evidence for clinical- or cost-effectiveness. A drive by government and healthcare authorities towards the lowest cost — but not necessarily most effective — options will likely only exacerbate the growing wound care problem. It is therefore the duty of wound care companies and, indeed, key healthcare influencers to generate cost-effectiveness data to help healthcare institutions implement effective care protocols. A dressing that is demonstrated to facilitate wound healing in clinical studies (Kammerlander et al, 2015; Harding et al, 2016) and case study evaluations (Woo, 2014; Walker et al 2015; Metcalf et al 2016a; Metcalf et al, 2017), as exemplified in this case study, may form part of effective protocols of care.

This case study is thought to be unique in that one of the authors (DM) is the patient case. DM is a PhD microbiologist with 13 years' experience in the wound care industry, 10 of which have been spent in Research and Development at ConvaTec Ltd. DM's focus has been on the science of wound biofilm and infection (Metcalf and Bowler, 2013; Metcalf et al, 2014), and the development of infection prevention products, including the first specifically-designed anti-biofilm wound dressing (Bowler and Parsons, 2016; Metcalf et al, 2016b).

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Table 1. Cost estimates of the care settings and wound management strategies experienced (National Institute of Health and Care Excellence [NICE], 2017)

Care type	Occurrence	Approximate cost	Reference
Walk-in visits	2	£250	Guest et al, 2015
A&E visits	2	£120	Guest et al, 2015
Overnight hospital stays	12	£15,000	Guest et al, 2015
Microbiological swabbing	2	£50	Personal communication (Austrian and Belgian physicians, 2012)
Ambulance transfer	1	£250	Guest et al, 2015
Antibiotics (oral)	5 days	£5	Regional Drug and Therapeutics Centre, 2017
Antibiotics (intravenous)	10 days	£100	Shenvi, 2015
Dressings, acute (gauze, pads, hosiery)	2	£10	Estimates using British National Formulary
Dressings, community (3 × silver gauze, 3 × foam dressings, pads, hosiery)	3	£39	Estimates using British National Formulary
Approximate total before AQUACEL Ag+ Extra and tissue viability assessment:		**£15,824**	
Antibiotics (oral)	13 days	£13	Regional Drug and Therapeutics Centre, 2017
Dressings, acute (6x AQUACEL Ag+ Extra 10 × 10, pads, hosiery)	3	£90	Estimates using British National Formulary
Dressings, community (6 × AQUACEL Ag+ Extra 10 × 10, pads, hosiery)	3	£90	Estimates using British National Formulary
Tissue viability nurse visit (1 hour)	2	£100	Guest et al, 2015
District nurse home visits (30 minutes)	3	£150	Guest et al, 2015
Approximate total after AQUACEL Ag+ Extra and tissue viability assessment:		**£443**	

£15,824

£443

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Avelle® portable
Negative Pressure Wound Therapy system

- Negative pressure causes mechanical stress to encourage wound closure
- **Avelle® portable, disposable NPWT system** includes:
  - A wound dressing
  - Fixation strips
  - A sealing mechanism
  - Portable tubing
  - A portable vacuum pump providing -80 mmHg

Avelle®: powered by pump & Hydrofiber™

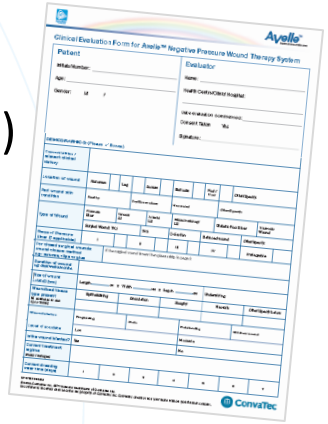
- A key difference in Avelle® compared to other portable, disposable NPWT systems is the dressing core and wound interface technology

- The only NPWT system offering **Hydrofiber™** technology

1. **Superior exudate management**
2. **Longer usage** – 30-day pump life
3. Can **purchase dressings separately** to the pump

Clinical evaluation – Methods

- Avelle® pumps and dressings supplied free of charge to NHS Trusts
- Standard evaluation forms used to capture:
  - Patient medical and wound history (inc prior wound management)
  - Wound management protocols implemented
  - Avelle® NPWT system performance and wound outcomes



- **Inclusion criteria:**
  - Mild to moderately exuding wounds
  - Wounds not responding to current management
  - Wounds currently being managed with another disposable NPWT system

- **Key Avelle® NPWT system parameters to be reported:**
  1. **Duration** of therapy
  2. **Clinical efficacy** – (i) **Wound outcomes;** (ii) **clinician opinion**

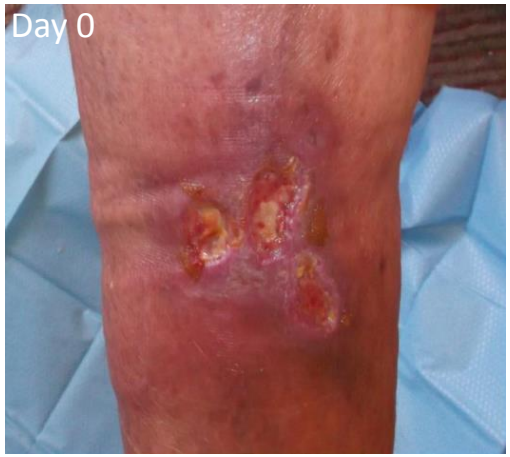
- **Duration of evaluations:**
  - Until clinician decided that the wound had improved, such that NPWT could be stepped down to dressing management
  - The NPWT needed to be discontinued for any reason, including patient choice

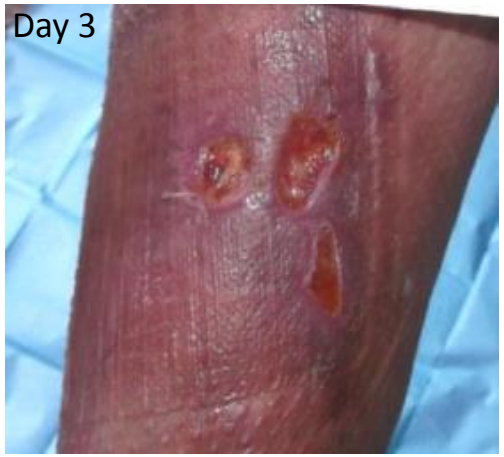
Clinical evaluation – Results

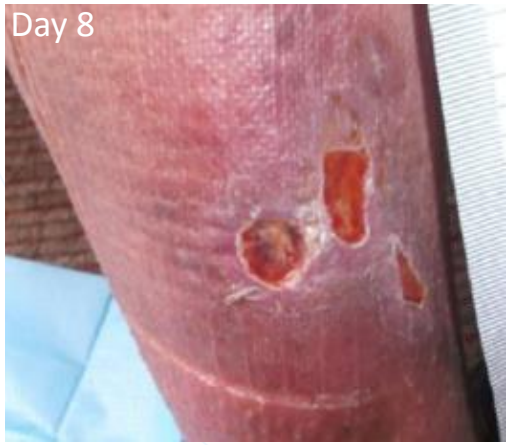
Baseline	
Sites	11
Clinicians	11
Patients	13 (5 female, 8 male)
Mean patient age	64 years
Wounds	13
Wound types	4 trauma, 3 pressure ulcer, 1 venous leg ulcer, 5 'other'
Exudate levels	11 moderate, 2 mild
After evaluations	
Duration of Avelle® usage	**26.4 days** (range 6-63 days)
Wound outcomes	• **1 wound healed** • **12 wounds improved** (reduction in wound volume, and/or increase in healthy wound bed tissue) • Peri-wound skin improved (n=6) or remained healthy (n=4)

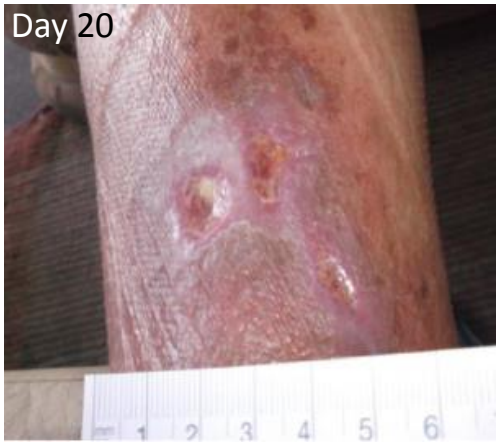
Clinical evaluation – Case study

- Male (91), mixed leg ulcer cluster (1 year), each 1.5 cm x 1 cm x 0.2 cm









- Medihoney®, Zetuvit™ pads, K-Lite™ compression
- Avelle® NPWT system usage – 26 days total:
  - **11 days on**
  - 3 days off (AQUACEL® Extra™, Biatain™ silicone foam: deteriorated)
  - **15 days on**
- Day 20: Wounds all reduced in size and less slough on wound bed
- Day 26: Stepped down to AQUACEL® Foam

- Clinician: ***"Fantastic – wounds looking great – cleaner & smaller!"***

Results summary

- The **Avelle® NPWT system** delivered effective, comfortable, convenient and easy-to-use NPWT in a 13-patient UK evaluation
- **Avelle®** is differentiated from other portable NPWT systems:
  1. Superior exudate management due to **Hydrofiber™**
  2. Longer usage – 30-day pump life
  3. Can purchase dressings separately to the pump unit
- It was concluded that the **Avelle® NPWT system** can be used to successfully deliver clinically effective NPWT within a healthcare setting
- Further clinical evaluations across Europe (300+)

The future

Hydrofiber™ foundation

Prevention

Diagnostics

Conclusions

- **Hydrofiber™** and **ionic silver** technology is the foundation of a 20-year wide range of safe and effective wound dressings
- Biofilm is now recognised as a precursor to wound infection, and a cause of delayed wound healing (in at least 78% of chronic wounds)
- **AQUACEL® Ag+ Extra™** combines effective **exudate** (Hydrofiber™), **infection** (ionic silver) and **biofilm** (Ag+ Technology™) management
- AQUACEL® Ag+ Extra™ appears to be a safe, well-tolerated dressing for effective management of difficult wounds in protocols of care
- Ag+ Technology™ works by disrupting biofilm structure, enhancing silver penetration into biofilm, and killing microorganisms within
- Hydrofiber™ also differentiates the new portable, disposable **Avelle® NPWT system**
- Ag+ Technology™, driven by Hydrofiber™, has further potential in wound dressings and devices