



**ANTIMICROBIAL DRESSING WITH ACTIVATED CARBON
FIBRE (ACF)**

**HEALTH TECHNOLOGY ASSESSMENT SECTION
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
013/2014**

DISCLAIMER

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It has been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

Please contact: htamalaysia@moh.gov.my, if you would like further information.

Health Technology Assessment Section (MaHTAS),
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590 Putrajaya

Tel: 603 88831246

Fax: 603 8883 1230

Available at the following website: <http://www.moh.gov.my>

Prepared by:

Dr. Nur Farhana Binti Mohamad
Assistant Director
Health Technology Assessment Section (MaHTAS)
Ministry of Health Malaysia

Reviewed by:

Datin Dr. Rugayah Bakri
Deputy Director
Health Technology Assessment Section (MaHTAS)
Ministry of Health Malaysia

DISCLOSURE

The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

EXECUTIVE SUMMARY

Introduction

Intact skin provides a barrier to protect from pathogen invasion. When damage to the skin occurs, the safeguard is broken and the chance of infection is dramatically increased. A major factor, common to all wound care, is the prevention of infection. Antibiotics were once powerfully effective medicines for controlling pathogenic infection. However, the emergence of various antibiotic-resistant organisms has impeded and limited the broad efficacy of antibiotics. Using alternatives to antibiotics to manage wound infection would help overcome the problems of antibiotic-resistance.

As a result, silver is now widely used in wound dressing for controlling infection. As of now, various commercial silver-containing dressings have been developed and these dressings can be made of various materials which determine the property of the dressing. However, there are concerns regarding cell toxicity with exposure to high silver concentration in certain wound dressing.

The new development in wound dressing includes the impregnation of silver to Activated Carbon Fibre (ACF) by Bio-Medical Carbon Technology (BCT™) which was claimed to support the silver component and produce a suitable wound dressing with good antimicrobial properties that also reduces cell cytotoxic affection.

This technology review was requested by Senior Assistant Director of Medical Resources Unit, Medical Development Division, Ministry of Health, Malaysia to review the evidence on BCT™ Antimicrobial Dressing with ACF for wound care.

Objective/aim

To assess the safety, effectiveness and cost-effectiveness of BCT™ Antimicrobial Dressing with ACF for wound care.

Results and conclusions

There was very limited and fair quality of retrievable evidence from the scientific databases to suggest that the use of BCT™ Antimicrobial Dressing with ACF is effective in wound care. There was no report of adverse events on the use of this technology. However, it has been approved by United States Food and Drug Administration (US FDA) and classified as class II and class IIb medical device in Canada and Taiwan respectively.

Methods

Literature search was done to search for published articles to assess the safety, efficacy or effectiveness and cost-effectiveness of BCT™ Antimicrobial Dressing with ACF for wound care. The following electronic databases were searched via OVID Interface: MEDLINE (1946 to 20 June 2014), EBM Reviews-Cochrane Database of Systematic Reviews (2005 to May 2014), EBM Reviews-Cochrane Central Register of Controlled Trials (May 2014), EBM Reviews–Database of Abstracts of Review of Effects (2nd Quarter 2014), EBM Reviews-Health Technology Assessment (2nd Quarter 2014) NHS economic evaluation database (2nd Quarter 2014) , Pubmed, INAHTA database, HTA database and also in general databases. The last search was run on 20 June 2014.

ANTIMICROBIAL DRESSING WITH ACTIVATED CARBON FIBER (ACF)

1. INTRODUCTION

The skin is the largest organ of the human body. Intact skin provides a barrier to protect from pathogen invasion. In the event of injury, the skin initiates a cascade of events including tissue fluid secretion, inflammation and tissue remodelling. When damage to the skin occurs in such forms as abrasions, punctures, burns, surgical wounds or chronic wounds, the safeguard is broken and in turn, the chance of infection is dramatically increased.¹

A major factor, common to all wound care, is the prevention of infection. However, infection control is a contentious issue, particularly against background of the continuous and expanding number of resistant organisms. Antibiotics were once powerfully effective medicines for controlling pathogenic infection however, the emergence of various antibiotic-resistant organisms has impeded and limited the broad efficacy of antibiotics.² Using alternatives to antibiotics to manage wound infection would help overcome the problems of antibiotic-resistance organisms.

As a result, silver is now widely used in wound dressing for controlling infection. Although silver has been used for centuries in water recycling and sanitisation, in complementary health care and to inhibit bacteria in food, the introduction of silver into wound care is relatively recent.² As of now, various commercial silver-containing dressings have been developed and these dressings can be made of various materials which determine the property of the dressing. In addition, many factors such as silver concentration, the type of silver used, the amount of silver ion released and the manufacturing process used all affect the antimicrobial activities of silver-containing dressings. However, there are concerns regarding cell toxicity with exposure to high silver concentration in certain wound dressing.²

The new development in wound dressing includes the impregnation of silver to Activated Carbon Fibre (ACF) by Bio-Medical Carbon Technology (BCT™) which claimed to support the silver component and produce a suitable wound dressing with good antimicrobial properties that also reduces cell cytotoxic affection. Similar technology was developed by Johnson & Johnson Medical LTD in the dressing namely Actisorb Silver 220 using activated charcoal with silver. However, the former has additional claims of absorbing odour and helping to reduce infections in partial and full thickness wounds.

This technology review was requested by Senior Assistant Director of Medical Resources Unit, Medical Development Division, Ministry of Health, Malaysia to review the evidence on BCT™ Antimicrobial Dressing with ACF for wound care.

2. OBJECTIVE / AIM

To assess the safety, effectiveness and cost-effectiveness of BCT™ Antimicrobial Dressing with ACF for wound care.

3. TECHNICAL FEATURES

3.1 What is BCT™ Antimicrobial Dressing?

BCT™ Antimicrobial Dressing is a specially designed and commercially available product of activated carbon wound dressing. It is also marketed as KoCarbon Ag Antimicrobial dressing by BCT™ in Malaysia and ASEAN countries.³



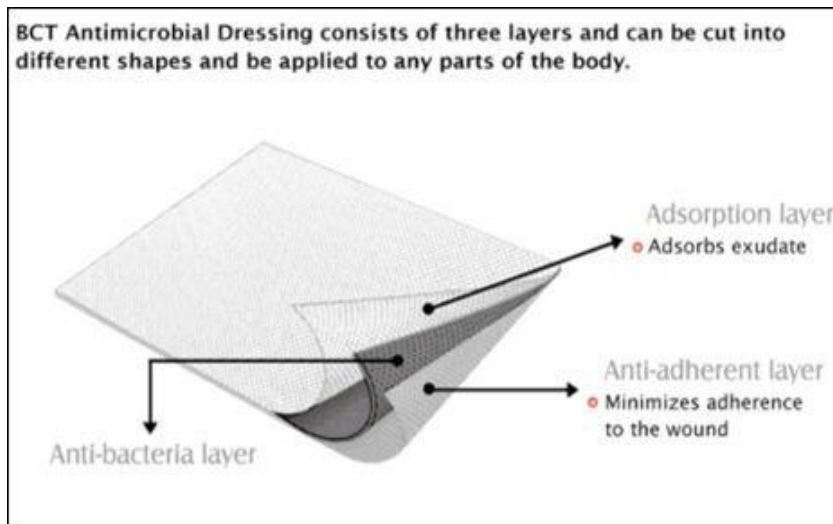
BCT™'s ACF material was invented by Dr. Tse-Hao Ko. He co-founded Bio-Medical Carbon Technology and created a wide range of advanced wound care dressings. This technology has been presented at the 24th Conference of the European Wound Management Association (EWMA) in May 2014 at Madrid, Spain.³

BCT™'s ACF material and technology has been patented in 11 countries including United States of America, Canada, Singapore and Taiwan. It has obtained registration with Malaysia Medical Device and certifications as medical device class II and IIb from Canada and Taiwan respectively. This technology has also been approved by USFDA since 2009.

BCT™ Antimicrobial Dressing is intended for the management of wounds and to provide an antimicrobial barrier. These dressings are applied topically and are in direct contact with the wound. It is intended to be used for indications such as partial and full thickness wounds, pressure ulcers, diabetic ulcers, surgical wounds and acute wounds.³

3.2 Mechanism of action

BCT™ Antimicrobial Dressing with ACF consists of polyethylene terphthalate (PET) non-woven, silver coated activated carbon cloth and polyethylene (PE) film. The dressings contain 100µg/cm² of silver and are available in several sizes to accommodate different wound sizes.



BCT™ Antimicrobial dressing comprises of three layers and can be cut into different shapes and be applied to any parts of the body. The first layer is an anti-adherent layer of PE Membrane, the second layer is an antimicrobial layer of activated carbon fibre and the third layer is an absorbent layer of non-woven fabric. The dressings are individually packaged in a pouch. All dressings are sterile and are for single use only.

It is claimed that when the dressing touches the wound exudates, the absorbent and moist-retaining activated carbon fibre absorbs exudates and bacteria thus maintaining a moist wound environment while ionic silver is being released.³

BCT™ Antimicrobial Dressing with ACF claimed to have antimicrobial activity on numerous bacteria including *Pseudomonas aeruginosa*, *Methicillin-Resistant Staphylococcus Aureus (MRSA)*, *Enterococcus faecalis*, *Acinobacter haemolyticus* and *Multi-drug Resistant Acinobacter baumannii*. It is said that the ionic silver destroys both bacterial cell membrane and cell nucleus to eliminate bacteria and to create a barrier to prevent wound infection and to reduce odour. It is also claimed that the ACF contains Far Infrared Rays (FIR) which can promote blood circulation and metabolism to reduce healing period.³

4. METHODS

4.1. Searching

Electronic databases searched through the Ovid interface:

- MEDLINE (R) In-Process and Other Non-Indexed Citations and Ovid MEDLINE (R) 1946 to present
- EBM Reviews- Cochrane Central Registered of Controlled Trials- May 2014
- EBM Reviews- Database of Abstracts of Review of Effects- 2nd Quarter 2014
- EBM Reviews- Cochrane Database of Systematic Reviews- 2005 to May 2014
- EBM Reviews- Health Technology Assessment- 2nd Quarter 2014
- EBM Reviews- NHS Economic Evaluation Database- 2nd Quarter 2014

Other databases:

- Pubmed
- Other websites: INAHTA

Additional articles were identified from reviewing the references of retrieved articles. General search engine was used to get additional web based information. The search was limited to articles on human. There was no language limitation in the search. Appendix 1 showed the detailed search strategies. The last search was conducted on 20 June 2014.

4.2. Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full-text articles for final article selection. The inclusion and exclusion criteria were:

Inclusion criteria

Population	Patients with wound
Interventions	Antimicrobial dressing with Activated Carbon Fibre (ACF) / activated charcoal dressing
Comparators	Current silver dressings, no comparator
Outcomes	Wound healing rate, Quality of life (QOL), and quality adjusted life years gained (QALY) gained. Cost, cost-benefit, cost-effectiveness, cost utility, and economic evaluation
Study design	Systematic review (SR), Health Technology Assessment (HTA) reports, Randomised Controlled Trial (RCT), non-randomised controlled trial, cohort study, pre and post intervention study, cross sectional study, case control study, case series, case report

Exclusion criteria

- i) Animal study / laboratory study
- ii) Narrative review
- iii) Non English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) checklist and evidence graded according to the US/Canadian Preventive Services Task Force (See **Appendix 2**)

5. RESULTS AND DISCUSSION

There were two retrievable articles (three RCTs) related to the effectiveness of activated carbon dressing for wound care. However, there was no retrievable evidence on the cost-effectiveness of this technology.

5.1. SAFETY

With regards to safety, Soriano J V et al. (2004) and Kerihuel J C (2010) found that none of the patients developed side effects from the application of activated charcoal silver dressings in the studies.^{4,5} From the documents submitted by the distributor, BCT™ Antimicrobial Dressing with ACF is classified as class II and class IIb medical device in Canada

and Taiwan respectively. This technology has also been approved by United States Food and Drug Administration (US FDA) in April 2009.

From the documents submitted by the distributor, BCT™ Antimicrobial Dressing with ACF had passed the seal peel test, burst and creep test and dye penetration test. According to the result, the package remains integrated after three years of storage. In addition, BCT™ Antimicrobial Dressing with ACF also completed its sterilization validation test.

5.2 EFFICACY/EFFECTIVENESS

An article by Kerihuel J C (2010) described two separate RCTs which were done in Paris, France. The RCTs were conducted to compare the ability of activated charcoal dressings with hydrocolloid dressing to reduce the wound area of chronic wounds. The first RCT compared the use of Actisorb (activated charcoal dressing without silver) with hydrocolloid dressing on pressure ulcers. Sixty patients were recruited with 29 patients were randomly assigned to the treatment group and 31 to the control group. The test dressing was applied for four weeks. Median reduction in wound area (cm²) and median percentage reductions in wound size were compared with the baseline. The study found that there were no statistically significant differences between the two groups in median wound area reduction (week four: -4.3cm² in treatment group and -3.1cm² in control group, P > 0.05) and median percentage reductions in wound size throughout the four-week study period (week four: -26.9% in treatment group and -18.5% in control group, P > 0.05).^{4, level II-2}

The second RCT compared the use of Actisorb Silver 220 (activated charcoal dressing with silver) with hydrocolloid dressing on venous leg ulcers. Sixty patients were recruited with 30 patients were randomly assigned to the treatment group and 30 others to the control group. The test dressing was applied for four weeks. Median reduction in wound area (cm²) and median percentage reductions in wound size were compared with the baseline. The study also found that there was no statistically significant difference between the two groups in the median wound area reduction (week four: -4.5cm² in treatment group and -3.5cm² in control group, P > 0.05) and median percentage reductions in wound size (week four: -35.6% in treatment group and -40.9% in control group, P > 0.05) throughout the four-week study period. The authors concluded that the clinical data indicated the potential usefulness of using activated charcoal impregnated with silver in the management of chronic wounds.^{4, level II-2} However, these studies had small sample size thus were underpowered.⁴
Level II-2.

Another RCT was conducted by Soriano J V et al. (2004) in Spain to explore the effect of an activated charcoal silver dressing with cleansing and debridement in reducing the level of bacteria in chronic wounds with no clinical signs of local infection. One hundred and twenty-five patients were enrolled into the study with 67 patients were randomly assigned to the intervention group (activated charcoal silver dressing) and 58 to the control group (cleansing and debridement). Patients were monitored for two weeks. Bacterial status was determined using the four-item classification; contaminated ($\leq 10^3$ colony-forming units (CFU), colonised ($\leq 10^4$ CFUs), high level of bacteria (between $\geq 10^4$ and $\leq 10^5$ CFUs) and infected ($\geq 10^5$ CFUs). Reduction in bacterial levels was measured after two weeks. At baseline, there were 71.6% of the wounds were contaminated, 7.5% had high level of bacteria and 20.9% were infected. In the control group, at baseline, 65.5% of the wounds were contaminated, 6.9% colonised, 6.9% had a high level of bacteria and 20.7% were infected. The study found that there was a statistically significant difference between the two groups in the total reduction of bacterial levels; 85.1% of the wound in the intervention group compared with 62.1% in the control group ($P = 0.003$).⁵ Level II-2 The study also found that after two weeks, there were only 7.1% wounds were infected in the intervention group compared to 75.0% in the control group ($P \leq 0.001$). The authors concluded that the activated charcoal dressings that contain silver control infection and eliminate bacterial barriers.^{5, level II-2}

5.3 COST-EFFECTIVENESS

There was no retrievable evidence from the scientific databases on the cost- effectiveness of BCT™ Antimicrobial Dressing with ACF for wound care.

5.4 LIMITATIONS

This technology review has several limitations. The selection of studies was done by one reviewer. Although there was no restriction in language during the search but only English full text articles were included in this report. Animal and laboratory studies were also excluded. Most of the studies involved small sample size and short duration.

6. CONCLUSION

There was very limited and fair quality of retrievable evidence from the scientific databases to suggest that the use of BCT™ Antimicrobial Dressing with ACF is effective for wound care. There was no report of adverse events on the use of this technology. However, it has been approved by US FDA and classified as class II and class IIb medical device in Canada and Taiwan respectively.

7. REFERENCES

1. Lin YH, Hsu WS, Chung WY et al. Evaluation of various silver-containing dressing on infected excision wound healing study. J Mater Sci: Mater Med. 2014;25:1375-1386.
2. Leaper DJ. Silver dressings: their role in wound management. Int Wound J. 2006;3:282-294.
3. BCT™ Antimicrobial Dressing. Available at http://www.bm-carbon.com/BCT/product_detail.php?prd_seq=10. Accessed on 20.06.2014.
4. Kerihuel J C. Effect of activated charcoal dressings on healing outcomes of chronic wounds. J Wound Care. 2010; 19(5):208, 210-212, 214-215.
5. Soriano JV, Lopez JR, Cuervo FM et al. Effects of an activated charcoal silver dressing on chronic wounds with no clinical signs of infection. J Wound Care. 2004; 13(10): 419, 421-423

8. APPENDIX

8.1. Appendix 1: LITERATURE SEARCH STRATEGY

Ovid MEDLINE® In-process & other Non-Indexed citations and OvidMEDLINE® 1946 to present
--

- 1 exp "Wounds and Injuries"/
- 2 wound*.tw.
- 3 injur*.tw.
- 4 trauma*.tw.
- 5 (wounds adj1 injur*).tw.
- 6 injury.mp. and wound.tw. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
- 7 injuries.mp. and wound*.tw. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
- 8 wounds.mp. and injur*.tw. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
- 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
- 10 (carbon adj1 vitreous).tw.
- 11 carbon.tw.
- 12 activated carbon fib*.tw.
- 13 Carbon/
- 14 Silver/
- 15 Silver.tw.
- 16 Silver ion*.tw.
- 17 Silver compound*.tw.
- 18 Biocompatible Materials/
- 19 Infrared Rays/
- 20 (ray* adj1 infrared).tw.
- 21 (heat adj1 wave*).tw.
- 22 far infrared rays.tw.
- 23 antimicrobial dressing.tw.

- 24 Occlusive Dressings/
- 25 (occlusive adj1 dressing*).tw.
- 26 (occlusive adj1 bandage*).tw.
- 27 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
- 28 23 or 24 or 25 or 26
- 29 27 and 28
- 30 9 and 29
- 31 limit 30 to (english language and humans)

OTHER DATABASES	
EBM Reviews - Cochrane Central Register of Controlled Trials	} Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews - Database of Abstracts of Review of Effects	
EBM Reviews - Cochrane database of systematic reviews	
EBM Reviews - Health Technology Assessment	
EBM Reviews- NHS economic evaluation database	
INAHTA	Activated Carbon Fibre

PubMed

(((((Wound and injuries[MeSH Terms])) OR wound*[Title/Abstract]) OR injur*[Title/Abstract])) AND (((dressing, occlusive[MeSH Terms]) OR antimicrobial dressing[Title/Abstract])) AND (((((((carbon[MeSH Terms]) OR activated carbon fiber[Title/Abstract]) OR silver[MeSH Terms]) OR silver ion[Title/Abstract]) OR silver compound[Title/Abstract]) OR biocompatible coated materials[MeSH Terms]) OR infrared rays[MeSH Terms]) OR far infrared rays[Title/Abstract]))

8.2. Appendix 2

HIERARCHY OF EVIDENCE FOR EFFECTIVENESS STUDIES

DESIGNATION OF LEVELS OF EVIDENCE

- I Evidence obtained from at least one properly designed randomized controlled trial.

- II-1 Evidence obtained from well-designed controlled trials without randomization.

- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

- III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

**SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE
(Harris 2001)**

Evidence Table : Effectiveness

Question : Is BCT™ Antimicrobial dressing with ACF effective in wound care?

Bibliographic citation	Study Type / Methods	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up	Outcome measures/ Effect size	General comments															
1. Kerihuel J C. Effect of activated charcoal dressings on healing outcomes of chronic wounds. J Wound Care. 2010; 19(5):208, 210-2, 214-5.	<p>Two randomised controlled trials</p> <p>Aimed to compare the ability of activated charcoal dressings with that of a hydrocolloid dressing to reduce the wound area of chronic wounds.</p> <p>First RCT:</p> <p>Method: Patients were randomly assigned to the treatment group and to the control group. Test dressing was applied to the pressure ulcer wounds for four weeks. Median reduction in wound area and median percentage reductions in wound size were measured.</p>	II-2	<p>First RCT:</p> <p>60 patients with pressure ulcer wounds were recruited. 29 patients receive activated charcoal dressing without silver (Actisorb) in the treatment group and 31 patients receive hydrocolloid dressing in the control group.</p>	Activated charcoal dressing without silver (Actisorb)	Hydrocolloid dressing	Four weeks	<p>Outcomes:</p> <ul style="list-style-type: none"> Reduction in wound area Median percentage reductions in wound size <p>First RCT:</p> <p>Results:</p> <p>1) <u>Median reduction in wound area (cm²):</u> Results reported as median (range).</p> <table border="1"> <thead> <tr> <th></th> <th>Treatment group (n = 29)</th> <th>Control group (n = 30)</th> </tr> </thead> <tbody> <tr> <td>Week One</td> <td>-2.5 (-22.4 – 18.4)</td> <td>0.0 (-8.8 – 24.0)</td> </tr> <tr> <td>Week Two</td> <td>-2.8 (-41.2 – 16.1)</td> <td>-2.7 (-24.1 – 24.0)</td> </tr> <tr> <td>Week Three</td> <td>-4.2 (-28.2 – 11.7)</td> <td>-1.8 (-24.1 – 28.7)</td> </tr> <tr> <td>Week Four</td> <td>-4.3 (-31.2 – 13.8)</td> <td>-3.1 (-24.1 – 46.0)</td> </tr> </tbody> </table> <p>The differences were not statistically significant. P > 0.05</p>		Treatment group (n = 29)	Control group (n = 30)	Week One	-2.5 (-22.4 – 18.4)	0.0 (-8.8 – 24.0)	Week Two	-2.8 (-41.2 – 16.1)	-2.7 (-24.1 – 24.0)	Week Three	-4.2 (-28.2 – 11.7)	-1.8 (-24.1 – 28.7)	Week Four	-4.3 (-31.2 – 13.8)	-3.1 (-24.1 – 46.0)	<p>Blinding done</p> <p>Small sample size</p> <p>Short duration</p>
	Treatment group (n = 29)	Control group (n = 30)																					
Week One	-2.5 (-22.4 – 18.4)	0.0 (-8.8 – 24.0)																					
Week Two	-2.8 (-41.2 – 16.1)	-2.7 (-24.1 – 24.0)																					
Week Three	-4.2 (-28.2 – 11.7)	-1.8 (-24.1 – 28.7)																					
Week Four	-4.3 (-31.2 – 13.8)	-3.1 (-24.1 – 46.0)																					

Evidence Table : Effectiveness

Question : Is BCT™ Antimicrobial dressing with ACF effective in wound care?

Bibliographic citation	Study Type / Methods	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up	Outcome measures/ Effect size	General comments															
	<p>Second RCT:</p> <p>Method: Patients were randomly assigned to the treatment group and to the control group. Test dressing was applied to the pressure ulcer wounds for four weeks.</p>	II-2	<p>Second RCT:</p> <p>60 patients with venous leg ulcer wounds were recruited.</p>	Activated charcoal dressing with silver (Actisorb Silver 220)	Hydrocolloid dressing	Four weeks	<p>2)Median percentage reductions in wound size: Results reported as median (range).</p> <table border="1" data-bbox="1381 621 1856 932"> <thead> <tr> <th></th> <th>Treatment group (n = 29)</th> <th>Control group (n = 30)</th> </tr> </thead> <tbody> <tr> <td>Week One</td> <td>-11.7 (-55 – 130.5)</td> <td>0.0 (-85.7- 24.0)</td> </tr> <tr> <td>Week Two</td> <td>-25.0 (-73 – 114.5)</td> <td>-14.1 (-95 - 148.1)</td> </tr> <tr> <td>Week Three</td> <td>-30.8 (-72.6 – 61.6)</td> <td>-10.3 (-95.6 – 215.8)</td> </tr> <tr> <td>Week Four</td> <td>-26.9 (-82 – 97.9)</td> <td>-18.5 (-100- 260.9)</td> </tr> </tbody> </table> <p>The differences were not statistically significant. P > 0.05</p> <p>Second RCT:</p> <p>Results:</p>		Treatment group (n = 29)	Control group (n = 30)	Week One	-11.7 (-55 – 130.5)	0.0 (-85.7- 24.0)	Week Two	-25.0 (-73 – 114.5)	-14.1 (-95 - 148.1)	Week Three	-30.8 (-72.6 – 61.6)	-10.3 (-95.6 – 215.8)	Week Four	-26.9 (-82 – 97.9)	-18.5 (-100- 260.9)	
	Treatment group (n = 29)	Control group (n = 30)																					
Week One	-11.7 (-55 – 130.5)	0.0 (-85.7- 24.0)																					
Week Two	-25.0 (-73 – 114.5)	-14.1 (-95 - 148.1)																					
Week Three	-30.8 (-72.6 – 61.6)	-10.3 (-95.6 – 215.8)																					
Week Four	-26.9 (-82 – 97.9)	-18.5 (-100- 260.9)																					

Evidence Table : Effectiveness

Question : Is BCT™ Antimicrobial dressing with ACF effective in wound care?

Bibliographic citation	Study Type / Methods	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up	Outcome measures/ Effect size	General comments																														
	Median reduction in wound area and median percentage reductions in wound size were measured		30 patients received activated charcoal dressing with silver (Actisorb Silver 220) in the treatment group and 30 patients received hydrocolloid dressing in the control group				<p>1)Reduction in wound area (cm²): Results reported as median (range).</p> <table border="1" data-bbox="1388 557 1856 865"> <thead> <tr> <th></th> <th>Treatment group (n = 30)</th> <th>Control group (n = 30)</th> </tr> </thead> <tbody> <tr> <td>Week One</td> <td>-2.2 (-21.2- 5.0)</td> <td>-0.1 (-84 – 82.9)</td> </tr> <tr> <td>Week Two</td> <td>-3.2 (-27.7 – 5.2)</td> <td>-1.3 (-49.5 - 4.5)</td> </tr> <tr> <td>Week Three</td> <td>-4.5 (-26.4 – 14.0)</td> <td>-2.3 (-53.3 – 18.4)</td> </tr> <tr> <td>Week Four</td> <td>-4.5 (-30.9 – 22.5)</td> <td>-3.5 (-53.3 – 18.5)</td> </tr> </tbody> </table> <p>The differences were not statistically significant P > 0.05</p> <p>2)Median percentage reductions in wound size: Results reported as median (range).</p> <table border="1" data-bbox="1388 1057 1856 1365"> <thead> <tr> <th></th> <th>Treatment group (n = 30)</th> <th>Control group (n = 30)</th> </tr> </thead> <tbody> <tr> <td>Week One</td> <td>-16.4 (-100 – 80)</td> <td>-0.9 (-84 - 82.9)</td> </tr> <tr> <td>Week Two</td> <td>-18.7 (-100- 61.5)</td> <td>-14.6 (-96.4 -10)</td> </tr> <tr> <td>Week Three</td> <td>-29.5 (-100 – 156.4)</td> <td>-24.3 (-100- 50)</td> </tr> <tr> <td>Week Four</td> <td>-35.6 (-100 -182.1)</td> <td>-40.9 (-100- 308.3)</td> </tr> </tbody> </table> <p>The differences were not statistically significant. P > 0.05</p>		Treatment group (n = 30)	Control group (n = 30)	Week One	-2.2 (-21.2- 5.0)	-0.1 (-84 – 82.9)	Week Two	-3.2 (-27.7 – 5.2)	-1.3 (-49.5 - 4.5)	Week Three	-4.5 (-26.4 – 14.0)	-2.3 (-53.3 – 18.4)	Week Four	-4.5 (-30.9 – 22.5)	-3.5 (-53.3 – 18.5)		Treatment group (n = 30)	Control group (n = 30)	Week One	-16.4 (-100 – 80)	-0.9 (-84 - 82.9)	Week Two	-18.7 (-100- 61.5)	-14.6 (-96.4 -10)	Week Three	-29.5 (-100 – 156.4)	-24.3 (-100- 50)	Week Four	-35.6 (-100 -182.1)	-40.9 (-100- 308.3)	Blinding was not mentioned Small sample size Short duration
	Treatment group (n = 30)	Control group (n = 30)																																				
Week One	-2.2 (-21.2- 5.0)	-0.1 (-84 – 82.9)																																				
Week Two	-3.2 (-27.7 – 5.2)	-1.3 (-49.5 - 4.5)																																				
Week Three	-4.5 (-26.4 – 14.0)	-2.3 (-53.3 – 18.4)																																				
Week Four	-4.5 (-30.9 – 22.5)	-3.5 (-53.3 – 18.5)																																				
	Treatment group (n = 30)	Control group (n = 30)																																				
Week One	-16.4 (-100 – 80)	-0.9 (-84 - 82.9)																																				
Week Two	-18.7 (-100- 61.5)	-14.6 (-96.4 -10)																																				
Week Three	-29.5 (-100 – 156.4)	-24.3 (-100- 50)																																				
Week Four	-35.6 (-100 -182.1)	-40.9 (-100- 308.3)																																				

Evidence Table : Effectiveness

Question : Is BCT™ Antimicrobial dressing with ACF effective in wound care?

Bibliographic citation	Study Type / Methods	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up	Outcome measures/ Effect size	General comments
							<p>Conclusion:</p> <p>The authors concluded that the clinical data indicated the potential usefulness of using activated charcoal impregnated with silver in the management of chronic wounds. However, these studies had small sample size thus were underpowered.</p>	

Evidence Table : Effectiveness

Question : Is BCT™ Antimicrobial dressing with ACF effective in wound care?

Bibliographic citation	Study Type / Methods	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up	Outcome measures/ Effect size	General comments																		
<p>2. Soriano JV, Lopez JR, Cuervo FM et al. Effects of an activated charcoal silver dressing on chronic wounds with no clinical signs of infection. J Wound Care. 2004; 13(10): 419, 421-423.</p>	<p>Randomised controlled trial</p> <p>Aimed to explore the effect of an activated charcoal silver dressing with cleansing and debridement in reducing the level of bacteria in chronic wound with no clinical signs of local infection</p> <p>Method: Patients were randomly assigned to the treatment group and to the control group. Patients were followed up for two weeks. Bacterial status and reduction in bacterial level were determined.</p>	II-2	125 patients included in the study. 67 in the treatment group and 58 in the control group.	Activated charcoal silver dressing (Actisorb Plus)	Cleansing and debridement	Two weeks	<p>Outcomes:</p> <ul style="list-style-type: none"> Bacterial status: <ul style="list-style-type: none"> -Contaminated -Colonised -High level of bacteria -Infected Reduction in bacterial status <p>Results:</p> <p>Before treatment:</p> <table border="1" data-bbox="1381 906 1860 1385"> <thead> <tr> <th>Initial bacterial status</th> <th>Treatment group</th> <th>Control group</th> </tr> </thead> <tbody> <tr> <td>Contaminated wounds (n=86)</td> <td>71.6% (48)</td> <td>65.5%(38)</td> </tr> <tr> <td>Colonised wounds (n=4)</td> <td>0</td> <td>6.9% (4)</td> </tr> <tr> <td>High level bacteria wounds (n=9)</td> <td>7.5% (5)</td> <td>6.9% (4)</td> </tr> <tr> <td>Infected wounds (n=26)</td> <td>20.9% (14)</td> <td>20.7%(12)</td> </tr> <tr> <td>Total number of wounds</td> <td>100% (67)</td> <td>100% (58)</td> </tr> </tbody> </table>	Initial bacterial status	Treatment group	Control group	Contaminated wounds (n=86)	71.6% (48)	65.5%(38)	Colonised wounds (n=4)	0	6.9% (4)	High level bacteria wounds (n=9)	7.5% (5)	6.9% (4)	Infected wounds (n=26)	20.9% (14)	20.7%(12)	Total number of wounds	100% (67)	100% (58)	<p>Small sample size</p> <p>Short duration</p>
Initial bacterial status	Treatment group	Control group																								
Contaminated wounds (n=86)	71.6% (48)	65.5%(38)																								
Colonised wounds (n=4)	0	6.9% (4)																								
High level bacteria wounds (n=9)	7.5% (5)	6.9% (4)																								
Infected wounds (n=26)	20.9% (14)	20.7%(12)																								
Total number of wounds	100% (67)	100% (58)																								

Evidence Table : Effectiveness

Question : Is BCT™ Antimicrobial dressing with ACF effective in wound care?

Bibliographic citation	Study Type / Methods	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up	Outcome measures/ Effect size	General comments																					
							<p>After two weeks of treatment:</p> <table border="1" data-bbox="1381 581 1860 1141"> <thead> <tr> <th data-bbox="1381 581 1562 638">After two weeks</th> <th data-bbox="1562 581 1711 638">Treatment group</th> <th data-bbox="1711 581 1860 638">Control group</th> </tr> </thead> <tbody> <tr> <td data-bbox="1381 638 1562 722">Contaminated wounds (16/86)</td> <td data-bbox="1562 638 1711 722">16.7% (8/48)</td> <td data-bbox="1711 638 1860 722">21%(8/38)</td> </tr> <tr> <td data-bbox="1381 722 1562 776">Colonised wounds (3/4)</td> <td data-bbox="1562 722 1711 776">0</td> <td data-bbox="1711 722 1860 776">75% (3/4)</td> </tr> <tr> <td data-bbox="1381 776 1562 860">High level bacteria wounds (3/9)</td> <td data-bbox="1562 776 1711 860">20% (1/5)</td> <td data-bbox="1711 776 1860 860">50% (2/4)</td> </tr> <tr> <td data-bbox="1381 860 1562 945">Infected wounds (10/26)</td> <td data-bbox="1562 860 1711 945">7.1% (1/14)</td> <td data-bbox="1711 860 1860 945">75%(9/12)</td> </tr> <tr> <td data-bbox="1381 945 1562 976"></td> <td data-bbox="1562 945 1711 976">P≤0.001</td> <td data-bbox="1711 945 1860 976">P≤0.001</td> </tr> <tr> <td data-bbox="1381 976 1562 1141">Total number of wounds with reduction in bacterial level</td> <td data-bbox="1562 976 1711 1141">85.1% (57/67) P=0.003</td> <td data-bbox="1711 976 1860 1141">62.1% (36/58) P=0.003</td> </tr> </tbody> </table> <p>Conclusion: The authors concluded that activated charcoal dressings that contain silver control infection and reduce healing times,eliminating bacterial barriers.</p>	After two weeks	Treatment group	Control group	Contaminated wounds (16/86)	16.7% (8/48)	21%(8/38)	Colonised wounds (3/4)	0	75% (3/4)	High level bacteria wounds (3/9)	20% (1/5)	50% (2/4)	Infected wounds (10/26)	7.1% (1/14)	75%(9/12)		P≤0.001	P≤0.001	Total number of wounds with reduction in bacterial level	85.1% (57/67) P=0.003	62.1% (36/58) P=0.003	
After two weeks	Treatment group	Control group																											
Contaminated wounds (16/86)	16.7% (8/48)	21%(8/38)																											
Colonised wounds (3/4)	0	75% (3/4)																											
High level bacteria wounds (3/9)	20% (1/5)	50% (2/4)																											
Infected wounds (10/26)	7.1% (1/14)	75%(9/12)																											
	P≤0.001	P≤0.001																											
Total number of wounds with reduction in bacterial level	85.1% (57/67) P=0.003	62.1% (36/58) P=0.003																											