Clinical Trial of BCT KoCarbon® Hydrophilic Wound Dressing

The Clinical Application and Efficacy Verification of an Innovative Carbon Fiber Dressing

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Study Duration: 2012/08/09~2013/08/08
CMUH IRB No.: DMR101-IRB2-156
ClinicalTrials.gov Identifier: NCT01921725

I. Summary of proposal

1. Aim:

This study adopted the KoCarbon® Hydrophilic Wound Dressing invented by BCT, to verify the efficacies of the ACF-based wound dressing on various types of wounds, and to investigate the possibilities for improvement.

2. Number of subjects:

60 eligible subjects

3. Enrollment criteria:

(1) Male/Female of any race aged between 20 - 85 years old

(2) Criteria of four types of wound

Wound Type	Inclusion criteria	Exclusion criteria
General traumatic wounds	1. Wound with its length less than 20 cm, area less than 100 cm^2 and depth less than 0.5 cm	1. Infection 2. Unhealed longer than one week
Elective surgery wounds	1. Wound size less than 20 cm. 2. Apply KoCarbon® hydrophilic wound dressing right after operation	1. Infection 2. Delayed primary closure
Diabetic foot ulcer (level 2)	1. Wound with its size between 0.5 cm x 0.5 cm～5 cm x 5 cm。	1. Wound combined with necrotizing fasciitis 2. Bone exposure
Chronic wounds	1. Wound unhealed over one month 2. Wound size between 0.5 cm x 0.5 cm～10 cm x 10 cm。	1. Wound combined with necrotizing fasciitis 2. Bone or tendon exposure

4. Procedure

(1) This is an uncontrolled study. After cleansed with normal saline, all the wounds were covered with the KoCarbon® Hydrophilic Wound Dressing completely (the dressing should overlap surrounding

skin by at least 2 to 3 cm). In the case of highly exuding wounds, an absorbent secondary dressing was applied.

(2) Change the dressing when exudate covers more than 80% of the dressing until the wound healed.

Expected duration of observation and frequency of dressing change:

Type of Wound	Treatment	Observed duration	Frequency of dressing change
General traumatic wounds	Applying KoCarbon® Hydrophilic Wound Dressing right after debridement.	2 to 3 weeks	~2 days
Elective surgery wounds	Applying KoCarbon® Hydrophilic Wound Dressing right after operation	2 to 3 weeks	~2 days
Diabetic foot ulcer (level 2)	1. Applying KoCarbon® Hydrophilic Wound Dressing right after cleaning the wound with normal saline. 2. Infected wound proceed debridement and bacterial culture before applying KoCarbon® Hydrophilic Wound Dressing.	2 to 3 months	1 to 2 days
Chronic wounds	1. Applying KoCarbon® Hydrophilic Wound Dressing right after cleaning the wound with normal saline. 2. Infected wound proceed debridement and bacterial culture before applying KoCarbon® Hydrophilic Wound Dressing.	2 to 3 months	1 to 2 days

5. Data Collection and Outcome Measurements

PI would assess the healing effects of KoCarbon® Hydrophilic Wound Dressings on the reference wounds by comparing the retrospective medical records of the same kind of wounds in the following aspects:

(1) The healing rate. Photographs of wounds were taken, and pictures were imported to image-analyzing software for the calculation of wound area.

(2) Infection rate.

(3) Measurement of pain. The pain is measured using a 10-grade linear scale ranging from no pain (0) to the intolerable pain (10).

(4) Scar evaluation. The scar development was assessed by Patient and Observer Scar Assessment Scale (POSAS).

5.1 Outcome Measurements

(1) Primary：

The dose and frequency of antibiotics usage

The healing percentage and the healing rate

Wound infection rate

Scar development

(2) Secondary：

Wound-related pain and itching

Scar assessment on 1 month after the wound had healed

II、Closed Report of Clinical Trial

1. Date of Close Report: 2013/10/8

2. Study Duration: 2012/08/09~2013/08/08

3. Data Analysis

(1) Whether the dressing facilitates the wound healing was the primary outcome measure, represented by the healing percentage and the healing rate. Photos were taken on the scheduled time point, and the wound area was calculated.

(2) Both level II diabetic foot ulcer and chronic wounds are difficult to heal unless they are cared properly. Therefore, these wounds were statistically defined as “non-heal”, and the healing percentage of the wounds after using KoCarbon® Hydrophilic Wound Dressings for a certain period was evaluated and viewed as the effectiveness of the dressing.

(3) General traumatic wounds and surgery wounds heal in 14 days generally. Hence these wounds

were statistically defined as “heal in 14 days”, and the healing percentage of the wounds after using KoCarbon® Hydrophilic Wound Dressings for a certain period was evaluated and viewed as the effectiveness of the dressing.

4. Results:

(1) Number of subjects in each wound type:

General traumatic wounds: 8

Elective surgery wounds: 36

Diabetic foot ulcer (level 2): 3

Chronic wounds: 13

Total number of patients included: 60；36 male and 24 female.

(2) The dose and frequency of antibiotic usage: No difference.

(3) The wound infection rate: No obvious difference.

(4) Scar development: No obvious difference.

(5) Mean pain score: 3.2

General traumatic wounds: 4.3

Elective surgery wounds: 3.2

Diabetic foot ulcer (level 2): 3.0

Chronic wounds: 2.8

(6) Number of patients feeling wound-related itching: 6

5. Discussion

The majority of enrolled participants belonged to the surgical wound group or the general traumatic wounds group. The beneficial effects of KoCarbon® Hydrophilic Wound Dressings on wound care were obvious. Notably, the growth of granulation tissues was significant in several deeper chronic wounds. This study yielded positive information about the feasibility of clinical application of KoCarbon® Hydrophilic Wound Dressings.

(1) In the surgical wound group, we observed that the frequency of dressing changes was reduced, the adherent level was low, and the mean pain score of subjects was 3.2, all of which increased

quality of treatment. Although it was unable to determine whether the wound underneath suture healed completely by the naked eye, the incidence of delayed healing was lower which was observed when stitches were remove routinely.

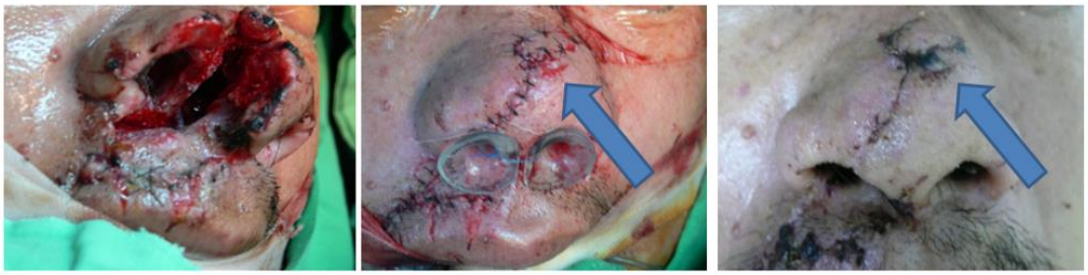
(2) The sample size in the diabetic foot ulcer (level 2) group was small, but the wound healing was significantly progressing in the type II diabetes mellitus-related ulcer. Wound swelling was evidently reduced (may be due to promotion of microcirculation), however, the metabolism of the surface stratum corneum was not changed. Extended trial period and increased sample size were required to verify the effects of KoCarbon® Hydrophilic Wound Dressings on diabetic foot ulcer.

(3) The participants in the traumatic wound group were satisfied with the KoCarbon® Hydrophilic Wound Dressing, because of the less adherence, higher comfort, and reduced sensations of pain and itching. No redness and swelling occurred in the wounds of this group. The frequency of dressing changes was elevated on the wounds producing a large amount of exudate, such as large-area abrasion. In this circumstance, it is found that creating several drainage pores on the dressing and covering the dressing with gauze could effectively improve the absorption ability of it.

6. Case Discussion

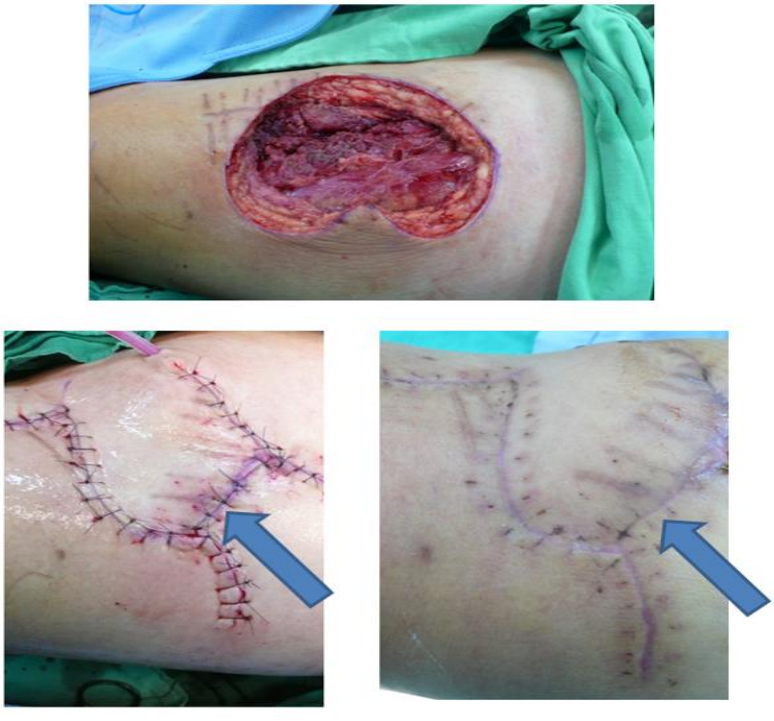
Case No. 1: Traumatic wound

The suture edge necrosis is also easy to occur on the irregular edge of traumatic wounds. The application of KoCarbon® Hydrophilic Wound Dressings made the wound heal successfully without edge necrosis, possibly due to FIR emitted from the dressing.



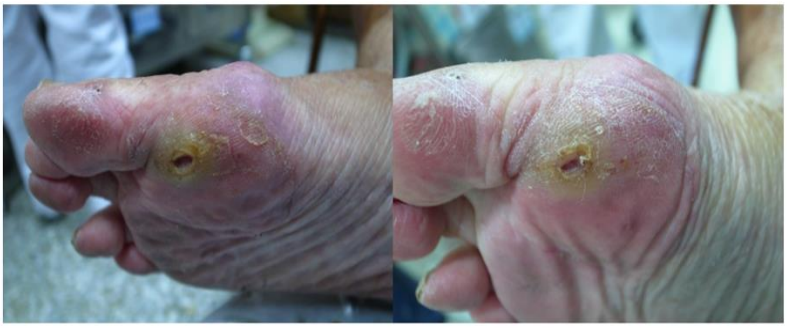
Case No. 2: Post reconstruction surgery wound

The flap edge necrosis is very common among high tension suture wounds. This case indicated that KoCarbon® Hydrophilic Wound Dressing is capable of reducing the chance of edge necrosis by the effect of FIR.



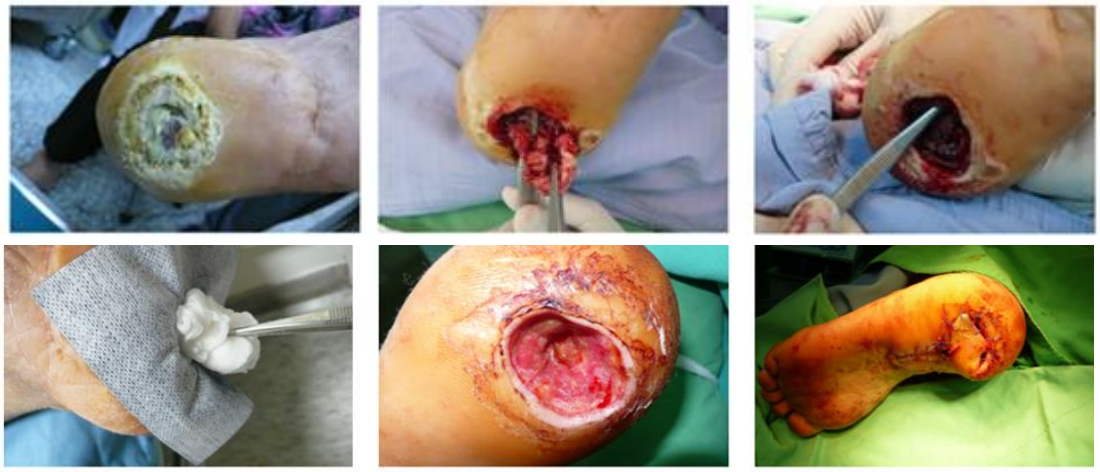
Case No. 3： Diabetic Foot Ulcer (Level 2)

A 0.5 x 0.4 x 0.4 cm right plantar ulcer failed to heal for a long time. It is clinically determined as a level 2 diabetic foot ulcer. After using KoCarbon® Hydrophilic Wound Dressings for 1 week, the skin color of the edge of the wound became red and glossy. This suggested that the establishment of microcirculation promoted wound healing.

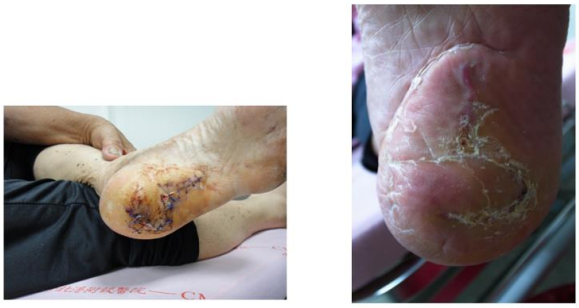


Case No. 4: Chronic Wound- Complex wound with combined treatment

This wound is quite deep; therefore FIR was expected to promote the formation of the granulation tissue. During the follow-up period, it was clinically observed that the granulation tissue grew well. This may suggested that the FIR emitted from the dressing accelerated wound healing via increased microcirculation and metabolism rate.



2nd week 3rd week



4th week 6th week

7. Conclusion

(1) It was preliminarily proven that the FIR emitted from the KoCarbon® Hydrophilic Wound dressing reduced the incidence of wound edge necrosis.

(2) It was preliminarily proven that the FIR emitted from the KoCarbon® Hydrophilic Wound dressing promoted the growth of granulation tissues, which is beneficial for future reconstruction.

(3) It will be better if the ability of exudate absorption of the KoCarbon® Hydrophilic Wound dressing is ameliorated.

(4) The dose and the frequency of antibiotic usage: There was no obvious difference when compared the medical records of patients in this study with those before.

(5) The percentage and the rate of wound healing were significantly improved in groups of traumatic wound, chronic wound and diabetic foot ulcer (level 2)；Whereas, there was no obvious difference in the surgical wound group.

(6) The infection rate: There was no obvious difference when compared the medical records of patients in this study with those before.

(7) Pain and itching were significantly decreased when compared the medical records of patients in this study with those before.

(8) Scar development: No difference was observed during the trial. The extended follow-up period was needed to examine the inhibition effect of scar development of the dressing.