Clinical Trial of BCT KoCarbonAg® Silver Bandage

A Comparative Efficacy and Safety Study between Bio-Medical Carbon Technology Silver Bandage and Aquacel® Ag Dressing In Obstetrical and Gynecological Post-Operation Wound Healing

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Study Duration: 2012/6/1~ 2013/10/16
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I. Summary of proposal

1. Study objective

The objective of this study is to evaluate the clinical efficacy and safety of BCT Silver Bandage in obstetrical and gynecological wound healing with Aquacel® Ag dressing as the comparison.

2. Criteria

Inclusion criteria	Exclusion criteria
1. Male/Female of any race aged between 18 - 70 years old. 2. The subject is having surgery (Casearian/pfannenstiel or Open Laparotomy incision) within 1 week.	1. Patients with known allergy or topical hypersensitivity to ionic silver or alginate. 2. Any systemic or local active dermatological disease that might interfere with the evaluation of the surgical site such as eczema, psoriasis, skin cancer, scleroderma, chronic urticarial. 3. Patients undergoing MRI (Magnetic Resonance Imaging) examination.

3. Study design

- Randomized, Open-label, interventional, comparative, preventive study with Blinded evaluator.
- All subjects must meet all the inclusion & exclusion criteria to enter this study in pre-operative phase.
- Eligible subjects will be enrolled after a scheduled operative procedure.
- There is SEVEN visits in this study (one screening eligibility phase up to 7 days before OP day, and four post-op treatment scheduled visits consisting on 1st , 3rd, 5th, 12th day and two follow up visit on the 28th and the 42nd post-operative day.
- During each scheduled visit, each subject will have colored picture on wound area after removal of dressing, and on visit 6 for wound evaluation by blinded PI.

Study device: BCT Silver Bandage

Comparator device: "ConvaTec" Aquacel® Ag Hydrofiber Dressing

4. Efficacy Measurements

Primary:

(1) The incidence of postoperative skin reactions (defined as blisters, itching, erythematous change around the surgical wound site) within 5 days after operation.

(2) Wound infection rate within 5 days after operation.

(3) Wound healing evaluation by Stony Brook Scar Evaluation Scale (SBSES), to be evaluated by blinded PI at V6.

Secondary:

(1) Skin discoloration around the incision wound and/or wound keloid formation rate at V6.

(2) Patient and Observer Scar Assessment Scale (POSAS) on V3, V5 and V6

II. Close Report of Clinical Trial

1. Date of Close Report: 2013/10/16

2. Study Duration: 2012/6/1~2013/10/16

3. Outcome Analysis

(1) Patient Characteristics

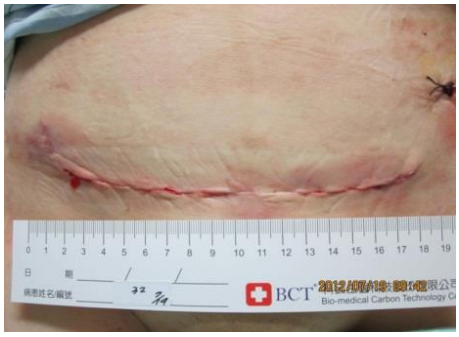
	BCT Silver Bandage	**Aquace$^{l®}$ Ag dressing**
Patient number (n)	15	23
Average Age (years-old)	45.8	45.3
Surgery type:		
cesarean section	1	0
myomectomy	4	12
hysterectomy	3	4
radical hysterectomy	3	3
cancer debulking surgery	3	4
benign ovarian cyst surgery	1	0

(2) Post Operation Follow Up

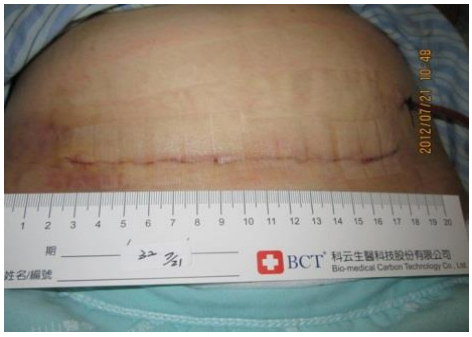
	BCT Silver Bandage	Aquacel® Ag dressing	P value
POSAS score on post-operation day 12 (Visit 5)	Score 11 13 Score 12 1 Score 17 1 **Average 11.47**	Score 11 15 Score 12 3 Score 13 1 Score 14 2 Score 15 1 Score 16 1 **Average 11.87**	0.21
POSAS score on post-operation day 42 (Visit 7)	Score 11 11 Score 12 1 Score 14 1 Score 17 1 Score 26 1 **Average 12.67**	Score 11 14 Score 12 2 Score 13 3 Score 14 1 Score 16 1 Score 17 1 Score 30 1 **Average 12.78**	0.47
SBSES score on post-operation day 42 (Visit 7)	Score 5 13 Score 4 1 Score 3 1 **Average 4.8**	Score 5 17 Score 4 4 Score 3 2 **Average 4.65**	0.23
Keloid on post-operation day 42 (n) (Visit 7)	1	0	>0.5
Pigmentation on post-operation day 42 (n) (Visit 7)	0	1	>0.5

4. Case Discussion

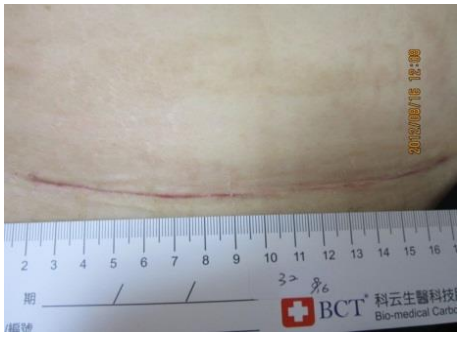
Case No.1: 49 year-old woman underwent surgery to remove the endometrial border-line tumor. BCT Silver Bandage was applied and changed every 2 days. After discharged on the 5th day post-OP, BCT silver bandage was changed once a week.



Day 1. The wound was 16 cm in length and showed redness and swelling.

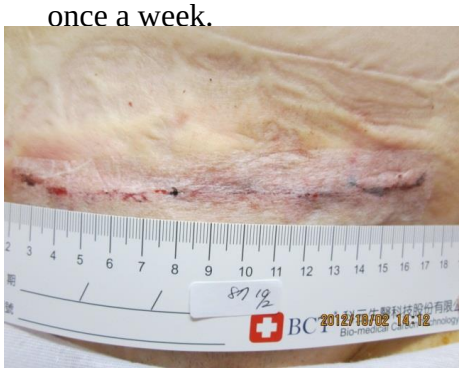


Day 3. Wound was completely closed. The symptom of redness and swelling had vanished.

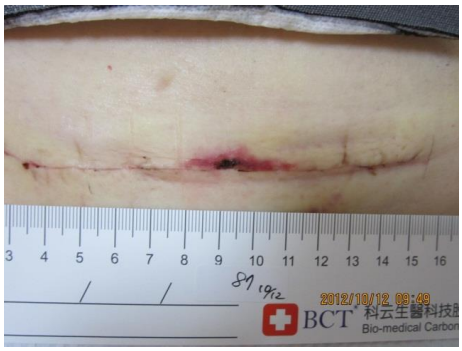


Day 29. The newly formed tissue was smooth and no obvious signs of scar formation were observed.

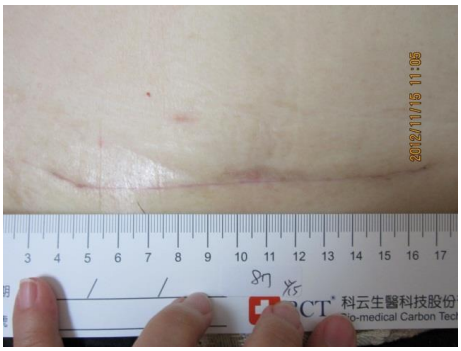
Case No.2: 49 year-old woman underwent myomectomy. BCT Silver Bandage was applied and changed three days later. After discharged on the 4th day post-OP, BCT silver bandage was changed once a week.



Day 1. The wound was 16 cm in length and showed redness and swelling.

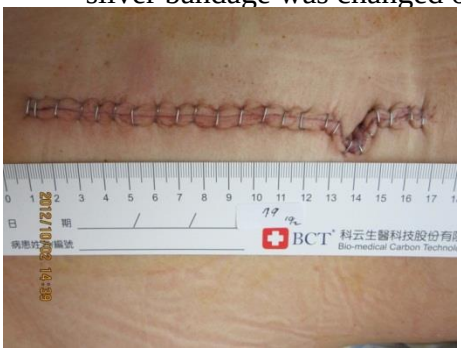


Day11. Wound was closed with ecchymoma around the center region.

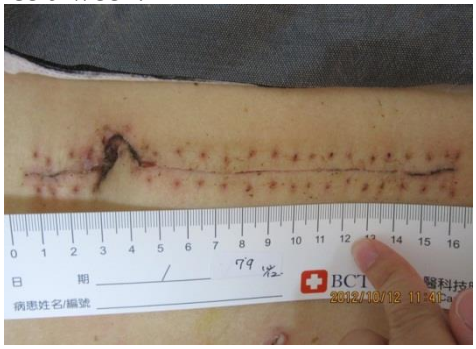


Day 45. The newly formed tissue was smooth and no obvious signs of scar formation were observed.

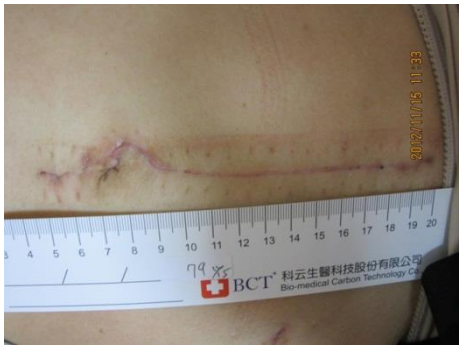
Case No.3: 46 year-old woman with cervical cancer underwent radical hysterectomy. BCT Silver Bandage was applied and changed every 3 days. After discharged on the 7th day post-OP, BCT silver bandage was changed once a week.



Day 1. The wound was 17 cm in length after operation.



Day11. Off staples. Wound was closed completely.



Day 45. The newly formed tissue was smooth and even.

5. Conclusion

(1) There were no adverse events in either BCT silver bandage group or Aquacel® Ag dressing group within 5 days after operation, indicating the safety of both dressings.

(2) No incidence of wound infection in both BCT silver bandage group and Aquacel® Ag dressing group within 5 days after operation.

(3) Based on the POSAS evaluation at 12 days after operation, regarding to vascularization, pigmentation, pain, itch, scar color difference, stiffness of the scar, thickness of the scar and scar appearance, BCT silver bandage group and Aquacel® Ag dressing group showed similar healing efficacy with score of 11.5 and 11.8, respectively. Lower score indicated better healing outcome.

(4) On 42 days after operation, the SBSES score in BCT silver bandage group and Aquacel® Ag dressing group were 4.8 and 4.65, respectively. This indicated both group had equal cosmetic effect.

(5) On the 42 day after operation, no subject had wound pigmentation in the BCT Silver Bandage Group, whereas one patient in the Aquacel® Ag dressing group has wound pigmentation.

(6) On the 42 day after operation, there was one subject developed keloid in the BCT Silver Bandage group. No subject in the Aquacel® Ag dressing group developed keloid.

(7) POSAS score on 42nd day after operation in BCT Silver Bandage group and Aquacel® Ag dressing group were 12.7 and 12.8, respectively, indicating both group had equal cosmetic effect.

(8) There were no adverse events in either group during entire applying period, indicating the safety of both dressings.