An Open Multicenter Comparative Prospective Randomised Clinical Study On A Fibrous Chitosan Wound Dressing (KytoCel®)

**Introduction**

An advanced wound care dressing that uses a natural resource in its ability to absorb and retain moisture as well as to provide antimicrobial properties, offers a new multi-functional, wound dressing (KytoCel® Aspen Medical Europe Ltd.) Several factors indicate the need for such a dressing namely: an ageing population inevitably increases the prevalence of wounds managed across acute and community settings. The prevention and management of infection remains a priority and the use of natural resources is generating interest. This poster presents the results of a randomised clinical study in the safety and efficacy of a chitosan gelling fibre dressing in the treatment of chronic non-healing wounds.

**Method**

The aim of this study was to demonstrate improved healing outcomes measuring the following criteria: baseline data wound aetiology, total wound surface area (including wound depth), exudate type and amount, dressing ability to manage wound fluid, clinical observation of tissue type, pain during wear time and dressing change using numerical pain score (0 = no pain – 10 = severe pain) over a four week period. An open multicentre randomised clinical study was conducted from November 2012 to July 2013. A total of 90 patients with a mean age of 61.2 (test group) to 63.2 (control group) were recruited from three centres in Guangdong Province, with non-healing chronic wounds that had failed to progress to healing over six weeks or more. Wounds treated in this study included pressure ulcers, leg ulcers, diabetic foot ulcers, and chronically infected. Exclusion criteria patients were those with shellfish allergy, pregnant women, patients with serious disease unsuitable for clinical trial, unable to provide written informed consent. Patients were divided into 2 groups (Control Group/Test Group) at the ratio of 1:1. The randomising grouping for all 90 subjects was formed into a Random Code Table (therapy allocation corresponding to a range of sequential numbers 01~90). The random code table was kept by a designated person (referred to as Keeper) in each centre. The Active dressing was KytoCel® and control arm was gauze.

**Results**

After 4 weeks treatment, the wound area reduction was significantly greater in the test group (65.97±4.48%) when compared to the control group (39.95±4.48%). The wound depth was reduced in the test group by 0.30±0.48cm and in the control group 0.54±0.86 cm. The mean pain score in the test group was significantly lower 1.2±0.23 compared to 2.3±0.23 in the control group. Wound tissue type and exudate handling had improved in the test group; the dressing could be removed integrally in both the test and control groups. The mean wound duration of the test group was 27.31±5.37 days and control group 27.09±6.64 days. Patients identified with clinically infected wounds in the test group had 43% increase in healing rate and demonstrated improved healing outcomes compared to 11.7% in the control group. 8 out of 35 patients in test group achieved a complete healing within 4 weeks, compared to 1 out of 34 in control group. A further 7 out of 33 patients in test group achieved a healing rate of 80% or above. This was based on predictions to heal from reduction in total wound surface area. No adverse events were reported in either group. 10 patients failed to attend the follow up and 1 patient withdrew from the study. Among these 11 patients, 3 were in the test group and 8 in the control group.

**Discussion**

Sheehan et al (2003) suggests that a percentage change in wound measurement over a four week period was a robust indicator to healing at twelve weeks in 203 patients with diabetic foot ulcers. KytoCel® wound dressing is an advanced wound dressing made from acylated chitosan fiber. The results across all parameters measured over four weeks demonstrated a significant reduction in wound size and depth, improved fluid handling in wear time and dressing change. The gelling fibre ability appeared to reduce pain during wear time and dressing change. 43% of the infected wounds in the test group achieved a healing rate of 80% or above. The healing rate results in this study supports the effectiveness of this dressing in supporting the reduction of bio-burden in wounds and risk of infection or in those wounds clinically infected.

**Conclusion**

KytoCel® has some unique properties in that it is a natural bacteriostatic with the ability to aid haemostasis and coagulation in a gelling fibre dressing. This study demonstrates the safety and efficacy of KytoCel® for clinical use for patients suffering with a variety of chronic non-healing wounds.

**References**


2. Sheehan E, Jones C, Cuddiff A, Guerin JM, Veves A. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. Diabetes Care 2003;26:1879-82.

Case Study 1

- Fig. 1 Wound on 12.11.12
- Fig. 2 Wound on 19.11.12
- Fig. 3 Wound on 12.12.12

Case Study 2

- Fig. 4 Wound on 16.10.12
- Fig. 5 Wound on 29.10.12
- Fig. 6 Wound on 31.10.12

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