

Funnel Chest Surgical Procedure Study Overview

A 40 patient randomized prospective study was conducted on Funnel Chest (Pectus excavatum) surgical patients from January 2004 to September 2005 at the University of Erlangen-Nuremberg, Germany, Pediatric Surgery Department. The patients were evenly divided into two treatment groups:

- (a) 20 patient Control Group: utilizing standard wound dressing and dry care protocol
- (b) 20 patient BioDerm Sciences Wound Management product Group: utilizing wound solution impregnated osmotic gradient dressing

Study Rationale

Germany is instituting a Diagnostic Related Group (DRG) system similar to that introduced by the United States and more recently the United Kingdom. The German DRG system is anticipated to evaluate post surgical wound management in pediatric populations based on at least the following five outcome criteria:

- (a) Time to Closure
- (b) Infection Rate
- (c) Crust Formation at 4 and 9 days post operation
- (d) Keloid Formation at 90 and 360 days post operation
- (e) Cost:
 - (1) Administration: (a) Direct and (b) Nursing care administration
 - (2) Adverse Events: (a) Infection

Subject Baseline Characteristics

Subject Characteristics	BioDerm Sciences Wound Solution and Dressing Care	Standard Dressing and Dry Care
Age		
Number	20	20
Mean (Std. Dev.)	19.3 (5.1)	15.5 (1.7)
Range	16-48	16-39
Gender		
Male	20	20

Post Surgical Wound Care: Clinical and Cost Comparisons

Outcome Parameter	BioDerm Sciences Wound Solution and Dressing Care Group	Standard Dressing and Dry Care Group
Time to Closure (in days)		
Mean	3.9	7.1
Range	3.2-4.5	5.7-8.0
Infection Rate (# of patients)	0% (0)	15% (3)
Crust Formation (avg. score)* 4 Days Post Operation	1.06	2.40

9 Days Post Operation Keloid Formation (avg. score)*	1.00	2.25
90 Days Post Operation	1.00	2.08
360 Days Post Operation	1.30	2.60
Post Surgical Wound Care Cost Administration Cost of Treatment		
Direct Product Acquisition	\$119.00^{\$}	\$12.00^{\$}
Nurse Administration [thru wound closure]	\$80.00	\$750.00
	One Dressing Administration Four reservoir loads Four syringes/needles One Dressing Removal	Avg. Six Dressing Administrations Avg. Six Dressing Debridements Avg. Six Dressing Removals
Mean Total Adm. Costs/patient	\$199.00	\$762.00
Total Administration Costs/study	\$3,980.00	\$15,240.00
Mean Adverse Event Treatment Costs Infection**	\$0.00	\$700.00/day Additional Hospital Stay Costs Once daily oral antibiotic \$10,500.00***
Total Adverse Event Costs	\$0.00	\$25,740.00
Total Post Surgical Wound Care Study Costs	\$3,980.00	
Total Mean Post Surgical Wound Care Cost	\$199.00	\$1,287.00
Per Subject		

* Results of independent evaluation of the wound site according to the following scale:

1= none; 2 = <10% of wound length; 3 = 10-20% of wound length; 4 = >40% of wound length

^{\$} Average Euro to Dollar Exchange Rate during the study period was 1.21

** Infection with this procedure results in an additional hospital stay at ~\$650/day

*** 3 patients with average 5 days hospital extension

Note Well: Funnel Chest surgery is performed on an otherwise healthy adolescent (or) young adult to prevent future chest compression growth and organ function complications. One of the biggest health risk factors with the procedure is the potential risk of infection. Many of the premier teaching facilities in the world that performs this procedure post a 2%-10% infection rate due the pressure on the wound during the first 96 hours Post Operation.

Randomized Prospective Funnel Chest Post Surgical Wound Care Study Results

In this independently reviewed study, the global review team found the following results to provide statistically better performance post op with the use of BioDerm

Sciences Wound Solution and Osmotic Gradient Dressing versus the globally recognized standard dressing and dry care regimen.

The BioDerm Sciences Wound Care regimen demonstrated a sixty percent (60%) faster closure rate when compared to the Global gold standard of care and on average reduced the time to closure by 3.1 days to 3.9 days.

Potentially in part due to the faster wound closure rate, the infection rate of 0% in the BioDerm Sciences group when compared to the infection rate of 10% with other premier centers utilizing the gold standard regimen, while remarkable, was even more significant by comparison to the standard care control group in this study of 15%.

While not a direct cost consideration for DRG analysis the BioDerm Sciences Wound Care regimen reduction in crust and keloid formation represents significant Quality of Life and Psychological parameter improvements compared to the Global Gold Standard regimen.

Recognizing the importance of optimizing nursing staff time in Europe, as in the United States, where nursing shortages are occurring, the BioDerm Sciences Wound Care regimen demonstrated a four-fold reduction in administration costs by comparison to the Global Gold standard regimen.

The Mean Total Post Surgical Treatment Cost with the BioDerm Sciences Wound Care regimen demonstrated a six-fold (6x) improvement in cost by comparison to the Global Gold Standard regimen. Two factors largely account for this drastic cost reduction:

- (1) Minimal costs associated with daily care and
- (2) A zero incidence of infection

While the BioDerm Sciences Wound Solution and Osmotic Gradient Dressing with Reservoir represent a statistically significant improvement to this Funnel Chest Surgical Post Op care regimen versus the Global Gold Standard, the independent review team believes that the BioDerm Sciences Wound Solution and Osmotic Gradient Dressing should be compared to standard regimen for Funnel Chest again in other centers to insure reproducibility of the study findings.