

# Efficacious and Cost-Effective Use of Small Intestinal Submucosa (SIS) Wound Matrix in a Community-Based Setting

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## INTRODUCTION

Chronic wounds represent >50% of nursing visits in the community. These wounds substantially impact public health and resources, and can lead to serious sequelae such as infection, cellulitis, sepsis, pain, osteomyelitis, and amputation, which can substantially reduce patient quality of life and dramatically increase costs.

Among patients with chronic wounds, a sizable population remains difficult to heal despite standard of care. We are interested in using biotechnology to increase healing rates and reduce the burden of care for these patients using cost-effective and practical methods. We therefore undertook an open study designed to evaluate OASIS® Wound Matrix for the treatment of difficult-to-heal or chronic wounds. OASIS® is a natural, biological extracellular matrix (ECM) that may help replace missing or dysfunctional ECM, thereby stimulating wound closure.

## METHODS

**Setting:** Community Care Access Centre (CCAC), Southern Ontario, Canada; a Best Practice Organization in Wound Care (RNAO Designated)—the first and only CCAC awarded this designation

**Inclusion criteria:** Patient age >16 yrs, ulcer size >2 cm<sup>2</sup>, viable wound bed with granulation tissue, ankle brachial index (ABI) >0.5, inadequate wound healing despite standard of care, client consent

**Exclusion Criteria:** Active systemic infection; diabetic uncontrolled (HbA1c >8.9%) or not offloaded; venous ulcer not in compression system ≥20 mmHg; pressure ulcer not offloaded; necrotic or debris on wound bed; slough that required debridement; eschar in wound; malignant wound; third-degree burns; allergy to porcine source or porcine material; Muslim active in religious beliefs

**Design:** Prospective, open study; historical case control

### Procedures:

• OASIS® applied to the wound and covered with a secondary dressing by an Advanced Practice Nurse (APN)

• OASIS® and secondary dressings reapplied as necessary; APN sharply debrided wounds as necessary

• Healing evaluated at weekly follow-up visits

• Costs of OASIS®, secondary dressings, and nursing time documented and calculated for each healed patient

• Follow-up continued for 17 weeks or until healing

**Matched historical control:** Charts reviewed from most recent backward and included only patients who had been treated with standard of care (i.e., past 2 years at CCAC); most recent match selected. Matched variables were age (+/- 5 years), wound type, major comorbidities, wound duration, wound size

## RESULTS

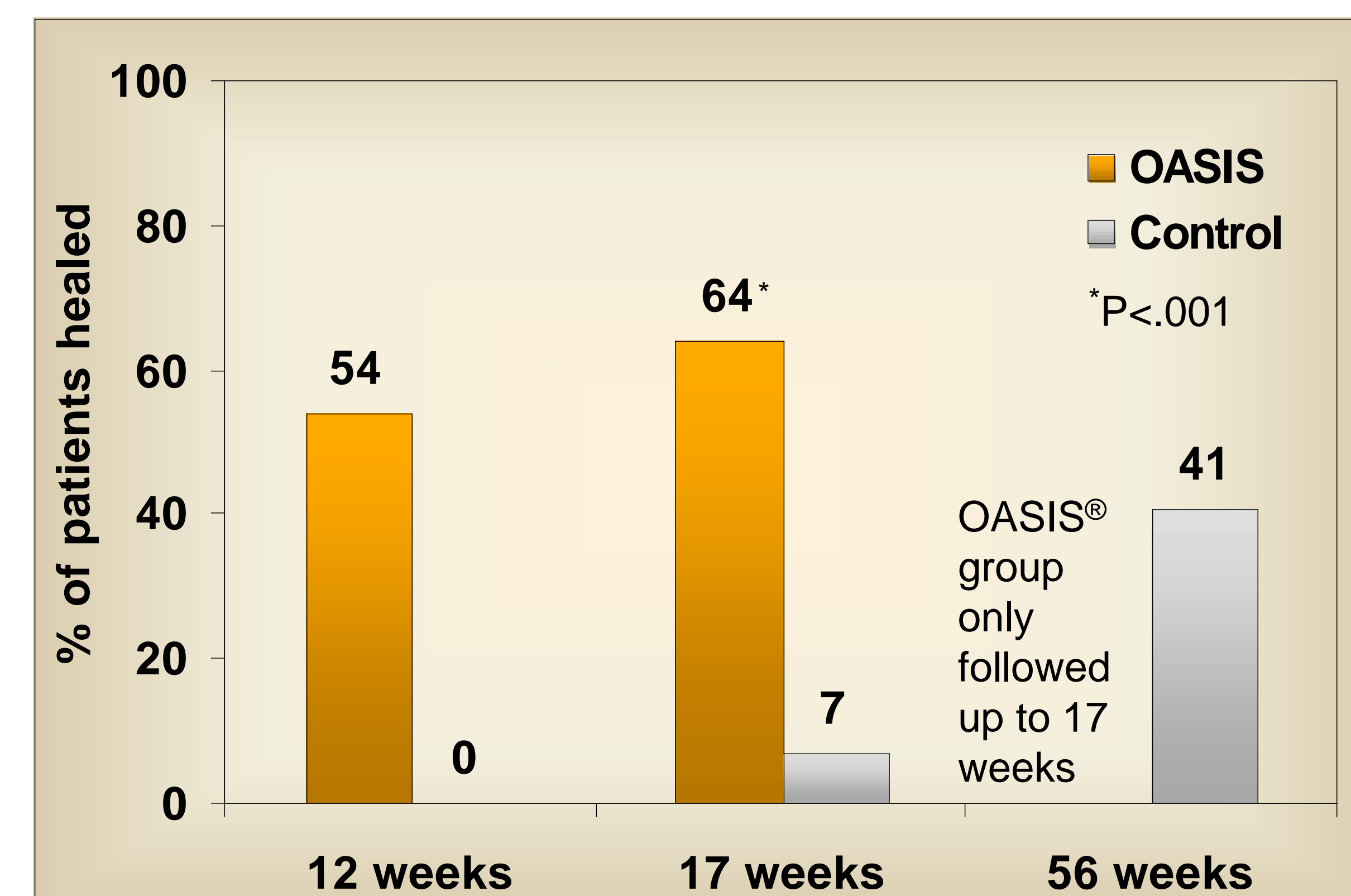
### DEMOGRAPHICS

	OASIS® (n=70)*	Historical Control (n=70)
Age, mean yrs (SD)	63.7 (16.4)	63.8 (15.5)
Patient gender	37 F, 33 M	33 F, 37 M
Ulcer type (n)		
Venous	14	14
Diabetic	19	19
Pressure	16	16
Arterial	7	7
Traumatic	4	4
Surgical	10	10
Ulcer size, mean cm <sup>2</sup> (SD)	6.1 (2.1)	6.0 (1.9)
Ulcer duration, mean wks (SD)	26.5 (25.2)	25.7 (24.6)
Ulcer pain at baseline from 1-10, mean (SD)	4.9 (2.3)	5.0 (2.3)
Patient nutrition status		
Stable	37	34
Fair	23	22
Poor	10	14

\*A total of 59 of 70 patients treated with OASIS® completed the study

### COMPLETE HEALING

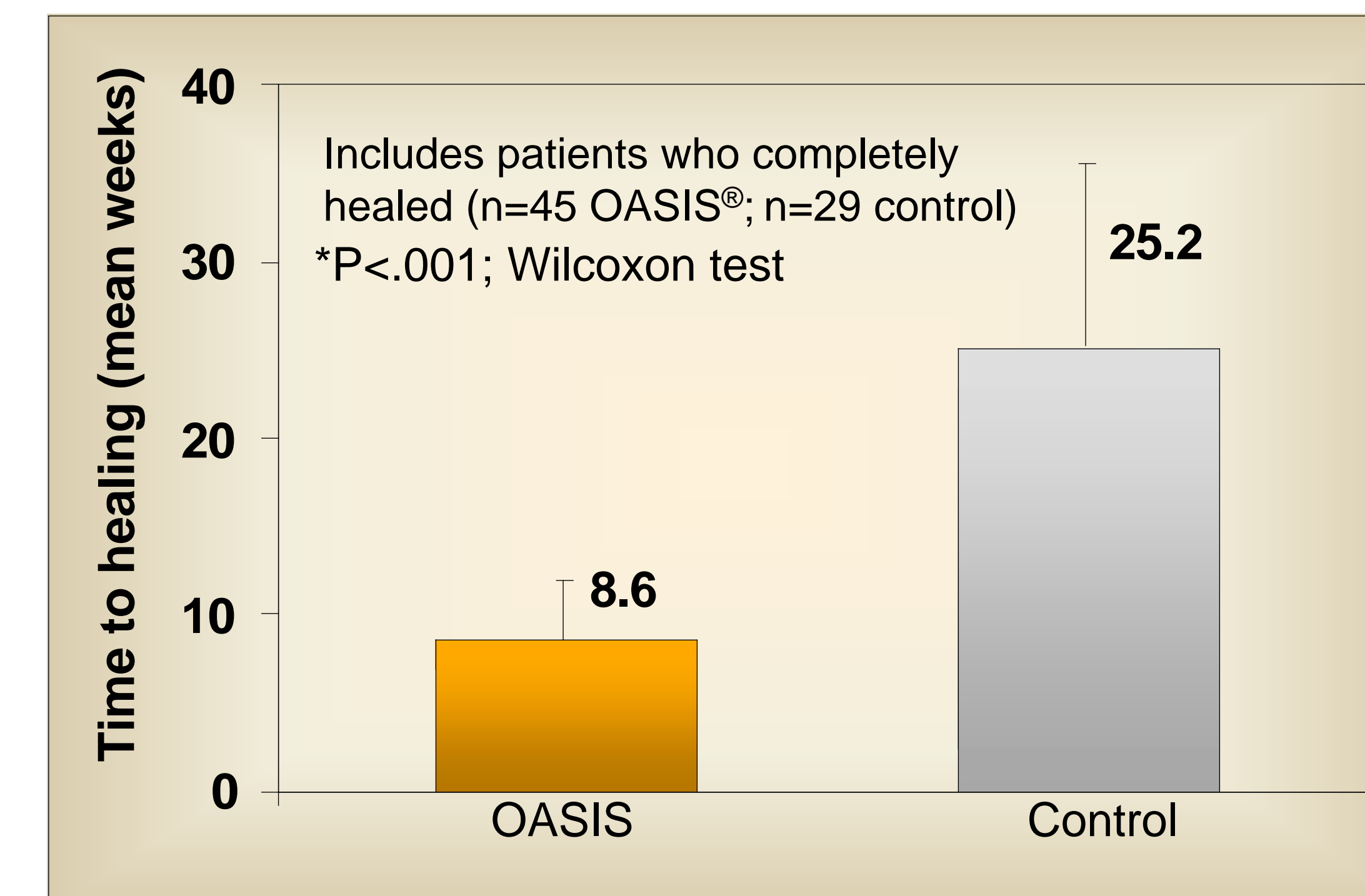
**OASIS® significantly increased % of patients completely healed at 12 weeks and 17 weeks**



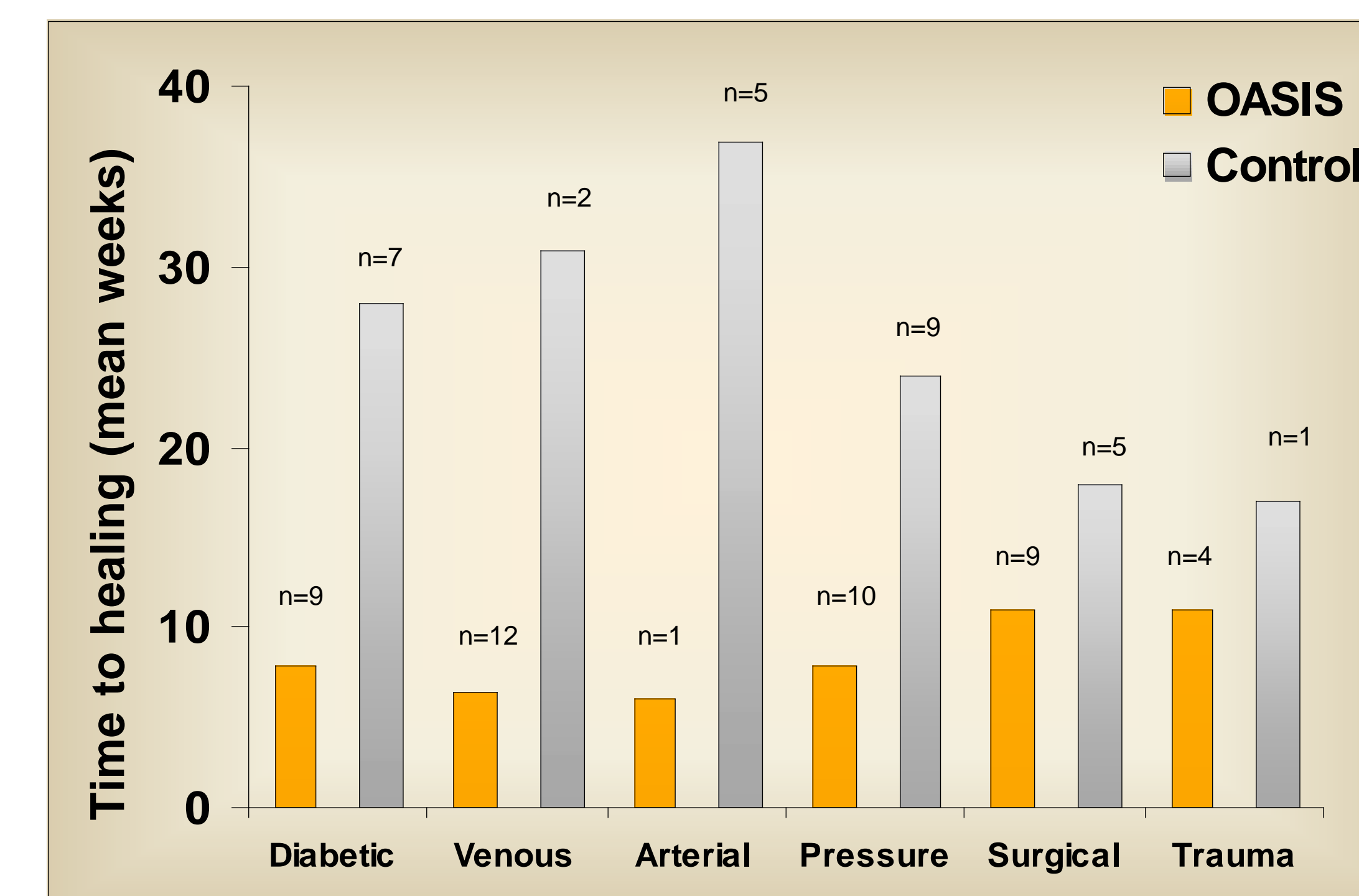
Patients treated with OASIS® were followed for up to 17 weeks; controls were followed for up to 56 weeks; n=70 per group  
\*P<.001 Fisher's exact test

### TIME TO HEALING

**OASIS® significantly decreased time to healing**



**OASIS® appeared effective for multiple wound types**



N values indicate number healed of 19 diabetic, 14 venous, 7 arterial, 16 pressure, 10 surgical, 4 trauma wounds per group

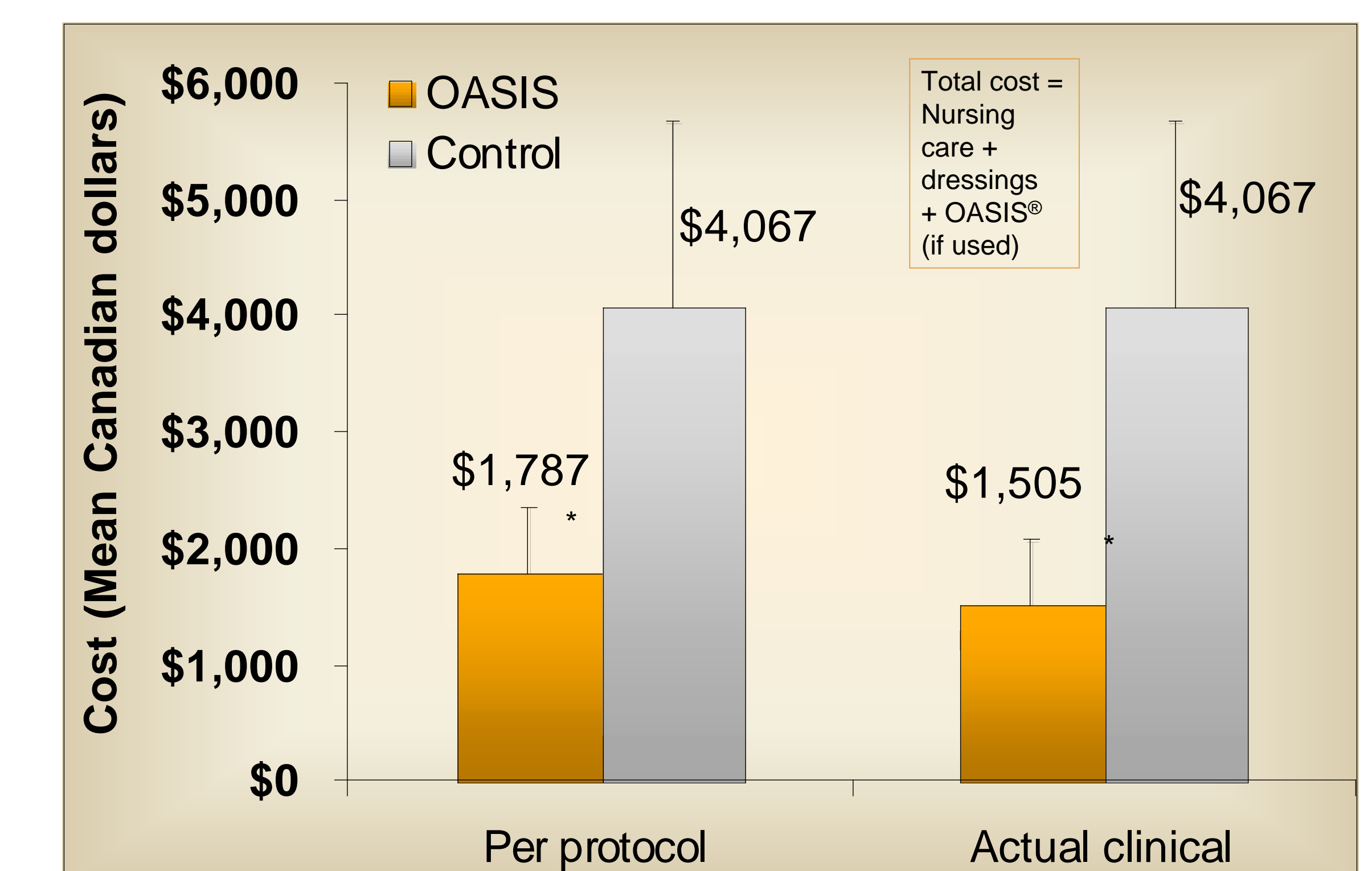
### COST AND DRESSING CHANGES

	OASIS®	Control
Total nursing costs for healed patients (mean, SD)	\$804 (\$270)	\$2,983 (\$1,167)
Wound dressing costs for all patients (mean, SD)	\$410 (\$323)	\$1,231 (\$1,178)
Frequency of dressing changes, every X days (mean, SD)	4.8 (2.0)	4.3 (2.1)

All costs in Canadian dollars

### COST OF HEALING

**OASIS® significantly reduced cost of healing**



Per protocol: Unused OASIS® discarded  
Actual clinical: Unused OASIS® could be used on wound

\*P<.001; Wilcoxon test

## DISCUSSION AND CONCLUSIONS

- Difficult-to-heal wounds can reduce patient quality of life, cause serious sequelae, and are resource intensive
- Healing these wounds as rapidly and cost effectively as possible is an important treatment objective
- Difficult-to-heal and chronic wounds have a dysfunctional ECM or lack an ECM
- ECM replacement with OASIS® appears to be a viable treatment strategy for these wounds
- OASIS® appeared to:
  - Significantly increase % of wounds completely healed
  - Significantly increase % healed within 12 and 17 weeks
  - Reduce time to healing
  - Significantly reduce total cost of healing
- No treatment-related adverse events reported
- Results supported by randomized, controlled trials<sup>1-3</sup>

## REFERENCES AND DISCLOSURE

<sup>1</sup>Niezgoda JA, et al. Adv Skin Wound Care. 2005;18(5 Pt 1):258-66.

<sup>2</sup>Mostow EN, et al. J Vasc Surg. 2005;41(5):837-43.

<sup>3</sup>Romanelli M, et al. Int Wound J. 2007;4(1):3-7.

The author has no financial interest in any of the products mentioned in this poster. Development of this poster was supported by Healthpoint, Ltd.