Comparative Effectiveness of a Collagen/Oxidized Regenerated Cellulose/Silver-ORC Dressing with Cellular Tissue Product Versus Cellular Tissue Product Alone in Wound Care

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Introduction

- A dressing formulated with collagen, oxidized regenerated cellulose (ORC), and silver-ORC, becomes a biodegradable gel in the presence of exudate.
- This dressing contacts all areas of the wound, and creates a microenvironment that facilitates chronic wound closure, inactivates proteases, provides antimicrobial protection, and protects growth factors.[1-3]

Purpose

- This study examined the difference in outcomes between wounds treated with collagen/oxidized regenerated cellulose/silver-ORC dressing (COSO)* and a cellular tissue product (CTP) and wounds treated with a CTP without COSO.

Methods

- Using U.S. Wound Registry data, 1,674 wounds treated with COSO+CTP were identified. Propensity score matching within each wound type was used to create a cohort of 1,674 control wounds that used CTP alone.
- Outcomes evaluated included the healing status and change in wound size. Chi-square and t-tests were used to evaluate differences between the two cohorts.

Table 1. Patient demographics after propensity score matching

		COSO+CTP	CTP alone	p values
Total number of patients		1674	1674	
Age at first treatment (years)	mean (sd)	65.03 (14.00)	65.35 (15.25)	0.5264
Age at last treatment (years)	mean (sd)	67.23 (13.88)	67.01 (15.24)	0.6679
BMI	mean (sd)	32.08 (9.38)	31.75 (9.84)	0.5067
Sex				0.1869
Male	n (%)	961 (57.41)	922 (55.14)	
Female	n (%)	713 (42.59)	750 (44.86)	
Race				0.8955
Caucasian	n (%)	1271 (75.93)	1291 (50.39)	
Hispanic	n (%)	56 (3.35)	45 (2.69)	
Native American	n (%)	35 (2.09)	17 (1.02)	
African American	n (%)	190 (11.35)	179 (10.70)	
Asian	n (%)	5 (0.30)	9 (0.54)	
Other	n (%)	117 (6.99)	132 (7.89)	
Ethnicity				0.5495
Hispanic	n (%)	97 (5.79)	49 (2.93)	
Non-Hispanic	n (%)	550 (32.86)	626 (37.40)	
Unknown	n (%)	1027 (61.35)	999 (59.68)	
Smoking Status				
Smoker (ever smoked)	n (%)	678 (40.50)	649 (38.77)	0.3056
Smoker (current smoker)	n (%)	222 (13.26)	179 (10.69)	0.0221‡
Never smoked	n (%)	1269 (75.81)	1240 (74.07)	0.2475

‡= significance at p<0.05

Results

- After propensity score matching, the two cohorts were balanced on most patient (**Tables 1-2**) and wound (**Table 3**, **Figure 1**) demographics.
- Those variables that were not fully balanced (wound age, smoking, and vascular disease) indicated that the wounds treated with COSO+CTP were older and on patients who had a higher percentage of risk factors.

Table 2. Patient comorbidities after propensity score matching

		COSO+CTP	CTP alone	p values
Diabetes	n (%)	1065 (63.62)	1023 (61.11)	0.1341
Type 1 Diabetes	n (%)	55 (3.29)	80 (4.78)	0.0281†
Type 2 Diabetes	n (%)	962 (57.47)	894 (53.41)	0.0181†
Arterial vascular disease	n (%)	653 (39.01)	527 (31.48)	<0.0001*
Vascular disease	n (%)	421 (25.15)	372 (22.22)	0.0464†
Hypertension	n (%)	1377 (82.26)	1341 (80.11)	0.1115
Dialysis	n (%)	107 (6.39)	94 (5.62)	0.3443
Lupus	n (%)	18 (1.08)	19 (1.14)	0.9697
scleroderma	n (%)	17 (1.02)	16 (0.96)	0.8611
pyoderma	n (%)	44 (2.63)	39 (2.33)	0.6566
Rheumatoid arthritis	n (%)	56 (3.35)	39 (2.33)	0.0769
Autoimmune Disease	n (%)	151 (9.02)	162 (9.68)	0.5138
Sickle cell anemia	n (%)	14 (0.84)	7 (0.42)	0.1255
Peripheral vascular disease (treated for PVD)	n (%)	179 (10.69)	157 (9.38)	0.2058
Peripheral vascular disease	n (%)	437 (26.11)	407 (24.31)	0.2325
Endovascular Treatment	n (%)	564 (33.69)	539 (32.20)	0.358
Anticoagulation Medication (Strong Meds)	n (%)	157 (9.38)	169 (10.10)	0.4843
Anticoagulation Medication	n (%)	711 (42.47)	696 (41.58)	0.5995
Antiplatelet Medication	n (%)	803 (47.97)	735 (43.91)	0.0184†
Plavix or Pletal Medications	n (%)	248 (14.81)	214 (12.78)	0.0885
Prednisone	n (%)	166 (9.92)	184 (10.99)	0.3093
Antirejection Medications	n (%)	53 (3.17)	54 (3.23)	0.9217
Immunosuppressive medications	n (%)	333 (19.89)	311 (18.58)	0.3348
Vasculitis	n (%)	24 (1.43)	15 (0.90)	0.1472
Unique medication count	mean (sd)	16.45 (9.94)	15.39 (10.79)	0.0031†
Unique prescription count	mean (sd)	3.79 (4.64)	2.90 (4.37)	<0.0001*

*= significance at p<0.0001
†= significance at p<0.05

Table 3. Wound demographics after propensity score matching

		COSO+CTP	CTP alone	p values
Initial area	mean (sd)	16.35 (44.58)	17.29 (47.44)	0.5543
	median (min, max)	4.19 (0, 825.00)	3.91 (0, 800)	
Wound age at first encounter	mean (sd)	206.82 (963.36)	143.83 (564.48)	0.0209†
	median (min, max)	35.00 (0, 18508.00)	31 (0, 12814)	
Wound healing index	mean (sd)	64.68 (15.42)	65.61 (15.90)	0.6624
TREATMENTS				
Offloaded for a pressure ulcer	n (%)	409 (24.43)	374 (22.34)	0.1531
Offloaded for a diabetic foot ulcer	n (%)	709 (42.35)	661 (39.49)	0.0916
Wound had negative pressure wound therapy	n (%)	412 (24.61)	365 (21.80)	0.0544
Wound had hyperbaric oxygen treatment	n (%)	374 (22.34)	284 (16.97)	<0.0001*
Antibiotics	n (%)	406 (24.25)	297 (17.74)	<0.0001*
Number of debridements	mean (sd)	10.44 (12.42)	7.18 (9.56)	<0.0001*
Number of sharp debridements	mean (sd)	6.82 (10.39)	4.72 (7.74)	<0.0001*
Frequency of debridement	mean (sd)	16.89 (20.04)	15.78 (22.86)	<0.0001*

*= significance at p<0.0001
†= significance at p<0.05

Figure 1. Wound type after propensity score matching

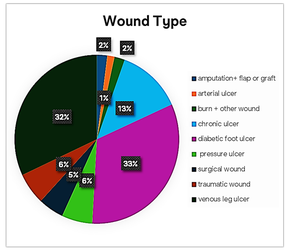


Table 4. Wound outcomes after propensity score matching

		COSO+CTP	CTP alone	p values
Healed vs other outcomes	n (%)	821 (49.04)	733 (43.79)	<0.0001†
Healed+wound improving vs other outcomes	n (%)	1395 (83.33)	1341 (80.11)	0.0158†
Wound worsening	n (%)	244 (14.58)	297 (17.74)	0.0128†
% change in wound size ((last area-first area)/ first area) get smaller (y/n)	mean (sd)	78.20 (1059.72)	98.90 (1685.66)	0.7013
	n (%)	1378 (82.32)	1354 (80.88)	0.0434†
%w/ Granulation=1* at 4 weeks	n (%)	431 (29.22)	442 (29.66)	0.7908
%w/ Granulation=1* at 6 weeks	n (%)	597 (40.47)	594 (39.87)	0.7353
%w/ Granulation=1* at 8 weeks	n (%)	710 (48.14)	709 (47.58)	0.7637
%w/ Granulation=1* at 12 weeks	n (%)	887 (60.14)	874 (58.66)	0.4127
%w/ Granulation=1* at 16 weeks	n (%)	1010 (68.47)	990 (66.44)	0.2379
%w/ Granulation=1* at 20 weeks	n (%)	1090 (73.90)	1056 (70.87)	0.0655

* 1=≥75% and no depth
†= significance at p<0.0001
‡= significance at p<0.05

Results (Cont'd)

- Significantly more wounds were healed when treated with COSO+CTP compared to CTP alone (49.0% versus 43.8%; p<0.0001) with an odds ratio of 1.24 (95% Confidence Interval: 1.09, 1.43) (**Table 4; Figures 2-4**).

Figure 2. Initial granulation score after propensity score matching (p=0.6851)

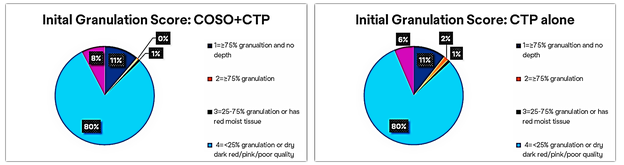


Figure 3. Wound outcome after propensity score matching (p=0.0009; significant at p<0.05)

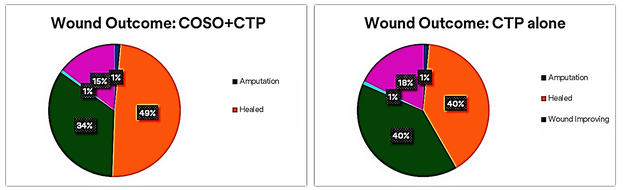
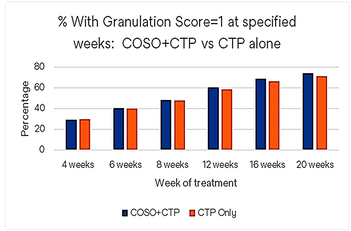


Figure 4. Percentage of granulation score =1 (≥75% and no depth) at 4-20 weeks of treatment, after propensity score matching



Results (Cont'd)

- When healed wounds were combined with wounds that improved, there continued to be a significant difference in favor of the COSO+CTP cohort (83.3% versus 80.1%; p=0.0158) (**Table 5**).
- There were no differences in the change in wound size.

Table 5. Healed status by wound type, after propensity score matching (odds ratio 1.244)

Wound type	COSO+CTP Healed (%)	CTP alone Healed (%)	P value
amputation+flap and graft	18 (52.94)	13 (38.24)	0.2269
arterial ulcer	10 (41.67)	13 (54.17)	0.3911
burn and other wounds	17 (50.00)	15 (44.12)	0.6296
chronic ulcer	92 (43.19)	97 (45.54)	0.6262
diabetic ulcer	274 (50.09)	228 (41.68)	0.0053‡
pressure ulcer	41 (40.59)	36 (35.64)	0.47
surgical wound	44 (52.38)	45 (53.57)	0.8775
traumatic wound	42 (41.18)	42 (41.18)	1
venous ulcer	283 (52.90)	244 (45.61)	0.0171‡

‡= significance at p<0.05

Conclusions

- Despite the COSO+CTP treatment group having a higher percentage of risk factors, this group had much better outcomes than the CTP only group.
- Using COSO+CTP for a wide range of wounds may help to improve patient outcomes.

References

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2. Kloeters O, Unglaub F, de Laat E, van Abeelen M, Ulrich D. Prospective and randomised evaluation of the protease-modulating effect of oxidised regenerated cellulose/collagen matrix treatment in pressure sore ulcers. *Int Wound J*. 2015;13(6):1231-1236. doi:10.1111/iwj.12449
3. Lobmann R, Zemlin C, Motzkau M, Reschke K, Lehnert H. Expression of matrix metalloproteinases and growth factors in diabetic foot wounds treated with a protease absorbent dressing. *J Diabetes Complications*. 2006;20(5):329-335. doi:10.1016/j.jdiacomp.2005.08.007

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NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

***Solventum™ Promogran Prisma™ Collagen Matrix with ORC and Silver (Solventum Corporation, Maplewood, MN)**

Laura Soloway and Leah Griffin are employees of Solventum.