NEW AMNIOTIC ALLOGRAFT USED TO TREAT CLINICALLY CHALLENGING CHRONIC WOUNDS

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SAWC Spring

VIVEX's Integrity Processing™ of CYGNUS® Matrix amniotic allograft and CYGNUS® Max amniotic membrane derived from the umbilical cord retains inherent extracellular matrix molecules, growth factors, and cytokines, and preserves up to 600+ signaling proteins.[1] The Integrity Processing™ of the multi-layer CYGNUS® Matrix (Vivex Biologics, Inc., Miami, FL) amniotic allografts helps retain the intermediate/spongy layer.

METHOD

We selected 4 complex patients with chronic wounds to evaluate the CYGNUS Matrix amniotic allograft and CYGNUS Max amniotic membrane derived from the umbilical cord in wound closure. We treated a 68 year-old male with BKA pressure wound, a 60 year-old male with a venous leg ulcer, a 75 year-old female with an arterial insufficiency wound, and a 68 year-old male with a pressure ulcer.

RESULTS

- All wounds responded with a progress to wound closure after treatment with traditional debridement and CYGNUS Matrix and CYGNUS Max applications
- The 2-year chronic pressure ulcer wound improved from 2.28W x 1.82L x 0.3D cm **(total 1.24 cm³)** to closure
- The 1-year BKA pressure wound improved from 2.75L x 2.15W x 1.0D cm **(total 5.91 cm³)** to 1.0L x 1.1W x 0.2D cm **(total 0.22 cm³)**
- The 2-year arterial insufficiency wound improved from 18.1L x 7.5W x 0.3D cm **(total 40.72 cm³)** to 12.78L x 5.64W x 0.1D cm **(total 7.2 cm³)** before the patient was lost to COVID-19 death.
- The 10-year chronic venous leg ulcer maintained size from 6.36L x 3.67W x 0.2D cm **(total 4.66 cm³)** to 5.83L x 3.66W x 0.2D cm **(total 4.22 cm³)** before the patient was lost to positive COVID-19 diagnosis and positive Rocky Mountain Spotted Fever diagnosis.

CYGNUS® VIVEX BIOLOGICS

PRESSURE ULCER: HEEL

START OF STANDARD CARE
1/06/21

START OF CYGNUS APPLICATIONS
2/24/21
2.28W x 1.82L x 0.3D (cm)

LAST CYGNUS APPLICATION
5/26/21
0.62W x 0.83L x 0.1D (cm)

CLOSURE
7/14/21

DURATION/REASON OF WOUND

2 year chronic wound from wheelchair foot rest

COMORBIDITIES

68 year-old male, paralyzed from waist down from spinal cord injury

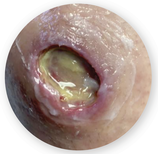
TREATMENT

DATE	LENGTH	WIDTH	DEPTH	TREATMENT
2/24/2021	2.28	1.82	0.3	CYGNUS MATRIX 2x3
3/03/2021	2.15	1.5	0.2	CYGNUS MATRIX 2x3
3/10/2021	1.58	1.25	0.2	CYGNUS MATRIX 2x3
3/16/2021	1.6	0.97	0.2	CYGNUS MATRIX 2x3
3/23/2021	1.45	1.01	0.2	CYGNUS MATRIX 2x3
4/07/2021	1.13	0.85	0.2	CYGNUS MATRIX 2x3
4/14/2021	1.15	0.82	0.2	CYGNUS MATRIX 2x3
4/21/2021	1.59	1.19	0.3	CYGNUS MATRIX 2x3
4/28/2021	1.0	1.71	0.2	CYGNUS MATRIX 2x3
5/12/2021	1.1	1.15	0.1	CYGNUS MATRIX 2x3
5/19/2021	0.76	0.61	0.1	CYGNUS MATRIX 2x3
5/26/2021	0.62	0.83	0.1	CYGNUS MATRIX 2x3
7/14/2021	PATIENT IN THE HOSPITAL FOR BOWEL OBSTRUCTION			
7/14/2021	1ST APPOINTMENT POST HOSPITAL – WOUND CLOSED			

PATIENT OUTCOME

100% closure after 12 CYGNUS Matrix applications over 12 weeks

PRESSURE ULCER: BELOW THE KNEE AMPUTATION (BKA)



START OF CYGNUS APPLICATIONS
2/23/21
2.15W x 2.75L x 1.0D (cm)

LAST CYGNUS APPLICATION
8/09/21
1.1W x 1.0L x 0.2D (cm)

DURATION/REASON OF WOUND

1 year chronic wound from prosthetic pressure point

COMORBIDITIES

68 year-old male, nicotine dependence, type 2 diabetes mellitus, GERD, hypertension, hyperlipidemia, depression, anxiety

TREATMENT

DATE	LENGTH	WIDTH	DEPTH	TREATMENT
2/03/2021	2.28	2.32	1.0	STANDARD OF CARE
2/23/2021	2.15	2.75	1.0	CYGNUS MATRIX 2x3
3/02/2021	2.59	1.73	0.9	CYGNUS MATRIX 2x3
3/08/2021	2.79	2.14	0.7	CYGNUS MATRIX 2x3
3/15/2021	1.49	2.44	0.8	CYGNUS MAX 2x3
3/23/2021	1.13	3.04	0.5	CYGNUS MAX 2x3
4/08/2021	1.15	2.43	1.0	CYGNUS MAX 2x3
4/12/2021	1.59	1.46	0.5	CYGNUS MAX 2x3
4/19/2021	1.0	1.04	0.5	CYGNUS MAX 2x3
4/26/2021	1.1	1.38	0.4	CYGNUS MAX 2x3
5/17/2021	0.76	1.69	0.4	CYGNUS MAX 2x2
5/24/2021	0.62	1.77	0.5	CYGNUS MAX 2x2
6/01/2021	1.95	1.13	0.5	CYGNUS MAX 2x2
6/08/2021	1.81	1.02	0.5	CYGNUS MAX 2x2
6/14/2021	1.67	1.34	0.5	CYGNUS MAX 2x2
6/29/2021	1.4	1.01	0.4	CYGNUS MAX 2x2
7/06/2021	1.45	0.92	0.4	CYGNUS MAX 2x2
7/12/2021	PATIENT RESCHEDULED, HOME HEALTH CHANGE DRESSING, NO GRAFT			
7/19/2021	1.2	0.9	0.4	CYGNUS MAX 2x2
7/26/2021	1.2	0.8	0.2	CYGNUS MAX 2x2
8/02/2021	PATIENT CHECKED INTO ER, MISSED APPOINTMENT			
8/09/2021	1.1	1.0	0.2	CYGNUS MAX 2x2
8/23/2021	0.8	1.3	0.2	CYGNUS MAX 2x2
MISSED VISITS DUE TO COVID-19				
9/13/2021	1.0	1.3	0.2	CYGNUS MATRIX 2x3
9/27/2021	0.5	1.1	0.2	CYGNUS MAX 2x2

PATIENT OUTCOME

Significant wound reduction after 22 CYGNUS Matrix and Max applications over 31 weeks

VENOUS LEG ULCER

START OF STANDARD CARE
9/25/20

START OF CYGNUS APPLICATIONS
5/17/21

PATIENT LOST TO POSITIVE COVID DIAGNOSIS AND ROCKY MOUNTAIN SPOTTED FEVER DIAGNOSIS

DURATION OF WOUND

- 10 year chronic wound
- Wound size maintained over 14 weeks with 7 CYGNUS Matrix applications
  - **Start of Advanced Care:** 6.36W x 3.67L x 0.2D cm
  - **Last CYGNUS Application:** 5.83W x 3.66L x 0.2D cm

COMORBIDITIES

60 year-old male noncompliant patient, removed graft and dressings multiple times, vascular insufficiency, history of substance abuse, seizures, depression, peripheral neuropathy

ARTERIAL INSUFFICIENCY

PATIENT LOST TO COVID-19 DEATH

START OF CYGNUS APPLICATIONS
5/12/21

DURATION OF WOUND

- 2 year chronic wound
- **Wound Size Started:** 13.8W x 5.5L x 0.2D cm
- **Wound Size Reduced to:** 12.78W x 5.64L x 0.1D cm

COMORBIDITIES

75 year-old female, arterial insufficiency, venous insufficiency, Stage 3 chronic kidney disease, heart failure

CONCLUSION

This case series of clinically challenging chronic wounds in patients with multiple comorbidities such as congestive heart failure, arterial insufficiency, hypertension, neuropathy, lymphedema, paraplegia, and nicotine dependence, demonstrates a notable rate of wound closure after advanced care treatment of CYGNUS Matrix and CYGNUS Max applications.

We believe the never delaminated and intact intermediate/spongy layer of the CYGNUS Matrix may contribute to the increased rate of wound closure.

VIVEX has used reasonable efforts to provide accurate and complete information herein, but this information should not be construed as providing clinical advice, dictating reimbursement policy, or as a substitute for the judgment of a health care provider. It is the health care provider's responsibility to determine the appropriate treatment, codes, charges for services, and use of modifiers for services rendered and to submit coverage or reimbursement-related documentation.

1. Data on file at Vivex Biologics, Inc.