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ORIGINAL RESEARCH

Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series

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Abstract

Background. Volumetric soft tissue loss is an urgent surgical issue and can frequently lead to suboptimal outcomes for patients due to significant soft tissue loss, compromised vital structures, and contamination. Ovine forestomach matrix (OFM) has demonstrated clinical success in the surgical management of soft tissue defects, especially in contaminated fields, and provides an effective option for immediate coverage of exposed vital structures before definitive closure.

Methods. This retrospective pilot case series (n = 13 defects) evaluated the clinical effectiveness of OFM (graft and/or particulate formats) in the surgical management of contaminated volumetric soft tissue defects. Patients presented with significant soft tissue loss, often with exposed viscera, tendon, bone, or muscle, and were treated with OFM as part of their inpatient surgical management. All patients had at least 1 significant comorbidity with the potential to complicate their healing trajectory. The primary study endpoint was time to 100% granulation tissue coverage (days), and the secondary endpoint was any device-related postoperative complications.

Results. A total of 13 volumetric soft tissue defects were evaluated in 10 patients who underwent surgical reconstruction. Mean defect age was 3.5 ± 5.6 weeks, and mean area was 217.3 ± 77.9 cm^2. Most defects had exposed structures (85%), and all defects were Centers for Disease Control and Prevention grade 2 or higher. Mean time to 100% granulation tissue formation was 23.4 ± 9.2 days, with a median product application of 1.0. Staged reconstruction was used in 7 of 13 defects, with the remainder (6 of 13) left to heal via secondary intention using standard wound care protocols. There were no major postoperative infections or adverse events (mean follow-up, 7.4 ± 2.4 weeks.)

Conclusions. This retrospective pilot case series builds on a growing body of evidence that OFM can be utilized to facilitate the formation of functional, well-vascularized soft tissue in large contaminated volumetric soft tissue defects.

Introduction

Complex soft tissue defects requiring reconstruction can be the result of a wide variety of etiologies, including necrotizing soft tissue infections (NSTIs), surgical dehiscence, burns, trauma, pressure injuries, and other etiologies. The resulting defect may heal by secondary intention but with relatively lengthy healing times involving frequent dressing changes, all while being prone to infection.[1] Surgical management of these full-thickness defects can vary widely and may include immediate coverage with a split-thickness skin graft (STSG), use of local or autologous free flaps, use of dermal matrices, and/or negative pressure wound therapy (NPWT). The current definition of a full-thickness wound is a defect that extends through the dermis, often with exposed structures (eg, bone, tendon, fascia, or muscle).[2] Often in trauma and acute care, full-thickness defects are relatively deep with loss of the dermal layer as well as the deeper subcutaneous tissue layers (eg, adipose, fascia, or muscle). To better classify the severity and depth of these defects, we propose an additional definition for these large 3-dimensional complex wounds, referring to these wounds collectively as “volumetric soft tissue defects.” This proposed terminology draws from the field of civilian and combat-related trauma where the term “volumetric muscle loss” (VML) is used to define significant loss of the musculature.[3] We propose that this terminology allows for a better visualization of the challenge in successfully reconstructing these large-volume, full-thickness dermal defects.

Initially, the primary goal of the reconstruction of a full-thickness wound is immediate coverage of exposed vital structures, such as viscera, bone, tendon, or fascia. This may be achieved via placement of a STSG, which decreases the potential for infection,[4] facilitates closure when healing by primary or secondary intention is not feasible,[5] and provides immediate coverage of any exposed structures.[6] However, in doing so, patients can be left with irregular scars that have significant differences in contour between the uninjured skin and the healed defect. In cosmetic surgery, this contour defect is often referred to as a “step-off” deformity.[7] This is exacerbated in volumetric soft tissue defects due to their depth, such that immediate application of a STSG in this scenario may lead to a step-off deformity. An alternate reconstructive approach to full-thickness and volumetric defects is a free flap procedure. However, a free flap procedure may result in overly prominent tissue requiring subsequent debulking procedures.[8] Additionally, volumetric soft tissue defects are not always candidates for local or free tissue flaps as they tend to have undermining sinus tracts and/or an irregular wound surface that can compromise the arterial blood flow necessary to facilitate flap success.[9]

Modern dermal matrices are now very much part of the reconstructive ladder and may provide an alternative to, or augment, more complex tissue transfer procedures. In some instances, dermal matrices may be deployed in the first instance so that more complex procedures can be held as a back-up to these local less invasive matrix-based approaches.[10] Dermal matrices include a variety of technologies, both synthetically manufactured or biologic, being derived from mammalian tissue extracellular matrix (ECM). ECM-based products are a good option in contaminated fields since typically synthetic dermal matrices are contraindicated for this environment as they may serve as a nidus for bacterial growth.[11] In contrast, ECM-based dermal matrices are generally tolerant of a contaminated surgical site.[12] For example, Ousey et al[13] have proposed that dermal matrices may be deployed in Centers for Disease Control and Prevention (CDC) grade 2 and grade 3 defects following adequate sharp debridement. As it relates to volumetric soft tissue defects, dermal matrices provide a robust option to traditional tissue transfer procedures (ie, STSG and free or rotational flaps) as they enable a staged approach to reconstruction, providing immediate coverage of exposed structures and tissue infill to enable contour restoration of these deep and typically irregular defects.

Ovine forestomach matrix (OFM) is a decellularized ECM biomaterial that has been fabricated into a variety of devices and utilized for soft tissue regeneration in a range of contaminated defects, including hidradenitis suppurativa,[14] pilonidal sinus,[15] chronic diabetic foot ulcers,[16] chest wall reconstruction,[17] and abdominal wall repair.[18-24] The success of OFM in these

reconstructions that involve contaminated fields can be attributed to its ability to form well-vascularized tissue[25] while modulating wound proteases that are known to prolong inflammation.[26] This, in theory, should allow the patient's immune system to primarily fend off persistent microbial contamination and progress the wound to an accelerated closure.[27]

In this retrospective pilot case series, we report our initial experience using OFM-based devices in conjunction with NPWT to provide coverage and tissue infill in volumetric soft tissue defects.

Materials and Methods

General

The retrospective study included patients who had undergone surgical reconstruction during the period January 2021 to February 2023 at a single facility. All patients provided written informed consent for their images and data to be used for research and publication purposes. The retrospective study was reviewed, and ethical oversight waived by WCG Clinical institutional review board (Puyallup, WA). The study was conducted in accordance with World Medical Association Declaration of Helsinki ethical guidelines. Patient demographics (eg, age, gender, significant baseline comorbidities), defect etiology and characteristics (eg, size, CDC grade), and outcomes (eg, 100% granulation tissue formation, recurrence, complications) were captured in Excel (Microsoft Corporation). The primary study outcome was defined as time (days) for complete graft integration and volumetric fill of the soft tissue defect with granulation tissue. Secondary endpoints included postoperative complications (eg, infection, pain, and recurrence). Descriptive statistics (eg, median, mean, SD) were computed using Excel.

Surgical Reconstruction

OFMs in either graft (Myriad Matrix Soft Tissue Bioscaffold; Aroa Biosurgery Limited) or morselized (particulate or powder) format (Myriad Morcells; Aroa Biosurgery Limited) were used according to the instructions for use. Patients were given general anesthesia, the surgical site was prepared with povidone-iodine (Betadine; Cumulus Pharmaceutical LLC), and the patient was surgically draped. The defects were thoroughly debrided to remove all necrotic tissue and lavaged with sterile saline. Defect dimensions and depth were recorded with a surgical ruler post debridement. Utilization of either the OFM graft (3- or 5-layer), morselized OFM, or a combination of the 2 products was based on clinical judgment of the attending surgeon. The OFM devices were rehydrated (<5 min, sterile saline), trimmed to size as required, and fixed to the defect edges with either suture or staples. The grafts were dressed with a nonadherent layer (Xeroform; McKesson Medical-Surgical), then NPWT interface black foam and the NPWT system (V.A.C. Therapy; 3M/KCI). NPWT systems were set to 125 mm Hg, and dressings were changed every 5 to 7 days. At dressing change, the defects were assessed for integration of the OFM graft and any complications. Complete graft integration and percentage granulation tissue formation was judged by the surgical team at the time of dressing change. At the discretion of the surgical team, definitive closure of the defects was achieved via STSG or secondary intention, according to institutional protocols.

TABLE 1. PARTICIPANT DEMOGRAPHICS

Participant#/ Defect#	Age/ Gender	Comorbidities	Defect description	Exposed structure	Wound age (weeks)	Prior surgical interventions	CDC grade	Surface area (cm^2)	Depth (cm)
1	28/M	PE/DVT, obesity, mental health disorder	High-velocity trauma; prior attempted closure resulting in abdominal dehiscence and frozen abdomen	NA	3	Surgical debridement's and attempted surgical closures (×3)	3	110.0	4.0
2A	61/F	Morbid obesity, HTN	MVA resulting in left arm trauma (Morel-Lavallee)	Tendon	1	Debridement	2	190.0	3.0
2B			MVA resulting in left leg trauma (Morel-Lavallee)	Bone	1	Debridement, failed STSG	2	140.0	1.0
3	53/F	Obesity, HTN	Prior ventral hernia repair leading to abdominal dehiscence	Exposed mesh	1	Post-dehiscence debridement	2	360.0	4.0
4	64/F	Morbid obesity, paraplegia, HTN, leukemia, DM2	Prior ventral hernia with synthetic mesh reinforcement; abdominal dehiscence with exposed synthetic mesh	Exposed mesh	1	Post-dehiscence debridement	2	304.0	3.0
5	37/M	Morbid obesity, spina bifida	Right groin NSTI (Fournier's Gangrene)	Exposed muscle, tendon	2	Debridement, antibiotics	3	300.0	3.0
6	56/T	HTN, HIV, homeless	Posterior left thigh NSTI (Fournier's Gangrene)	Tendon	1	Debridement, washout	3	210.0	2.0
7	72/F	ESRD, COPD, DM2, obesity, smoker	Traumatic injury resulting in compartment syndrome, left lower leg	NA	1	Fasciotomy	2	288.0	0.3
8A	58/M	Obesity, DM2, Afib	Right heel pressure injury (stage 4)	Bone	1	Debridement, antibiotics	3	88.0	0.5
8B			Left heel pressure injury (stage 4)	Bone	1	Debridement, antibiotics	3	135.0	0.5
9A	61/F	CHF, DM2, obesity, HTN, HLD, lupus, PE, hypothyroid, OSA	Subacute trauma, right lateral leg	Muscle	16	Debridement, antibiotics, outpatient wound care	2	190.0	0.5
9B			Subacute trauma, right posterior leg	Muscle	16	Debridement, antibiotics, outpatient wound care	2	210.0	1.0
10	36/M		Subacute trauma, right hip	Muscle	1	Debridement, antibiotics, outpatient wound care	2	234.0	20.0
	52.6 ± 14.2 (57.0)[a]				3.5 ± 5.6 (1.0)[a]			217.3 ± 77.9 (210.0)[a]	3.2 ± 5.2 (2.0)[a]

[a]Mean ± standard deviation; median is included in parentheses. Afib, atrial fibrillation; CDC, Centers for Disease Control and Prevention; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; DM2, diabetes mellitus type 2; DVT, deep vein thrombosis; ESRD, end-stage renal disease; F, female; HLD, hyperlipidemia; HTN, hypertension; M, male; OSA, osteoarthritis; PE, pulmonary embolism; T, transgender.

Results

Ten consecutive participants were included in the study who had presented with a total of 13 soft tissue defects at a single facility and had undergone surgical reconstruction with an OFM graft (**Table 1**). Mean participant age was 52.6 ± 14.2 years; 5 were female, 4 were male, and 1 was transgender (male-to-female). All participants except one presented with significant complicating comorbidities (**Table 1**). Surgical wound dehiscence (SWD) (23%) and trauma (38%) were the primary causes of the volumetric defects; 2 others were pressure injuries, and 1 arose from a surgical intervention (compartment syndrome). Overall mean defect age was 3.5 ± 5.6 weeks. Exposed structures (eg, bone, viscera) were present in 86% of the defects, and all defects were either CDC grades 2 (62%) or 3 (38%). The mean defect area was 217.3 ± 77.9 cm^2 with a mean depth of 3.2±5.2 cm.

TABLE 2. OUTCOMES

Participant#/ Defect#	Morselized[a]	Graft[b]	Number of product applications	Time to 100% granulation tissue (days)	%STSG take at 1 week	Over time to heal (weeks)	Complications	NPWT duration (weeks)	Last long-term follow-up visit (weeks)
1	Yes		1	21	NA	6	Minor wound dehiscence	3	6
2A	Yes	Yes	1	21	100%	4	None	3	7
2B		Yes	1	13	NA	6	None	3	
3	Yes	Yes	1	21	100%	LTFU	None	4	4
4	Yes		1	8	NA	LTFU	None	4	4
5	Yes	Yes	1	43	NA	LTFU	None	4	8
6	Yes	Yes	1	28	100%	6	None	4	8
7	Yes	Yes	1	28	NA	LTFU	None	3	5
8A	Yes		2	32	80%	7	None	4	8
8B	Yes		2	32	75%	8	None	4	
9A		Yes	1	21	100%	4	None	3	5
9B		Yes	1	21	100%	4	None	3	
10	Yes	Yes	1	15	NA	13	None	8	13
			1.2 ± 0.4 (1.0)[c]	23.4 ± 9.2 (21.0)[c]	93.6 ± 11.1% (100%)[c]	6.4 ± 2.8 (6.0)[c]		3.8 ± 1.3 (4.0)[c]	7.4 ± 2.4 (8.0)[c]

[a]Myriad Morcells.
[b]Myriad matrix.
[c]Mean ± standard deviation; median is included in parentheses. LTFU, lost to follow-up before defect closure; NA, not available; NPWT, negative pressure wound therapy; STSG, split-thickness skin graft.

Three defects were managed with the OFM matrix graft only, 4 received the OFM as a morselized format, and 6 defects received both, whereby the morselized graft was first applied to the wound bed, then the matrix graft was applied (**Table 2**). Both formats of the OFM graft were easy to deploy as part of the surgical procedure and could be trimmed to size and secured with sutures or staples as needed. The median product application was 1.0 across all defects. All defects received NPWT in conjunction with the OFM graft, with a mean duration of NPWT usage of 3.8 ± 1.3 weeks (**Table 2**). In all cases, the OFM grafts integrated into the regenerating tissue, with a mean time to complete integration of the graft and 100% granulation tissue of 23.4 ± 9.2 days.

Seven defects (54%) had a staged reconstruction in which STSG was used for definitive closure. Of those participants who received a STSG, the median STSG take at 1 week was 100%. Five of the 10 participants were lost to follow-up before complete healing, and the mean time to closure of defects in the remaining patients was 6.4 ± 2.8 weeks. There was one minor wound dehiscence reported (participant #1), but otherwise there were no infections, seromas, or other complications during the postoperative follow-up period (mean, 7.4 ± 2.4 weeks)(**Table 2**).

The following sections highlight 3 sample cases from the study data and do not reflect the chronological order of cases.

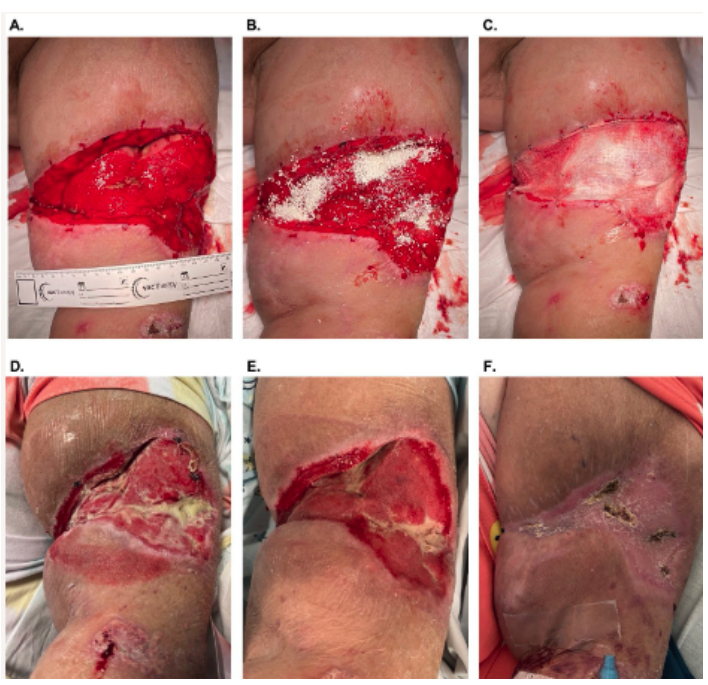

Figure 1. Case 1, participant 2, defect 2A. Traumatic defect to left arm resulting from motor vehicle accident. (A) Defect following surgical debridement. (B) Application of morselized OFM. (C) OFM graft, secured to defect perimeter. Postoperative day 13 (D), day 16 (E), and day 47, 3 weeks after application of a STSG (F). OFM, ovine forestomach matrix; STSG, split-thickness skin graft.

Case 1

A 61-year-old female patient (participant 2 ; **Table 1**) with morbid obesity and hypertension presented for follow-up evaluation of multiple soft tissue traumas sustained in a high-velocity motor vehicle accident, including Morel-Lavallee lesions of the left arm (**Figure 1**) and left leg (not shown). The patient had undergone multiple debridement procedures to both defects, and closure of the leg defect was attempted via placement of STSG that ultimately failed.

The patient was scheduled to undergo simultaneous reconstruction of the arm and leg defects with OFM. Before application of the OFM, the defects were irrigated with chlorhexidine solution, 50/50 povidone-iodine, and saline. After debridement, the arm defect measured 19 cm × 10 cm × 4 cm (**Figure 1A**). Morselized OFM was applied dry and rehydrated in situ with sterile saline and blood (**Figure 1B**). An OFM graft (10 cm × 20 cm, 5-layer) was rehydrated with saline, trimmed to size, then placed on top of the morselized OFM and secured to the defect (**Figure 1C**). The defects were dressed with an occlusive petrolatum dressing (Xeroform; Curad Medical), and a standard NPWT was placed at 125 mm Hg. NPWT was used for 3 weeks, with weekly dressing changes. Complete integration of the OFM graft and 100% granulation tissue over the exposed tendon was achieved in 21 days with the regenerated tissue being flush to the level of adjacent skin (**Figure 1E**). Definitive closure was achieved via application of a STSG at day 20, with 100% take of STSG after 1 week. At postoperative day 42, there was functional soft tissue with no complications (**Figure 1F**).

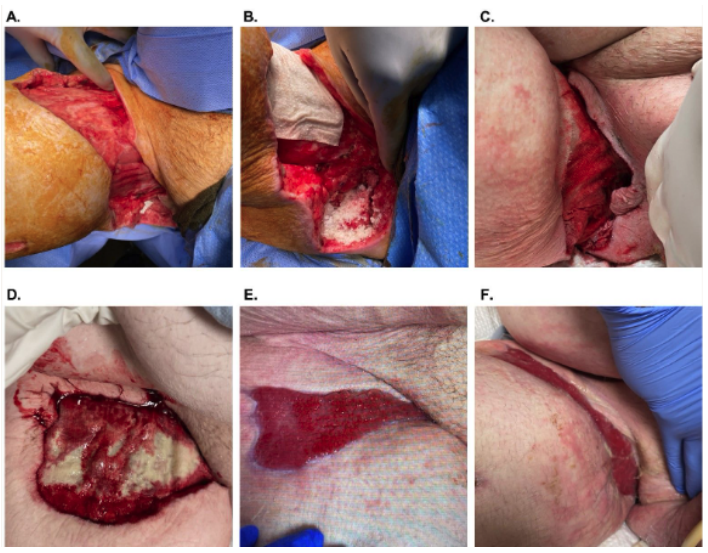

Figure 2. Case 2, participant 5. Fournier's gangrene, upper thigh and groin. (A) Defect following surgical debridement. (B) Application of morselized OFM (lower) and OFM graft (upper). Postoperative day 7 (C), day 14 (D), day 42 (E), and day 48 (F). OFM, ovine forestomach matrix.

Case 2

A 37-year-old male patient (participant 5) with obesity and spina bifida presented with an NSTI (Fornier's gangrene) of the right groin with exposed tendon and muscle (**Figure 2**). The patient had been admitted to the hospital the previous week and undergone multiple debridements and had subsequently been discharged to long-term acute care facility with standard NPWT (125 mm Hg). As the condition of the soft tissue defect continued to deteriorate, the patient was readmitted to the hospital for surgical intervention.

Upon readmission, the patient underwent surgical debridement and irrigation (chlorhexidine solution, 50/50 povidone-iodine, and saline) of the defect. After debridement, the defect measured 30 cm × 10 cm × 3 cm (**Figure 2A**). Morselized OFM was applied dry to the deepest and most irregular parts of the defect and rehydrated in situ with saline (**Figure 2B**). Two OFM grafts (10 cm × 20 cm, 5-layer) were rehydrated (saline), quilted together with absorbable polyglycolic acid suture to create a single larger graft, and then trimmed to the size of the defect. The OFM graft was applied over the morselized OFM and secured in the defect with staples (**Figure 2C**). The defect was dressed with a nonadherent layer and NPWT (125 mm Hg) as previously described. NPWT was continued for 4 weeks with weekly NPWT changes. At postoperative day 43 (**Figure 2E**), there was complete tissue coverage over the exposed bone and tendon and contour restoration. Standard wound care was initiated to close via secondary intention, and the participant was lost to follow-up after week 8.

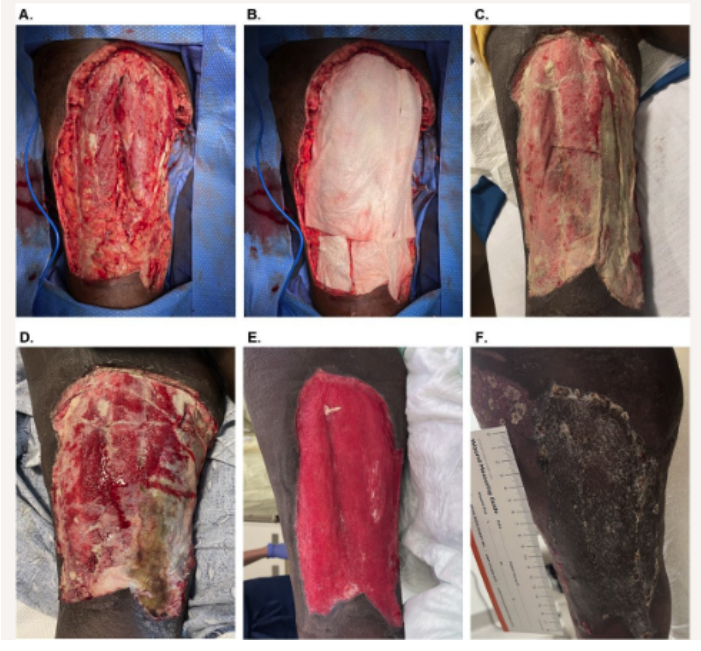

Figure 3. Case 3, participant 6. NSTI of the thigh. (A) Defect following surgical debridement. (B) Application of OFM graft. Postoperative day 12 (C), day 16 (D), day 28 (E), and day 56, 4 weeks after application of a STSG (F). NSTI, necrotizing soft tissue infection; OFM, ovine forestomach matrix; STSG, split-thickness skin graft.

Case 3

A 56-year-old transgender (male-to-female) patient (participant 6) with medical history significant for HIV infection and hypertension was experiencing homelessness and developed an NSTI of the posterior left thigh. The participant presented to the emergency department with worsening pain and swelling and was immediately admitted for surgical debridement of necrotic and infectious tissue. The patient was managed acutely by another health care professional, undergoing multiple surgical debridements over the course of several days before leaving against medical advice.

Subsequently, the patient presented to the authors' facility approximately 2 weeks after the initial admission. The patient was taken to surgery and underwent a sharp debridement, resulting in a defect measuring 21 cm × 10 cm × 2 cm (**Figure 3A**). Two OFM grafts (10 cm × 20 cm, 5-layer) were rehydrated (saline), trimmed, placed into the defect, and secured with absorbable sutures (**Figure 3B**). The graft was dressed with an occlusive petrolatum dressing (Xeroform; Curad Medical) and standard NPWT (125 mm Hg). The patient underwent dressing changes every 5 to 7 days whereby the NPWT interface foam was replaced, but the occlusive dressing was left in place so as to not disturb the underlying graft. At postoperative day 16, the graft was well adhered and had approximately 70% graft integration (**Figure 3D**). There was no sign of infection or complication, and NPWT was continued for an additional 12 days. By postoperative day 28, the defect's depth had significantly reduced such that the regenerating tissue was now approximately planar to the surrounding intact skin (**Figure 3E**), and a STSG was applied. At 1 week after STSG application, there was 100% graft take with no complications noted. Three weeks later, the defect was fully epithelialized with good tissue pliability (**Figure 3F**).

Discussion

Full-thickness wounds are commonly categorized and studied based upon wound etiology (eg, full-thickness burn, stage IV pressure injury, NSTI, and others). To the authors' knowledge, there is no existing term to group soft tissue defects based on wound bed complexity and depth regardless of the cause of initial defect. This void in nomenclature has prompted the authors to define the term "volumetric soft tissue defect" as a means to unify wounds of varying etiologies that share common features of irregular wound surface, depth that often includes the subcutaneous layers, exposed vital structures, and the high propensity for bacterial contamination (CDC grade 2 or higher).

The challenges with reconstruction of large volumetric soft tissue defects include the relative scale of these defects (depth and surface area); irregularity of the defect surface that may include undermining; presence of exposed vital structures that are prone to desiccation or necrosis; and frequent microbial contamination. Achieving rapid tissue infill of these defects and coverage of any exposed vital structures is the primary goal of reconstruction and has traditionally been approached with autologous tissue flaps. However, due to comorbidities, not all patients are suitable candidates for large autologous flap procedures,[28] and often the surgical

complexity of autologous tissue transfers brings a new set of challenges. Dermal matrices, like OFMs, are now an accepted part of the reconstructive ladder and facilitate the patient's own body to form a functional layer of well-vascularized tissue to provide coverage and fill the soft tissue defect. The use of dermal matrices was first proposed by Yannas and Burke,[29,30] who demonstrated clinically the use of a synthetic bilayer dermal matrix where the "artificial dermis resembles normal dermis and serves as a template for the synthesis of new connective tissue and the formation of a 'neodermis,' while it is slowly biodegraded." The development of dermal matrices enabled the advent of staged reconstructions to expedite definitive closure of complex tissue defects. Since these early studies the range of dermal matrices has ever expanded with new synthetic and naturally derived matrices being commercialized and adopted into clinical use. However, not all dermal matrices are the same with respect to clinical performance. For example, some synthetic dermal matrices are prone to infection or are relatively slow to integrate into the regenerating neodermis.[31] A subset of the available dermal matrices are naturally derived from human or animal tissue ECM. A key differential between ECM-based dermal matrices and their synthetic counterparts is a composition that includes naturally occurring proteins that exist in abundance in all soft tissues and are known to play key roles in soft tissue regeneration. ECM-based dermal matrices are known to rapidly vascularize and integrate into the regenerating neodermis and over time undergo a process of remodeling, mimicking the natural remodeling of ECM that occurs in all tissues.[32]

In this retrospective case series, there were a variety of volumetric soft tissue defects that included NSTIs, acute traumatic soft tissue injuries, and surgical wound dehiscence. There was a total of 13 defects included in this retrospective review where OFM matrix and/or morselized OFM were used to develop a healthy neodermis. In all cases, the defects were contaminated (CDC grade 2, or higher), and in 11 of the 13 cases, there was an exposed structure, including bone, surgical mesh, tendon, or viscera. The median time to complete integration of the graft and 100% granulation tissue formation was 21 days (mean, 23.4 ± 9.2 days). In 11 of the 13 defects, only a single application of OFM was required to regenerate a healthy neodermis. This is in contrast to the other available ECM-based surgical grafts where repeat applications are often necessary to achieve tissue infill of deep defects.[33,34]

One key goal of utilizing OFM in these volumetric defects is to restore the tissue depth and contour as close to anatomic normalcy as possible, as seen in **Figures 2E** and **3E**. This contour restoration can aid in maximizing function and cosmetic outcomes. Concurrent NPWT usage ranged from 3 to 8 weeks with a median of 4 weeks. Importantly, the authors found that the frequency of dressing changes (5-7 days) was reduced relative to the traditional frequency of 3 times per week.[35] This observation may have significant long-term impacts on the health economics of managing these complex defects by reducing the burden and costs associated with postoperative care of these patients. While reported costs vary, one publication estimated the mean theoretical cost of standard NPWT dressing change to be $94.01 per day,[36] so reducing the frequency of these dressing changes from 3 times per week to once per week is not insignificant. The use of ECM products adjunctively with NPWT to synergistically improve wound healing trajectory has been widely described in the scientific literature.[37-39] It has been postulated previously that collagen-based ECM products used concurrently with NPWT can enhance wound healing properties and shorten the duration of NPWT use.[40]

As previously discussed, the use of certain dermal matrices, including synthetic matrices, may result in higher rates of infection when placed in contaminated fields.[41,42] Infection rates seen for synthetic dermal matrices have been reported as high as 20%, 29.6%, and 18.1% in lower extremity reconstructions,[31] burns,[43] and trauma,[44] respectively. While methods to "milk" infection from these devices have been reported,[31] rates of graft loss as high as 20% have been reported in cases where this intervention was unsuccessful.[31] OFM is an intact ECM that is minimally processed to remove the ovine cells while maintaining ECM structure[45] and biology[46] with no chemical cross-linking that may otherwise inhibit the rate of neovascularization[47] and induce a proinflammatory tissue response.[48] In contrast to reports for synthetic dermal matrices,[42] we observed no infections in the current study, leading us to conclude that OFM is relatively resistant to infection and sufficiently robust to perform in a contaminated field.

Limitations

The current pilot study comprises observations from a single center with all the limitations of a retrospective case series. Not surprisingly, several of the patients included in the current report were lost to follow-up before complete closure of the volumetric defect (**Table 2**). This outcome, unfortunately, is entirely consistent with the high follow-up failure rate of trauma patients due to lack of insurance coverage, discharge to tertiary care facilities, and lack of patient education regarding the importance of follow-up care.[49-51] While the results of this case series are promising, there is a need for future research to expand the number of patients to validate these initial results. Future studies may involve a controlled study design, but this may be complicated by the absence of a "gold-standard" for the reconstruction of volumetric soft tissue defects.

Conclusions

This retrospective pilot case series builds on a growing body of evidence that OFM can be utilized to facilitate the formation of functional, well-vascularized soft tissue in large, contaminated, volumetric soft tissue defects. The OFM grafts were shown to complement NPWT and may reduce the frequency of dressing changes associated with NPWT usage in these complex soft reconstructive procedures.

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Ethics: WCG Clinical provided institutional review board (IRB) services under work order 1-1572217-1. IRB approval was obtained on August 3, 2022. All patients provided written informed consent for their images and data to be used for research and publication purposes.

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