



ORIGINAL RESEARCH

Safety of Ovine Forestomach Matrix Across 474 Soft Tissue Defects: Interim Results from the Prospective Multicenter MASTRR Registry

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ABSTRACT

Introduction: Well-powered, prospective, registry-based clinical studies present the opportunity for broad safety surveillance of bioscaffolds

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used in soft tissue reconstruction but remain limited in the field. The Myriad™ Augmented Soft Tissue Reconstruction Registry (“MASTRR Registry”) was established as an ongoing multicenter prospective registry to evaluate the real-world safety and performance of ovine forestomach matrix (OFM)-based devices in complex soft tissue reconstruction.

Methods: The interim safety analysis included prospective subject data from the first 411 subjects and 474 defects undergoing reconstruction with OFM-based devices from 10 participating sites. The analysis included subjects from

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trauma, colorectal, burn, and limb salvage specialties. All adverse events (AEs) were categorized based on severity, causality in relation to the investigational device, and correlated to the surgical procedure and relationship to the index defect.

Results: Subjects represented a medically complex population with substantial comorbidity burden and challenging defect characteristics. Most defects were chronic (59.8%) and classified as Centers for Disease Control class II (38.2%) or III (50.4%), indicating that nearly 90% of defects were clean-contaminated or contaminated. Exposed structures (11.4%) and osteomyelitis (15.0%) were also common. A broad range of defect etiologies were included, such as diabetic foot ulcers (22.6%), traumatic injuries (16.5%), ostomy takedowns (11.2%), and pilonidal sinuses (10.8%). Across 411 subjects 12.2% experienced one or more AE. No AEs were determined to be definitively related to OFM-based devices and only a single AE (0.2%) was considered probably device-related. AEs occurring at the index defect were infrequent and included superficial infection (2.9%), dehiscence (3.2%), and deep tissue infection (0.7%).

Conclusion: The registry framework provides a valuable mechanism for evaluating device safety and performance under real-world conditions. OFM-based devices demonstrated a favorable safety profile across a broad range of reconstructive applications, surgical specialties, and defect types, with only a single application required in most patients.

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Key Summary Points

Why carry out this study?

Soft tissue injuries often undergo surgical reconstruction with bioscaffolds to promote tissue regeneration; however, there is paucity of high-quality prospective evidence on the use of bioscaffolds in soft tissue reconstruction, including registry-based data.

The MASTRR Registry was developed to investigate the safety and performance of ovine forestomach matrix (OFM)-based devices in various soft tissue reconstruction procedures, across a diverse, real-world patient cohort.

What was learned from this study?

Across 411 subjects and 474 defects, no adverse events (AEs) were definitively related to OFM-based devices and only a single AE (0.2%) had a probable correlation to the device.

AEs that were unrelated to OFM but occurred at the index defect included superficial infection (2.9%), dehiscence (3.2%), and deep tissue infection (0.7%).

On the basis of this interim safety analysis OFM-based devices have a favorable safety profile in real-world settings treating a variety of complicated patients and defect types.

INTRODUCTION

Wounds with extensive soft tissue loss often require surgical reconstruction to achieve new tissue infill and restore function of the affected

area. Reconstructive surgery paradigms have been evolving over the past decades to accommodate an ever-changing landscape of novel procedures and technologies [1]. Regardless, the timely and effective restoration of form and function, while maximizing patient safety and satisfaction, has remained a central goal of reconstructive surgery [1]. Ultimately, the reconstructive approach that is taken depends on several factors, such as patient preference, candidacy, and likelihood of postoperative care compliance, as well as defect etiology, location, and size. When traditional reconstructive techniques such as skin grafting and flap procedures are not ideal options, advanced procedures can be pursued. These may include the surgical application of bioscaffolds which can be manufactured from natural or synthetic polymers, or be derived from xenogeneic or allogeneic tissues [2]. However, there is a paucity of high-quality, prospective data on the use of bioscaffolds for soft tissue reconstruction, including results from registry-based analyses.

The IDEAL (Idea, Development, Exploration, Assessment, Long-term study) framework provides a structured pathway for evidence generation from conceptualization to pilot and pivotal clinical investigations [3, 4]. While originally established for surgical procedures, the IDEAL framework is increasingly adopted for safety and performance evaluation of medical devices [4]. At the later stages of adoption, IDEAL emphasizes that randomized controlled trials (RCTs) are critical to establish efficacy, while recognizing their frequent lack of feasibility and need to be complemented with other prospective evidence [3]. For this reason, observational registries are suggested during both stage 2b and 4 of the IDEAL framework. In the exploratory stage 2b, registries provide the opportunity to obtain high-quality evidence with the adoption of the technology in diverse patient populations and various surgical approaches in order to capture real-world variations and to understand feasibility for more widespread applications [5]. In stage 4 of the IDEAL guidelines, prospective registries are recommended to monitor long-term outcomes, as well as rare or late adverse events (AEs), which RCTs are generally not able to capture [3]. In this sense, registries act as broad

surveillance systems in real-world contexts and provide insight that cannot be obtained by tightly controlled, costly, and “ideal world” RCTs.

Observational registries enable the collection of standardized subject data for subjects who share a particular disease, condition, or exposure/intervention [6]. Ideally registries are prospective in nature to enable standardized collection of real-world evidence (RWE) from a large population [7]. RWE is advantageous as it offers a more representative reflection of the routine usage, effectiveness, and safety of healthcare interventions [8]. For example, registries are frequently utilized in orthopaedics; in this field, they have been useful to identify long-term patient outcomes, complication patterns and improve patient safety, enable large-scale research, support evidence-based practice, and inform policy guidelines [9]. In this way, results from registry studies can complement conclusions drawn from tightly controlled RCTs, which are valuable to establish the effectiveness of an intervention in optimal, “ideal world” scenarios, but are not generally applicable to real-world clinical practice [7].

Ovine forestomach matrix (OFM)-based devices have found clinical adoption in the surgical reconstruction of complex soft tissue defects. The devices function as a temporary biological scaffold for cellular integration, neo-vascularization, and regeneration of missing or damaged tissue. Over time OFM-based devices are remodeled by the body and ultimately give rise to the restoration of functional tissue. Since these products were first introduced there have been a number of clinical studies presented in the literature across a spectrum of surgical procedures including reconstructions involving hidradenitis suppurativa [10–12], glossectomy [10, 13], complex extremity defects [11, 14], complex wounds [15], pilonidal sinus [16], perianal fistulae [17, 18], and traumatic soft tissue injuries [19]. The Myriad™ Augmented Soft Tissue Reconstruction Registry (“MASTRR Registry”) was established to provide a mechanism for the collection of standardized prospective subject data. The MASTRR Registry is an observational, multicenter, single-arm, phase IV study investigating the safety and efficacy of

OFM-based devices in the surgical reconstruction of a variety of soft tissues, in a broad patient population, with minimal exclusion criteria. Observational registries are widely recognized as valuable tools for the active surveillance of safety [20], and as such the primary endpoint of the MASTRR Registry is the safety of the devices across a real-world population. Here, we present the results of an interim safety analysis of the first 411 subjects, focusing on the incidence of AEs, as well as their nature, severity, and causality with respect to OFM-based devices.

METHODS

General

This prospective, multicenter, single-arm, open-label, observational, post-market study enrolled patients undergoing various reconstructive surgical procedures involving the use of OFM grafts and/or particulate.

Ethical Approval

Ethical oversight of the investigation was provided through a centralized institutional review board (IRB) (Advarra Inc., Maryland, USA; reference number Pro00058745; ClinicalTrials.gov, NCT05243966), with local site level IRB oversight as required by the participating institution (see Supplementary Material S.1). IRB approval included up to 15 investigational sites and up to 800 subjects. All patients provided written informed consent for all procedures and for their images and data to be used for research and publication purposes. The study was conducted in accordance with the World Medical Association Declaration of Helsinki of 1964 ethical guidelines and its later amendments.

Study Design

The investigation was designed as a prospective multicenter registry study collecting subject data across a range of surgical soft tissue

reconstruction procedures where OFM-based devices were used as part of the surgical repair. All procedures were performed in the operating room either in the inpatient setting or in an ambulatory surgical center. The primary safety endpoint of the study was defined as the “proportion of participants with treatment emergent AEs during the study.” This interim safety analysis included subject data from 10 participating US institutions, representing trauma, colorectal, burn, and limb salvage specialties. The inclusion/exclusion criteria were relatively broad to enable collection of RWE to support the safety and performance of the OFM-based grafts. During screening, all patients were assessed per the inclusion and exclusion criteria defined in Table 1. All subject data and images were recorded using a HIPAA-compliant, cloud-based electronic case report form (eCRF, Tissue Analytics platform, NetHealth Inc., Philadelphia, USA), available both as a mobile application and online. The eCRF enabled imaging of the defect, as well as wound telemetry (i.e., surface area, depth measurements) to be captured at scheduled subject visits. Electronic study data was stored electronically in a centralized database. Assessments were made: (1) during the screening visit (SV1); (2) at the index surgical procedure (TV1); and (3) at the scheduled follow-up visits. During SV1, subject demographics (e.g., age, ethnicity), and medical history (e.g., vascular disease, diabetes), were recorded (Fig. 1). During TV1, characteristics of the soft tissue defect (e.g., area, depth, age, anatomical location, extent and type of any exposed vital structures, Centers for Disease Control and Prevention (CDC) wound classification), as well as the type of defect (e.g., necrotizing soft tissue infection, perianal fistula), type of OFM device used, and surgical details (e.g., American Society of Anesthesiologists (ASA) physical classification, debridement type, placement of surgical drains, negative pressure wound therapy (NPWT) utilization). During scheduled follow-up visits, defects were assessed for the development of vascularized tissue coverage, wound closure, patient reported pain (visual analogue scale, VAS), and patient and observer scar score (modified Vancouver scar score).

Table 1 Inclusion and exclusion criteria

Inclusion	Exclusion
Willing and able to provide written informed consent and to comply with the requirements of clinical investigational plan	Patients with known sensitivity to ovine (sheep) derived material
Male or female patients aged 18 years or above	Patients with full-thickness (“third-degree”) burns
Patients where OFM graft or particulate were used as part of their soft tissue reconstruction procedure	Patients with wounds with uncontrolled clinical infection (CDC Contamination class IV)
Subjects that are willing and able to comply with all aspects of the treatment and evaluation schedule	Any medical condition or serious intercurrent illness that, in the opinion of the investigator, may make it undesirable for the patient to participate in the study
	Patients are currently participating or have participated in another clinical study within past 30 days prior to enrollment
	Pregnant or lactating women
	Any subject who, at the discretion of the investigator, is not suitable for inclusion in the study

OFM ovine forestomach matrix, *CDC* Centers for Disease Control and Prevention

For the current interim safety analysis, all subjects enrolled between 20 May 2022 and 1 July 2025 were included. The analysis included all subjects that had completed TV1 (index procedure) and at least one postoperative visit. OFM-based devices were used topically for dermal reconstruction, as an implant (e.g., to reinforce a soft tissue flap), or to augment healing of fistulae (e.g., perianal or rectovaginal). All subject records were reviewed and categorized based on the OFM device use, namely, dermal reconstruction, fistula augmentation, or implantation. Further, where OFM-based devices were used for dermal reconstruction, attending surgeons elected to close the dermal defect either via application of a split-thickness skin graft (STSG) or via secondary intention, so applicable records were further categorized to reflect this.

All AE reports were reviewed for the included subjects. Events were categorized for severity according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 severity grading framework [21], where grade 1 represents mild events and grade 5 represents death related to an AE, as follows: grade 1, “mild”; grade 2, “moderate”; grade 3, “severe

or medically significant”; grade 4, “life-threatening”; grade 5, “death.” Further, AEs were categorized according to their relationship to the investigational device in accordance with ISO 14155 guidance as “unrelated,” “unlikely,” “possible,” “probable,” or “causal/definitely related.” Finally, events were reviewed and categorized according to their anatomical location with respect to the index procedure as follows: “index defect,” where the event occurred at the site of application of the OFM bioscaffold; “non-index procedure,” where the event involved a site other than the index defect; “incidental,” where the event was systemic in nature and was incidental in relation to the index defect. The time to the event was computed from the date of the index procedure (TV1) to the date of the AE onset.

Statistical Analysis

Statistical analyses were computed using GraphPad Prism (version 10.6.1). Categorical variables were expressed as percentages. Continuous variables were expressed as medians (with interquartile ranges, IQR) when not normally distributed or means (with standard deviations) when



Fig. 1 Modified CONSORT (Consolidated Standards of Reporting Trials) diagram. *SV1* screening visit, *TV1* index surgical procedure, *n* sample size

normally distributed. Normality was assessed with Shapiro–Wilk tests.

RESULTS

A total of 450 patients were assessed and screened for eligibility in the study (SV1), with $n=26$ screen failures (Fig. 1). A total of $n=424$ underwent the index surgical procedure (TV1) where OFM-based devices were employed as part of the surgical reconstruction. For the

safety analysis, $n=13$ subjects were excluded from the analysis having been lost to follow-up or withdrawn following TV1, leaving a subject-level population of $n=411$ for the analysis. None of those withdrawn from the study were due to an AE. Given that many subjects presented with multiple index defects, $n=411$ subjects equated to $n=474$ defects in the index defect population.

Subject demographics for participants included in the safety analysis ($n=411$) are provided in Table 2. Subjects were primarily male (69.3%), middle-aged (median 54 years old),

Table 2 Subject characteristics

Subjects, <i>n</i>	411
Gender, <i>n</i> (%)	
Female	126 (30.7%)
Male	285 (69.3%)
Age, median (IQR) (years)	54 (39, 67)
BMI, median (IQR) (kg/m ²)	28.3 (24.2, 34.3)
Ethnicity, <i>n</i> (%)	
White	300 (73.0%)
Black or African American	65 (15.8%)
Asian	11 (2.7%)
Multiracial	5 (1.2%)
American Indian or Alaska native	2 (0.5%)
Other	28 (6.8%)
Diabetes, <i>n</i> (%)	
Controlled	48 (11.7%)
Uncontrolled	99 (24.1%)
None	264 (64.2%)
Current nicotine use, <i>n</i> (%)	98 (23.8%)
Vascular disease, <i>n</i> (%)	
Arterial	73 (17.8%)
Venous	9 (2.2%)
Mixed selection	43 (10.5%)
None	286 (69.6%)
ASA classification, <i>n</i> (%)	
Class I	35 (8.5%)
Class II	133 (32.4%)
Class III	218 (53.0%)
Class IV	25 (6.1%)
Defects per subject, median (IQR)	1 (1, 1)
1 defect, <i>n</i> (%)	368 (89.5%)
2 defects, <i>n</i> (%)	30 (7.3%)
3 defects, <i>n</i> (%)	8 (1.9%)
4 defects, <i>n</i> (%)	3 (0.7%)
5 defects, <i>n</i> (%)	2 (0.5%)

Percentages (%) are based on total subjects

BMI body mass index, *ASA* American Society of Anesthesiologists, *IQR* interquartile range, *n* sample size

and white (73.0%) (Table 2). Most patients were either considered ASA class II (32.4%), or class III (53.0%), indicative of a cohort with primarily severe systemic disease. Subjects commonly had type II diabetes (35.8%), vascular disease (30.5%), and utilized nicotine products (23.8%) (Table 2). The majority of subjects presented with a single defect that was enrolled in the study (89.5%), though several subjects presented with two or more index defects (10.4%).

Index defects were a mix of acute (15.2%), subacute (< 1 month, 25.1%), or chronic (> 1 month, 59.8%) (Table 3), and the majority were deemed either CDC class II (clean-contaminated, 38.2%) or CDC class III (contaminated, 50.4%) (Table 3). Several defects (11.4%) had exposed structures, including bone (*n*=30/54, 55.6%), tendon (*n*=11/54, 20.4%), tendon and bone (*n*=9/54, 16.7%), or viscera (*n*=5/54, 7.4%). Osteomyelitis was confirmed in 15.0% of the defects. For defects undergoing dermal reconstruction, for which a surface area was recorded at TV1 (*n*=309), the median defect area was 24.0 (IQR 7.8, 100.0) cm². The majority of defects undergoing reconstruction involved the lower extremities (46.2%) (Table 3).

There were a wide variety of soft tissue defects enrolled in the investigation (Table 4). Case examples of different defect etiologies treated with OFM-based devices are shown in Fig. 2. The five most commonly encountered etiologies were diabetic foot ulcers (DFUs, 22.6%), traumatic injuries (16.5%), ostomy takedowns (11.2%), pilonidal sinus (10.8%), and pressure injuries (PIs, 9.7%). Of the DFUs included in the investigation, the majority were Wagner 2 (*n*=31/107, 29.0%) or Wagner 3 (*n*=48/107, 44.9%). PIs included were mainly stage 4 (*n*=27/46, 58.7%), involving muscle and exposed structures. Deep partial-thickness burns represented most of the burns included in the analysis (*n*=29/41, 70.7%). In most cases, the OFM-based devices were applied topically for dermal reconstruction (65.2%), with definitive closure achieved via secondary intent healing (*n*=274/309, 88.7%), or application of a split-thickness skin graft (STSG, *n*=35/309, 11.3%) (Table 5). OFM-based devices were used in 46 (9.7%) cases of fistula augmentation, including in the reconstruction of perianal fistulae

Table 3 Index defect characteristics

Defects, <i>n</i>	474
Defect age, <i>n</i> (%)	
Acute	72 (15.2%)
< 1 month	119 (25.1%)
1–6 months	154 (32.5%)
6–12 months	51 (10.8%)
1–2 years	33 (7.0%)
2–5 years	29 (6.1%)
5+ years	16 (3.4%)
CDC, <i>n</i> (%)	
Class I—clean	54 (11.4%)
Class II—clean/contaminated	181 (38.2%)
Class III—contaminated	239 (50.4%)
Exposed structures, <i>n</i> (%)	54 (11.4%)
Bone	30 (55.6%)
Tendon	11 (20.4%)
Bone and tendon	9 (16.7%)
Viscera	4 (7.4%)
Osteomyelitis, <i>n</i> (%)	71 (15.0%)
Defect area [§] , median (IQR), cm ²	24.0 (7.8, 100.0)
Location, <i>n</i> (%)	
Abdomen	70 (14.8%)
Head/neck	2 (0.4%)
Intra-abdominal	1 (0.2%)
Lower extremity	219 (46.2%)
Pelvis	138 (29.1%)
Trunk/flank	10 (2.1%)
Upper extremity	34 (7.2%)

CDC Centers for Disease Control and Prevention, *n* sample size

[§]Defect area for defects undergoing dermal reconstruction only (*n* = 309). Percentages (%) are based on total defects or parent defect category

Table 4 Index defect etiology

Abdominal perineal resection, <i>n</i> (%)	1 (0.2%)
Anastomotic leak, <i>n</i> (%)	1 (0.2%)
Burn, <i>n</i> (%)	41 (8.6%)
Superficial	6 (14.6%)
Partial	6 (14.6%)
Deep partial	29 (70.7%)
DFU, <i>n</i> (%)	107 (22.6%)
Wagner 1	1 (0.9%)
Wagner 2	31 (29.0%)
Wagner 3	48 (44.9%)
Wagner 4	27 (25.2%)
STSG donor site, <i>n</i> (%)	1 (0.2%)
Fistula, <i>n</i> (%)	46 (9.7%)
EC	3 (6.5%)
PA	42 (91.3%)
RV	1 (2.2%)
Hematoma, <i>n</i> (%)	4 (0.8%)
Lower extremity amputation, <i>n</i> (%)	3 (0.6%)
NSTI, <i>n</i> (%)	16 (3.4%)
Ostomy takedown, <i>n</i> (%)	53 (11.2%)
Pilonidal sinus, <i>n</i> (%)	51 (10.8%)
Pressure injury, <i>n</i> (%)	46 (9.7%)
Stage 2	3 (6.5%)
Stage 3	16 (34.8%)
Stage 4	27 (58.7%)

Table 4 continued

Surgical dehiscence, <i>n</i> (%)	19 (4.0%)
Traumatic, <i>n</i> (%)	78 (16.5%)
Venous leg ulcer, <i>n</i> (%)	7 (1.5%)

n sample size, *DFU* diabetic foot ulcer, *STSG* split-thickness skin graft, *EC* enterocutaneous, *PA* perianal, *RV* rectovaginal, *NSTI* necrotizing soft tissue infection

Percentages (%) are based on total defects or parent defect category

(PA, *n*=42/46, 91.3%), enterocutaneous fistulae (EC, *n*=3/46, 6.5%), and a single case of a rectovaginal fistula (RV, *n*=1/46, 2.2%) (Table 4). The remaining index defects (25.1%) included in the study described OFM-based devices being implanted to reinforce a soft tissue flap, for example, as part of a pilonidal sinus or PI reconstruction. For the index defects included in the study a median of one product application was employed, and negative pressure wound therapy (NPWT) was used in 22.8% of procedures (Table 5).

A total of 59 AEs were reported across the 411 subjects and 474 defects (Table 6). The median follow-up across all patients was 27.1 (IQR 14.0, 54.0) weeks. Fifty subjects (12.2%) reported one or more AEs, where the median time to the AE from the index procedure (TV1) was 4.0 (IQR 1.7, 9.0) weeks. The majority of AEs reported across the population were deemed “mild” (44.1%) or “moderate” (13.6%) (Table 6, Fig. 3). Eight deaths were reported across the population. All deaths occurred in patients with substantial pre-existing comorbidities and/or advanced underlying disease, including severe cardiopulmonary, renal, and malignant conditions. On the basis of clinical review, all deaths were attributed to progression of these underlying illnesses or unrelated medical complications and were not considered related to the index procedure or study treatment. When AEs were assessed for causality in relation to the investigational device, none of the events were deemed to be “definitely” or “possibly” related to the use OFM devices, and a single event was deemed probably related (Table 6, Fig. 3). This “moderate”

AE involved redness, pain, and swelling on the index defect on the lower extremity possibly due to a suspected allergic reaction, which resulted in 40% OFM graft removal. After management of the cutaneous reaction with antihistamines, the patient underwent STSG placement and had a positive recovery and remained in the study to complete wound closure. The remaining recorded AEs were deemed either “unrelated” (*n*=47/59, 79.9%) or “unlikely” (*n*=11/59, 18.6%) related to the investigational device (Table 6, Fig. 3).

All AEs were further assessed according to the involvement of the index defect (Table 7). Thirty-three (55.9%) of the AEs were determined to be related to the index defect, while seven AEs (11.9%) were related to another site (“non-index defect”), and 19 AEs (32.1%) were systemic or determined to be “incidental” relative to the index procedure and the OFM-based devices. These incidental AEs included pneumonia, sepsis, and thrombophlebitis, among others (Table 7). Index defect AEs were further correlated to the surgical approach (i.e., dermal reconstruction, fistula augmentation, or implant) and the defect etiology (Table 8, Fig. 4). On the basis of defect etiology, pilonidal sinus reconstruction gave rise to the highest incidence of reported index defect related AEs (*n*=14, 23.7% of AEs, 3.4% of subjects) and included a single deep tissue infection, two superficial infections, and 11 reports of dehiscence (18.6% of AEs, 2.7% of subjects) of the primary closure following implantation. Superficial infections were also reported across varying defect etiologies and presented following dermal reconstruction (15.3% of AEs, 2.2% of subjects) and implantation (5.1% of AEs, 0.7% of subjects). Only three (5.1% of AEs) deep tissue infections were reported at the index defect, representing an infection rate of 0.7% across all subjects. The three deep tissue infections occurred in a perianal fistula repair, a pilonidal sinus reconstruction, and a traumatic defect reconstruction below the level of initial debridement and OFM application. None of the deep tissue infections resulted in device extraction. Two fistulae were reported and deemed unrelated to the device, along with a single incidence of seroma and recurrence, which was also considered unrelated to the device. A single



Fig. 2 Case examples 1–3. Case example 1: A–D 71-year-old female patient with an acute PI and NSTI. A Day 0, at presentation. B Day 17, 100% granulation tissue formation noted. C Day 42, marked re-epithelialization observed, with full closure at day 85 (not shown). D Day 117, long-term follow-up. Case example 2: E–H 30-year-old male patient deep partial-thickness burn to the abdomen. E Day 0, at presentation. F Day 5, OFM integration noted. G Day 12, full re-epithelialization. H Day 101, long-term

follow-up. Case example 3: I–L 32-year-old male patient with a traumatic abdominal defect subjected to laparotomies. I Day 0, second-look laparotomy completion followed by OFM implantation in the suprafascial plane for management of residual dead space. J Day 21, scar formation noted. K Day 84, further scar remodeling observed. L Day 430, long-term follow-up. *PI* pressure injury, *NSTI* necrotizing soft tissue infection, *OFM* ovine forestomach matrix

Table 5 Surgical approach

Dermal reconstruction, <i>n</i> (%)	309 (65.2%)
Secondary intention, <i>n</i> (%)	274 (88.7%)
STSG, <i>n</i> (%)	35 (11.3%)
Fistula augmentation, <i>n</i> (%)	46 (9.7%)
Implant, <i>n</i> (%)	119 (25.1%)
NPWT, <i>n</i> (%)	108 (22.8%)
Product applications, median (IQR)	1 (1, 1)

Percentages (%) are based on total defects or parent defect category

STSG split-thickness skin graft, *NPWT* negative pressure wound therapy, *IQR* interquartile range, *n* sample size

allergic reaction was also reported. Across the 33 AEs reported for the index defect, seven required reoperation, five of which were an incision and drainage. Four of those that underwent reoperation were deemed unrelated to OFM, while three were deemed unlikely related. One ostomy takedown that had resulted in an AE required an exploratory laparotomy, and one perianal fistula reconstruction required a fistulotomy because of the AE.

DISCUSSION

The use of IDEAL stage 2a/2b observational registries is especially prevalent in the field of robotic/laparoscopic surgery research [22–24], but are less commonly utilized to assess safety and performance of bioscaffolds in soft tissue reconstruction. To our knowledge, the MASTRR Registry is the largest such study, ultimately approved to enroll up to 800 patients across multiple US surgical centers. This interim safety analysis of the first 411 subjects and 474 defects demonstrated an incidence of AE across all subjects of 12.2%, or 8.0% when considering only AEs where the index defect was involved. The

Table 6 Safety outcomes

Total AEs, <i>n</i>	59
Safety follow-up, median (IQR), weeks	27.1 (14.0, 54.0)
Subjects with 1 or more AE, <i>n</i> (%) subjects)	50 (12.2%)
Time to AE, median (IQR) (weeks)	4.0 (1.7, 9.0)
AE severity, <i>n</i> (% AE) (% subjects)	
1—mild	26 (44.1%) (6.3%)
2—moderate	8 (13.6%) (1.9%)
3—severe or medically significant	15 (25.4%) (3.6%)
4—life-threatening	2 (3.4%) (0.5%)
5—death	8 (13.6%) (1.9%)
AE causality, <i>n</i> (% AE) (% subjects)	
Unrelated	47 (79.7%) (11.4%)
Unlikely	11 (18.6%) (2.7%)
Possible	—
Probable	1 (1.7%) (0.2%)
Causal/definite	—

Percentages (%) are based on total AEs (*n* = 59) and total subjects (*n* = 411), respectively

AE adverse event, *n* sample size, *IQR* interquartile range

interim analysis showed that OFM-based devices were safely employed across a large, complicated patient cohort with a wide variety of soft tissue defects, treated with different surgical approaches. Most subjects enrolled to date presented with several complicating comorbidities and challenging medical histories. For example, most subjects were overweight, had an ASA score indicative of a serious medical condition

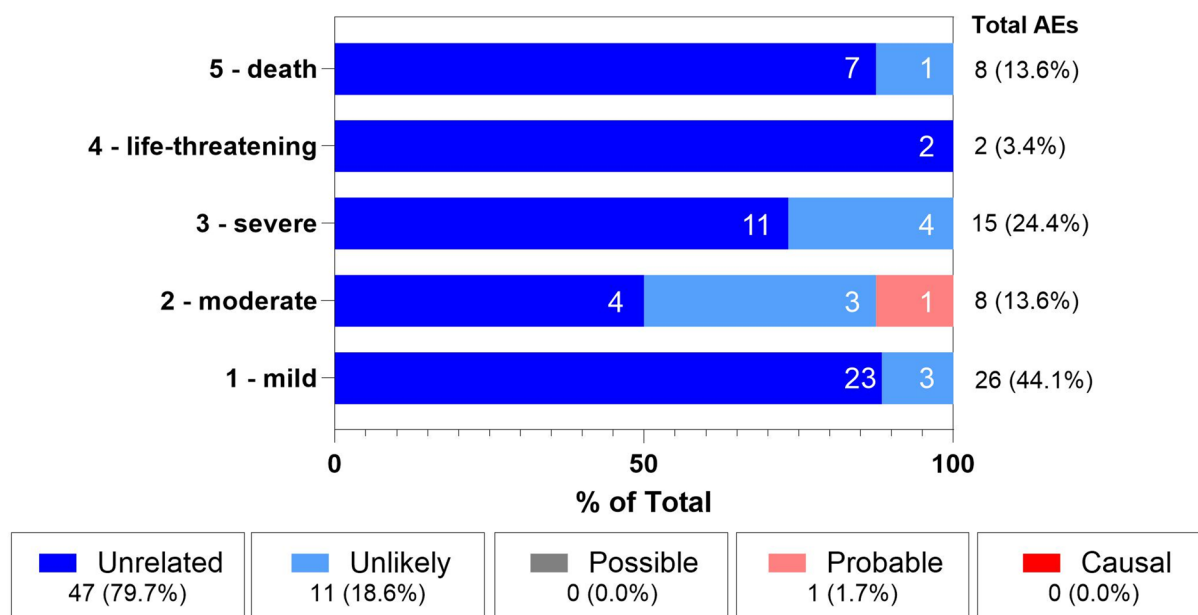


Fig. 3 Graphical representation of the causality and severity of all AEs reported across the $n=411$ subjects and $n=474$ index defects. Percentages (%) are based on the total AEs ($n=59$). *AE* adverse event

that limited daily function, and presented with defects that were primarily either clean-contaminated or contaminated, and chronic. Diabetes and vascular disease, as well as osteomyelitis and exposed structures, were also common. The diverse defect etiology (Table 4) further underscores the safety profile of OFM-based devices. Such heterogeneity is a defining feature of IDEAL stage 2b studies, which are intended to evaluate emerging technologies across multiple surgeons, institutions, patient populations, and clinical indications in order to establish generalizability and inform subsequent comparative evaluation. The broad applicability of OFM-based devices to surgical reconstruction is also a testament to its safety and versatility across different surgical approaches and surgical specialties. Given these factors, zero AEs definitively related to the device and a 0.2% incidence of AEs with probable device-relatedness are a positive indicator of the safety profile of OFM-based devices.

While registry-based evidence generation for bioscaffolds in complex reconstruction remains in its infancy, several prospective observational registry studies have been initiated to evaluate safety and performance of these devices across

diverse patient populations and clinical indications. For example, observational registries have been established to evaluate outcomes with a fish skin graft in soft tissue reconstruction ("SurgiBind Registry"; ClinicalTrials.gov, NCT05898711), and complex wounds ("Real-World Fish Skin Graft Registry"; ClinicalTrials.gov, NCT06384183), enrolling up to 200 and 600 subjects, respectively. An interim subgroup analysis from these registries of subjects undergoing Mohs surgery reported three serious AEs, concluded to be unrelated to the investigational device [25]. Observational registries of bioscaffold safety and performance have additionally been established for the outpatient wound care setting, rather than surgical reconstruction. For example, a large observational registry ("Cellular and Tissue Based Therapy Registry (CTPR)"; ClinicalTrials.gov, NCT02322554) targeting enrollment of 50,000 subjects has been established with a primary endpoint of wound healing, rather than safety. Similarly, the "The RESPOND Registry (RESPOND)" (ClinicalTrials.gov, NCT02322554) assessed healing outcomes of chronic wounds from 310 subjects with a type I collagen bioscaffold [26].

Table 7 Adverse event type

Index defect, AE <i>n</i> (% AEs) (% subjects)	33 (55.9%) (8.0%)
Superficial infection	12 (20.3%) (2.9%)
Dehiscence	13 (22.0%) (3.2%)
Fistula	2 (3.4%) (0.5%)
Deep tissue infection	3 (5.1%) (0.7%)
Recurrence	1 (1.7%) (0.2%)
Allergic reaction	1 (1.7%) (0.2%)
Seroma	1 (1.7%) (0.2%)
Non-index defect, AE <i>n</i> (%AEs) (% subjects)	7 (11.9%) (1.7%)
Amputation	1 (1.7%) (0.2%)
Infection	6 (10.2%) (1.5%)
Incidental, AE <i>n</i> (% subjects)	19 (32.1%) (4.6%)
Death	8 (13.6%) (1.9%)
Sepsis	1 (1.7%) (0.2%)
Thrombophlebitis	1 (1.7%) (0.2%)
Pneumonia	1 (1.7%) (0.2%)
Diabetic ketoacidosis	3 (5.1%) (0.7%)
Ileus	1 (1.7%) (0.2%)
UTI	2 (3.4%) (0.5%)
Fever	1 (1.7%) (0.3%)
Bowel obstruction	1 (1.7%) (0.3%)

Percentages (%) are based on total AEs (*n* = 59) and total subjects (*n* = 411), respectively

AE adverse event, *n* sample size, *UTI* urinary tract infection

An additional strength of the MASTRR Registry is its ability to support indication-specific subgroup analyses while maintaining a common prospective data collection framework. Consistent with the objectives of IDEAL stage 2b evaluation, the registry has enrolled a heterogeneous population of subjects undergoing

reconstruction for a broad range of soft tissue defects, thereby facilitating focused assessments of device performance within specific clinical applications. To date, the registry has generated multiple subgroup analyses, including lower extremity reconstruction, deep partial-thickness burns, trauma and acute care

Table 8 Index defect AEs correlated to surgical approach and defect etiology

	Total ^a	Superficial infection	Dehiscence	Fistula	Deep tissue infection	Recurrence	Allergic reaction	Seroma
Dermal reconstruction	11 (18.6%) (2.7%)	9 (15.3%) (2.2%)	1 (1.7%) (0.2%)	–	–	–	1 (1.7%) (0.2%)	–
Burn	1 (1.7%) (0.2%)	–	–	–	–	–	1 (1.7%) (0.2%)	–
Hematoma	1 (1.7%) (0.2%)	–	1 (1.7%) (0.2%)	–	–	–	–	–
Pressure injury	3 (5.1%) (0.7%)	3 (5.1%) (0.7%)	–	–	–	–	–	–
Traumatic	6 (10.2%) (1.5%)	6 (10.2%) (1.5%)	–	–	–	–	–	–
Fistula augmentation	2 (3.4%) (0.5%)	–	–	–	1 (1.7%) (0.2%)	1 (1.7%) (0.2%)	–	–
Fistula—PA	2 (3.4%) (0.5%)	–	–	–	1 (1.7%) (0.2%)	1 (1.7%) (0.2%)	–	–
Implant	20 (33.9%) (4.9%)	3 (5.1%) (0.7%)	12 (20.3%) (2.9%)	2 (3.4%) (0.5%)	2 (3.4%) (0.5%)	–	–	1 (1.7%) (0.2%)
NSTI	1 (1.7%) (0.2%)	–	1 (1.7%) (0.2%)	–	–	–	–	–
Ostomy take-down	3 (5.1%) (0.7%)	1 (1.7%) (0.2%)	–	1 (1.7%) (0.2%)	–	–	–	1 (1.7%) (0.2%)
Pilonidal sinus	14 (23.7%) (3.4%)	2 (3.4%) (0.5%)	11 (18.6%) (2.7%)	–	1 (1.7%) (0.2%)	–	–	–
Traumatic	2 (3.4%) (0.5%)	–	–	1 (1.7%) (0.2%)	1 (1.7%) (0.2%)	–	–	–

AE adverse event, *PA* perianal fistula, *NSTI* necrotizing soft tissue infection

^aPercentages are based on the total AEs ($n = 59$) and total subjects ($n = 474$), respectively

surgery defects, PIs, enterocutaneous (EC) fistulae, and pilonidal sinus reconstruction [27–31]. For example, a subgroup analysis ($n = 130$) by Lawlor et al. [27] described use of OFM-based devices in complex lower extremity reconstruction and demonstrated a median time to complete granulation tissue coverage and fill of 30.0 days, with a median of one OFM device

application. Similarly, in a separate analysis of subjects presenting with traumatic soft tissue defects across four level 1 trauma centers, treatment with OFM-based devices resulted in vascularized tissue coverage in a median of 22.5 days, and a literature synthesis demonstrated the cost-effectiveness relative to other bioscaffolds used in trauma reconstruction [28]. Nasser et al. [29]

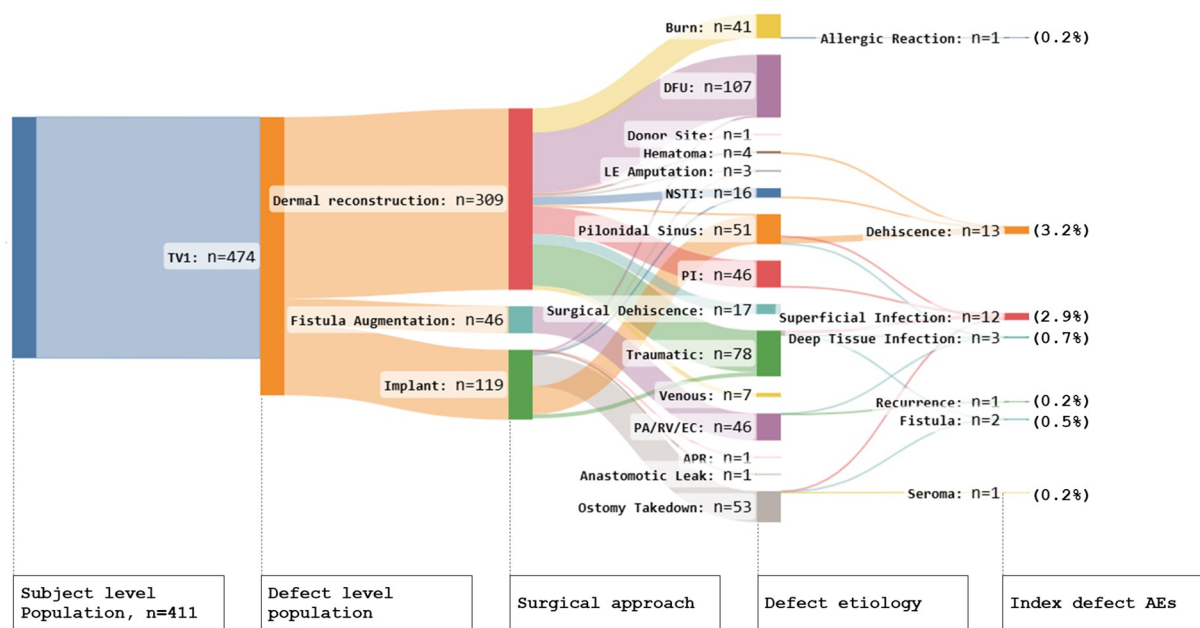


Fig. 4 Sankey diagram representing the subject and defect populations, surgical approach, defect etiology and the reported index defect AEs. Numbers represent sample size for each category. Percentages (%) are based on the total subjects. *TV1* first treatment visit, *n* sample size, *DFU*

diabetic foot ulcer, *LE* lower extremity, *NSTI* necrotizing soft tissue infection, *PI* pressure injury, *PA/RV/EC* perianal fistula/rectovaginal fistula/enterocutaneous fistula, *APR* abdominal perineal resection, *AEs* adverse events. Sankey diagram generated using www.sankeymatic.com

published a subgroup analysis of pilonidal sinus reconstruction from MASTRR and compared it to a matched retrospective cohort reconstructed using the same surgical approach but without the OFM graft. The authors demonstrated that implantation of an OFM graft under a fasciocutaneous advancement flap significantly reduced the incidence of surgical dehiscence, reduced the overall treatment cost, and increased patient quality of life. In deep partial-thickness burns, a single OFM application resulted in a 14-day median healing time, minimal pain, and positive scar satisfaction scores [32]. In a subgroup analysis of 12 late-stage PIs (stage 3 and stage 4) in nine trauma subjects, OFM-based devices achieved approximately 60% reduction in wound area, eradication of tunnelling and undermining, and no postoperative complications [30]. Collectively, these studies demonstrate the versatility of the registry platform and illustrate how prospective observational data can be leveraged to evaluate safety, performance, and clinical outcomes across distinct patient

populations and reconstructive indications. The productivity of the registry framework further supports its value as a mechanism for generating RWE and informing the use of OFM-based devices in complex soft tissue reconstruction.

One finding from the current study is the relatively low incidence of postoperative infection reported across the cohort. When considering only those AEs involving the index defect, the incidence of superficial infection was 2.9% and deep tissue infection was 0.7%. This finding is consistent with the low incidence of AEs, including infection, previously reported for studies of OFM-based devices in complex reconstruction [14, 15, 19, 33]. It is interesting to compare these findings in light of the many publications that have proposed theoretical infection-related advantages for synthetic bioscaffolds over tissue-derived bioscaffolds (“biologics”), such as OFM-based devices [34–36]. For example, a recent meta-analysis of a polyurethane-based bioscaffold in complex soft tissue reconstruction identified 34 studies spanning a pooled sample size

of 208 subjects and reported an overall complication rate of 27.9%, and an infection rate of 25.8% [37]. Findings from this meta-analysis led the authors to caution clinicians who implement this product in their reconstructive armamentarium [37]. Similarly, in their comparative meta-analysis, He et al. [38] reported an incidence of postoperative infection of 26.24% for burns treated with the polyurethane bioscaffold and 18.79% for burns treated with a crosslinked collagen/chondroitin sulfate bioscaffold. These results were pooled from 35 studies and 674 subjects. Another meta-analysis of outcomes with a crosslinked collagen/chondroitin sulfate bioscaffold in wound repair the authors presented a generalized incidence of infection of 16.9% from $n=602$ subjects across 26 articles [39]. This finding also prompted these authors to advise practitioners to perform careful risk–benefit analyses before utilizing this synthetic product, while also discussing the elevated infection risks with their patients [39]. Taken together, these observations challenge the notion that synthetic bioscaffolds confer a clinically meaningful reduction in infection risk and suggest that OFM-based devices may offer a comparable, if not favorable, infection profile in complex soft tissue reconstruction.

This interim analysis should be interpreted in the context of several limitations. First, the MASTRR Registry was designed as a prospective observational study and did not include a contemporaneous control group reconstructed without OFM-based devices or with an alternative bioscaffold. As a result, direct comparative conclusions regarding the relative safety of OFM-based devices cannot be drawn. Second, the broad inclusion criteria and heterogeneous study population, while consistent with the objectives of an IDEAL stage 2b evaluation, introduced variability within the subject- and defect-level populations. Although this heterogeneity enhances the generalizability of the findings, it may also obscure indication-specific differences in outcomes. Third, the current report represents an interim analysis with a median follow-up of approximately 27 weeks. Longer-term follow-up is required to fully characterize late complications, durability of reconstruction, and long-term clinical outcomes. Fourth, AEs while

categorized to standardized methods were investigator assessed and therefore remain subject to the inherent limitations of clinical judgment. Future analyses of the fully enrolled registry population may permit more detailed risk-factor modelling and comparative assessments across specific patient and defect subgroups.

CONCLUSIONS

This interim analysis of the MASTRR Registry represents one of the largest prospective evaluations of a bioscaffold used in soft tissue reconstruction reported to date. Across 411 subjects and 474 defects treated at 10 participating centers, OFM-based devices were safely utilized in a broad range of reconstructive applications, including dermal reconstruction, fistula augmentation, and implantation. Consistent with the objectives of IDEAL stage 2b evaluation, the registry captured a heterogeneous patient population characterized by substantial comorbidity burden, contaminated and chronic defects, exposed critical structures, and diverse surgical indications. Despite this complexity, no AEs were determined to be definitively related to OFM-based devices and only a single event (0.2% of subjects) was considered probably related to the investigational device. These findings support the favorable safety profile of OFM-based devices in complex soft tissue reconstruction and demonstrate the value of prospective multicenter registries for generating RWE to inform clinical practice.

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Data Availability. The datasets generated during and/or analyzed during the current study are not publicly available due to patient privacy. De-identified data may be provided upon reasonable request to the corresponding author.

Declarations

Conflict of Interest. Tracee Short, Moshe Barnajian, Christopher A. Butts, John J. Choi, Michael Cormican, Claire S. Dillingham, Pranat Kumar, John Lawlor, Patrick Martyka, Yosef Y. Nasser, Alison A. Smith, W. Matthew Vassy, Nicole P. Bernal, and Joshua H. Wolf are consultants for Aroa Biosurgery Limited (Auckland, New

Zealand). Jessica Simon, Brandon A. Bosque, D. Adam Young, and Barnaby C. H. May are employees of Aroa Biosurgery Limited. Jessica M. Felton, John H. Loftus, Lung Lau, Christopher A. Butts, and Kyle J. Leneweaver have nothing to disclose.

Ethical Approval. Ethical oversight of the investigation was provided through a centralized institutional review board (IRB) (Advarra Inc., Maryland, USA; reference number Pro00058745; ClinicalTrials.gov, NCT05243966), with local site level IRB oversight as required by the participating institution (see Supplementary Material S.1). IRB approval included up to 15 investigational sites and up to 800 subjects. All patients provided written informed consent for all procedures and for their images and data to be used for research and publication purposes. The study was conducted in accordance with the World Medical Association Declaration of Helsinki of 1964 ethical guidelines and its later amendments.

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