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ORIGINAL ARTICLE
Reconstructive

Lower Third Leg Trauma Management Algorithm; Kasr Alainy Protocol

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Background: Soft tissue defects in the lower third of the leg present significant challenges for surgeons. Despite various options available for soft tissue coverage, selecting the most suitable option is limited by potential complications. In response to this challenge, some surgeons have sought to develop algorithms to guide decision-making in the management of lower leg trauma.
Methods: This prospective observational cross-sectional study included 53 patients with traumatic injuries to the lower third leg and ankle regions. Each patient underwent a management plan based on our proposed algorithm, which incorporated the utilization of negative pressure wound therapy and dermal substitutes. Outcomes were assessed in terms of the ability to achieve complete coverage, complication rates, duration of hospital stay, and return to normal daily activity.
Results: The proposed algorithm proved to be comprehensive and easily applicable, achieving complete coverage in 98.1% of cases. The mean duration for definitive coverage was 21.89 ± 12.84 days, and the majority of cases (81.1%) returned to normal daily activity within a mean duration of 60.69 ± 56.7 days. The use of dermal substitutes resulted in achieving coverage in wounds with exposed structures, with favorable outcomes in cases with a mean size of 11.39 ± 10.05 cm².
Conclusions: Our algorithm provides a safe and effective approach to manage traumatic defects of the lower third leg and ankle, considering the patient's general condition and the complexity of the wound. Proper utilization of dermal substitutes and negative pressure wound therapy is emphasized in the algorithm.
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INTRODUCTION

The management of post-traumatic lower limb defects has undergone significant evolution in the past three decades, now making limb salvage a routine practice that would have previously necessitated amputation. This transformative approach requires a multidisciplinary team involving orthopedic, vascular, and plastic surgery specialists.[1]

Complex wounds in the distal third of the leg or around the ankle region frequently involve bone fractures. Achieving successful and stable soft tissue coverage is paramount, particularly when the bone or other structures are exposed. This is crucial for creating optimal conditions that facilitate the healing process and contribute to successful limb salvage.[2]

A variety of reconstructive options are available for lower leg defects. Traditionally, the conventional methods for addressing lower extremity defects involved the use of local muscle flaps or free flaps. Meanwhile, there is a growing preference for perforator-based flaps in the reconstruction of lower extremity defects.[3,4]

Negative pressure wound therapy (NPWT) is used until the patient is adequately prepared for surgery or to optimize local wound conditions for flap or graft coverage. In recent times, dermal substitutes have emerged as an additional option for effectively covering these defects.[5,6]

The relatively recent use of dermal substitutes, available in injectable or sheet forms, involves vascularization of the wound bed through the dermal substitute matrix, forming a neo-dermis. Originally developed for burn reconstruction, dermal substitutes are now applied in various reconstructive situations.[7,8]

Several algorithms have been proposed for traumatic leg reconstruction, each with unique approaches. The algorithm introduced by Saleh et al in 2007 was basic,

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focusing broadly on the entire leg.[9] Another study conducted by Ivanove et al in 2016 prioritized patient general condition, emphasizing the utilization of local and free flaps for leg reconstruction.[10] In their literature review, AlMugaren et al introduced a comprehensive algorithm, considering the zone of injury, wound complexity, and defect size.[11] An extensive overview of modalities for managing lower third leg injuries was introduced by Zeiderman and Pu in 2021.[12]

The complexity of wounds in the lower third and ankle region, coupled with the array of reconstructive options, necessitates a clear and applicable management plan. Our study introduces an easily applied algorithm for the management of post-traumatic defects in the lower third and ankle region, facilitating stable and complete coverage. The algorithm allows for the individualization of the management plan for each patient, appropriately allocating different reconstructive options, assessing their outcomes, and addressing possible complications. Importantly, it underscores the significance of integrating dermal substitutes in managing these defects.

Takeaways

Question: How to choose the optimum plan of management for patients presenting with lower third leg post-traumatic soft tissue defects.

Findings: A prospective observational cross-sectional study included 53 patients with traumatic injuries to the lower third leg. The proposed algorithm proved to be successful in coverage of these types of defects and was comprehensive and easily applicable, with low complication rate.

Meaning: When managing soft tissue defects of the lower third leg and ankle region, surgeons must consider an algorithmic approach of management while considering the general patient condition and the complexity of wounds.

PATIENTS AND METHODS

We conducted a prospective observational cross-sectional study from May 2019 to July 2021 on patients who presented to our institute with traumatic injuries to the lower. A total of 53 patients were enrolled during the period of study.

The inclusion criteria encompassed (1) post-traumatic injuries to the lower third of the leg and ankle region, (2) presenting within 1 month of the initial trauma, and (3) involving both sexes. The exclusion criteria included patients presenting with a mangled limb with a mangled extremity severity score of seven or more.[13]

Preoperative Preparation

Before surgery, patients underwent preoperative counseling that covered the plan of management, expected recovery time, benefits of the procedure, possible complications, and their management. Written informed consent, inclusive of agreement for the use of photographs and data in the study without disclosure of identity, was obtained from all participants.

History Taking and Demographic Data Collection

Comprehensive history taking included information on age; the mode, type, and time of injury; and associated medical comorbidities. A thorough examination of the general condition and well-being of the patient was done. The injured limb was examined, documenting the site and size of the defect, and details of exposed structures (bare bone, tendons, nerves, or vessels), along with the presence of concomitant vascular or orthopedic injuries.

Assessment of Patient General Condition and Fitness for Surgery

The general condition of the patient and well-being play a crucial role in determining the suitable plan of treatment. Patients were considered unfit for definitive management if they had severe trauma with associated life-threatening condition; vitally unstable, uncontrolled comorbidities such as hypertension, diabetes mellitus, peripheral arterial disease, or epilepsy; unstable psychological condition; or other conditions that may delay the definitive management or may preclude the performance of lengthy or morbid procedures.

Assessment of the Adjoining Areas of the Defect

In addition to routine laboratory tests, x-rays of the affected extremity in two views (antroposterior and lateral), and duplex scans were performed to exclude vascular injuries, with marking of nearby perforators.

Surgical Procedure

After preoperative preparation, wounds were debrided under regional or general anesthesia. The wounds were then classified into two categories: simple wounds, (which only include injury to the skin) and complex wounds (which include injury of more than one anatomical structure as bone/vessel/nerve/tendon as defined by Park et al.[14])

Simple Wounds

1. Simple wounds with no skin loss: are for primary closure.
2. Simple wounds with skin loss:
   - No exposed vital structures (no bare bone, tendon, or neurovascular bundles): skin grafts were applied [Split thickness skin graft (STSG)/full-thickness skin graft after proper wound preparation.
   - Exposed vital structures:
     - For minor exposures equal to or less than 25 cm^2, temporary coverage with NPWT alone or combined with dermal substitutes (when available) are considered followed by skin graft.
     - For major exposure more than 25 cm^2, flap coverage is recommended. Determining the type of flaps used in the algorithm is based on the general guidelines for flap coverage, availability of enough local tissues, size of the defect, patient fitness for surgery, and the surgeon's preferences.

Complex Wounds

Gustilo score was used to assess and determine the best option for coverage:

1. Gustilo I: Wounds are treated with primary suturing.
2. Gustilo II: We attempt primary suturing with or without minor undermining.
3. Gustilo III A/B (no vascular intervention): If the patient is fit for surgery, attempt flap coverage; if unfit for surgery, temporary coverage with dermal substitute and/or NPWT is used until the patient is fit for definitive coverage.
4. Gustilo III C (vascular repair): In case of competent vascular repair, we choose the appropriate flap for coverage. While if the vascular repair is questionable and limb vascularity is not yet established, temporary coverage is used as mentioned above.

The classification and management plan are illustrated in Figure 1.

Discharge and Follow-up

Patients were discharged after the definitive coverage plan was implemented. Subsequently, they were followed up weekly in the outpatient clinic until complete healing of the wounds, and at 3 months, 6 months, and at 12–18 months according to the need for following up the function and stability of coverage, and also depending on the compliance of the patient.

Postoperative Data Collection

Data collected included details of wound dimensions, operative details of surgical procedures, success rate in covering exposed areas, duration of hospital stay, total duration for coverage of soft tissue defects (from the day of trauma to the completion of wound healing), and complications.

Statistical Analysis

The analysis used SPSS (version 24), incorporating descriptive statistics for both qualitative and quantitative data. Qualitative data were depicted through frequency and percentage, whereas quantitative data were represented by mean and SD. Statistical tests, such as the Mann Whitney U test and Pearson correlation coefficient, were used. Significance levels were determined with *P* value.

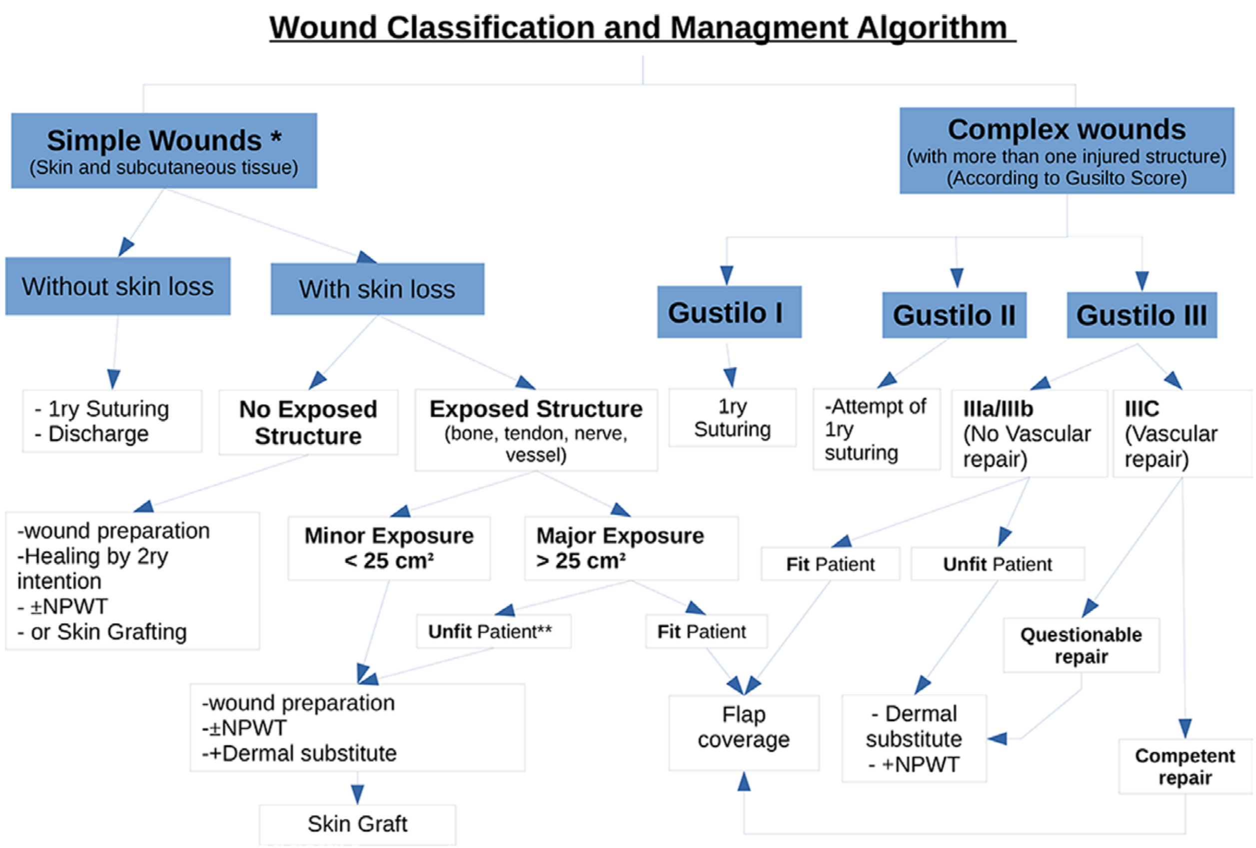

Fig. 1. Algorithm illustrating the classification and management of distal leg traumatic injuries. *As defined by Park et al, the wounds were classified into two categories; simple wounds, that only include injury to the skin, and complex wounds that include injury of more than one anatomical structure as bone/vessel/nerve/tendon.[14] **Patients were considered unfit for definitive managment if they had severe trauma with associated life-threatening condition, vitally unstable, or uncontrolled comorbidities as hypertension, diabetes, peripheral arterial disease, epilepsy, unstable psychological condition, or other conditions that may delay the definitive management or may preclude the performance of lengthy or morbid procedures.

RESULTS

The study includes 53 patients who presented after acute post-traumatic lower third leg and ankle soft tissue defects with or without bone fracture. Men constituted 81.13%, and women, 18.9%, with a mean age of 23.60 ± 15.27 SD. Comorbidities were present in 7.5% of cases, and 26.4% were smokers (Table 1).

Table 2 shows the distribution of injuries, with lacerations being the most common (47.1%) type. Complex wounds, involving structures like bone, tendons, or neurovascular structures, constituted 69.9%. Associated vascular injuries occurred in 5.7%, and associated bone injury in 62.2% of cases.

Table 3 illustrates the description of the soft tissue defects in the studied group. The defects had a mean size of 112.79 ± 107.94 cm^2. Eighty-eight percent of cases had exposed structures (bare bone, tendon, or neurovascular bundle), with a mean size of exposed area of 26.21 ± 44.2 cm^2.

Regarding the management approach, NPWT was used for 43 patients with a mean duration of NPWT of 2.08 ± 1.61 weeks. Dermal substitutes were used for 23 (43.4%) patients with a mean duration of application of 9.48 ± 3.94 days. Successful coverage was achieved in 98.1%. About 71.7% of cases needed two to three debridement sessions, and only one case was managed with primary sutures (Table 4).

In Table 5, the mean duration till definitive coverage was 21.89 ± 12.84 days, the mean duration of hospital stay was 28.72 ± 14.85 days, and most cases (81.1%) returned to normal daily activity within a mean duration of 60.69 ± 56.7 days. The delay in resuming normal daily activities was attributed to the orthopedic management plan; otherwise, the duration would have been shorter.

Regarding patient outcomes and complication rates, complete coverage without major complications was achieved in 83.1% of cases. Major complications, in the form of flap compromise or infection over dermal substitutes, occurred in 16.9% of cases, as illustrated in Table 6.

In the analysis of outcomes for patients treated with dermal substitutes, no statistically significant differences were observed concerning total hospital stay and days required for definitive coverage. The use of dermal substitutes resulted in successful coverage in wounds with exposed structures, and this success was noted in cases with a mean size of 11.39 ± 10.05 cm^2, aligning with the criteria outlined in our proposed algorithm ($P > 0.05$) (Table 7).

Table 8 reveals no statistically significant differences between major complications regarding dermal substitutes, local flaps, and perforator flaps ($P > 0.05$). Figures 2–4 illustrate patients' management according to our algorithm.

Table 1. Demographic Information of the Studied Group (n = 53)

Study Group (n = 53)			
Category		**No.**	**%**
Age (y)		23.60 ± 15.27	
Sex	Female	10	18.9
	Male	43	81.13
Comorbidities	Yes	4	7.5
Smoker	Yes	14	26.4

Table 2. Examination of Injury among the Studied Group (n = 53)

Study Group (n = 53)			
Category		**No.**	**%**
Type of injury	Crushed	9	16.9
	Degloved	19	36
	Lacerated	25	47.1
Zone of injury	ankle	10	18.8
	Ankle & foot	1	1.9
	Ankle + proximal	7	13.2
	Lower third leg	34	64.2
	Middle + lower third leg	1	1.9
Type of wound (n = 53)	Simple	16	30.1
	Complex	37	69.9
Associated vascular injury	Yes	3	5.7
Associated bone injury	Yes	33	62.2

Table 3. Details of the Defect among the Studied Group (n = 53)

Study Group (n = 53)		
Category	**No.**	**%**
Exposed structure: yes	47	88.7
Size of defect (cm^2)	112.79 ± 107.94	
Size of exposed structure (cm^2)	26.21 ± 44.2	

DISCUSSION

Surgeons encounter significant challenges when dealing with soft tissue defects in the lower third of the leg. Although various possibilities exist for soft tissue coverage, the choice of the most suitable option is constrained by potential complications.[11] In response to this dilemma, some surgeons have attempted to develop algorithms that aid in making a definitive plan of management for lower leg trauma. These algorithms aim to streamline the decision-making process and enhance the overall effectiveness of treatment strategies.

Fasciocutaneous flaps, perforator flaps, and dermal substitutes play pivotal roles in mitigating donor site morbidity while preserving muscle function. In the context of complex leg injuries, it is crucial to consider emerging trends in lower leg defect reconstruction.[3,11,15]

The utilization of diverse modalities is influenced by the significant impact and potential morbidities linked to the use of local or free flaps. When faced with small defects with exposed structures, the addition of a flap may impose undue burdens on both patients and surgeons, necessitating the exploration of simpler solutions for achieving stable coverage. In the context of multitrauma patients with critical injuries, the suboptimal general condition of the individuals might prevent

Table 4. Management Data of the Studied Group (n = 53)

Study Group (n = 53)			
Category		**No.**	**%**
Negative pressure wound therapy duration (wk)		2.08 ± 1.61	
Dermal substitutes duration (d)		9.48 ± 3.94	
Primary suture	Yes	1	1.9
Dermal substitutes	Yes	23	43.4
Primary grafting (STSG/FTSG)	Yes	14	26.4
Local flap	Yes	9	17
Perforator flap	Yes	6	11.3
Free flap	Yes	9	17
Cross leg flap	Yes	1	1.9
Complete coverage of raw area	Yes	52	98.1

Table 5. Outcome of the Studied Group (n = 53)

Study Group (n = 53)			
Category		**No.**	**%**
Duration for definitive coverage (d)		21.89 ± 12.84	
Total hospital stays (d)		28.72 ± 14.85	
Duration to return to normal activity (wk)		8.67 ± 8.1	
Functional outcome	Limited range of motion (ROM)	19	35.8
	Normal ROM	34	64.2
Return to normal daily activity (n = 53)	Yes	43	81.1

Table 6. Complications of the Studied Group (n = 53)

Study Group (n = 53)			
Category		**No.**	**%**
Minor complications	Yes	6	11.3
Major complications	Yes	9	16.9

performing prolonged or medically complex procedures.[16] Therefore, the temporary coverage of wounds becomes imperative until both general and local wound conditions can be improved.

The use of NPWT reduces tissue edema, and thus decreases the limb circumference and wound surface area. It also promotes granulation tissue, increases microcirculation, and improves local wound conditions.[6]

The introduction of dermal substitute scaffolds has significantly expanded reconstructive possibilities in lower extremity reconstruction. Dermal matrices have demonstrated satisfactory outcomes, particularly in addressing small areas of exposed bone and tendon that necessitate only a thin layer of soft tissue coverage.[17] Dermal substitutes offer several advantages, such as easy and rapid application, suitability for wounds of any size, and the absence of donor site morbidity.

Dermal matrices can cover areas of exposed vital structures traditionally considered non-graftable, as demonstrated by Lee et al, who described their efficacy in preventing free flap or limb amputations in complex lower limb injuries with exposed bones, joints, or tendons.[8] The dermal substitutes should primarily be used in appropriately selected patients as an alternative reconstructive option in the presence of severe comorbidities, where local flaps are unavailable, or when the patient is not suitable for free tissue transfer and prolonged anesthesia, or in situations where microvascular surgical services are not available.[12]

Simple reconstruction options are essential to reduce morbidity and ensure fast recovery. The optimal flap for coverage should possess specific characteristics, such as matching skin, sufficient padding, possible sensibility, resistance to shear forces, and abilitiy to cover defects without tension to ensure success.[18–20] Patient selection is crucial with regard to flap coverage, optimal general condition, available donor site, and patient acceptance of donor site morbidity.[18] Although some surgeons consider free tissue transfer a standard treatment option, controversies persist regarding wounds in the distal third of the leg that are either too small for free flap surgery or too large for primary suturing.[21,22] The increasing pattern of using fasciocutaneous perforator flaps provides more alternatives for lower limb reconstruction.[20,23]

In our study, we have developed an algorithm influenced by previous studies and known management protocols, and taking into account the available services and materials. We took into consideration that our algorithm incorporates modalities such as dermal substitutes and NPWT, aiming to enhance their efficacy in the overall reconstruction strategy.

In our study, we succeeded in achieving complete coverage of exposed structures in defects with a surface area of the average size about 11.39 ± 10.05 cm^2, using dermal substitutes (Pelnac Gunze Co., Ltd., Kyoto, Japan). We found no statistical difference in the complication rates between flap surgery and applying dermal substitutes followed by STSG. Although infection over the dermal substitute was the main observed complication, it still carries the advantage of avoiding donor site morbidity.

While revisiting previous algorithms proposed by reconstructive surgeons for managing such defects, it is evident that the integration of dermal substitutes and negative pressure wound therapy (NPWT) is not adequately emphasized in most of them, despite the significant value these techniques have demonstrated in soft tissue reconstruction over the past years.

In 2007, Saleh et al proposed an algorithm for traumatic leg reconstruction, encompassing the thigh, knee, and leg. Although the algorithm was straightforward, it lacked comprehensiveness. The general condition of the patient and the local wound/limb condition were not considered, despite their potential influence on decision-making. Additionally, the size of the defect and the presence of exposed structures were not specified as criteria for selecting the appropriate modality. Notably, the study did not address the utilization of negative pressure wound therapy (NPWT) or dermal substitutes.[9]

In a prospective clinical study conducted by Ivanove et al in 2016, the suggested plan for reconstructing primary traumatic soft tissue defects in the leg was depending on the severity of the patient's general condition and the zone of injury. However, it is important to note that the study was not specifically focused on lower third leg

Table 7. Relation between Dermal Substitutes and Different Parameters among the Studied Group

Variable		Size of Exposed Structure (cm^2)	Total Hospital Stay	Days for Definitive Coverage
Dermal substitutes	No (n|=|30)	37.57|±|55.85	25.5 (17–41.5)	17 (9.5–35.25)
	Yes (n|=|23)	11.39|±|10.05	25 (18-36)	21 (16-31)
Test	Z		-0.575	-0.817
	P		0.565	0.414

Mann Whitney test (mw).

Table 8. Relation between Major Complications and Different Parameters among the Studied Group

			Major Complications		Tests	
Variable			**No (n = 43)**	**Yes (n = 9)**	**X^2**	***P***
Dermal substitutes	No **(n = 30)**	**N**	26	3	1.383	0.240
		%	60.5%	40.0%		
	Yes **(n = 23)**	**N**	17	6		
		%	39.5%	60.0%		
Free flap	No **(n = 44)**	**N**	38	6	4.633	**0.031** *
		%	86.4%	13.6%		
	Yes **(n = 9)**	**N**	6	3		
		%	55.6%	44.4%		
Perforator flap	No **(n = 47)**	**N**	38	8	0.021	0.884
		%	80.9%	19.1%		
	Yes **(n = 6)**	**N**	5	1		
		%	83.3%	16.7%		
Local flap	No **(n = 47)**	**N**	35	8	0.426	0.514
		%	79.5%	20.5%		
	Yes **(n = 6)**	**N**	8	1		
		%	88.9%	11.1%		

*Chi-square test.

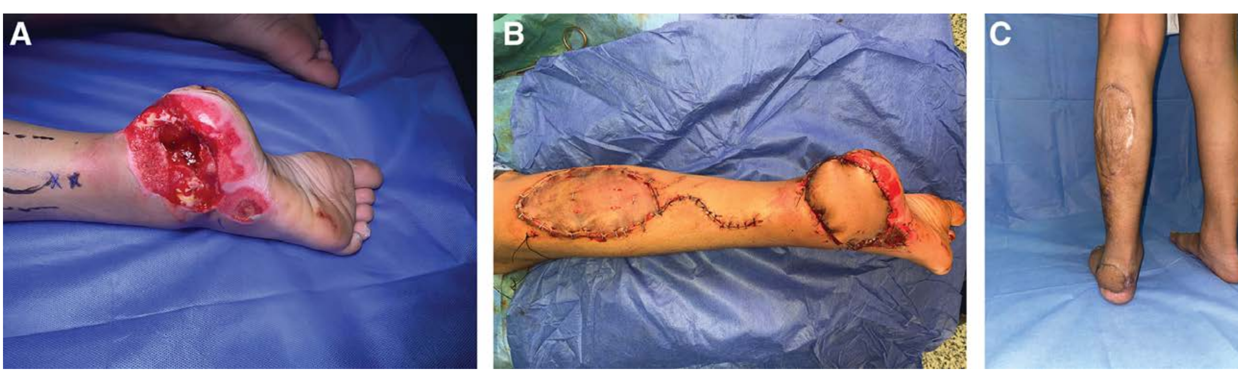

Fig. 2. Patient presenting with a post-traumatic defect over the lower third of the left leg and ankle with exposed bone. Reversed sural flap is used for coverage. A, Raw area. B, Reversed sural flap inset. C, Appearance at 8-month follow-up.

injuries and relied on limited parameters as the sole determinants for the optimal management plan. Additionally, their algorithm for soft tissue coverage exclusively incorporated local and free flaps, without acknowledging the potential role of alternative options. Despite recognizing the impact of defect size on flap selection, the study did not address other potential challenges in the reconstruction process.[10]

The algorithm presented by AlMugaren et al in 2020[11] relies on a selection process guided by the zone of injury, complexity of the wounds, and the size of the defect. Despite being a literature review rather than a clinical study, the algorithm demonstrated greater comprehensiveness compared with previously proposed management plans, incorporating valuable considerations for the optimal management of leg injuries. However, it is noted that the inclusion of dermal substitutes and negative pressure wound therapy (NPWT) in the algorithm had no clear indications.[11]

In a review article by Zeiderman and Pu in 2021,[12] they introduced an algorithm for managing traumatic defects in the lower third leg. The article comprehensively reviewed various modalities for management, emphasizing the significance of emerging techniques like dermal substitutes, negative pressure wound therapy (NPWT), and the increasingly popular use of

Fig. 3. Patient presenting with a post-traumatic defect over the lower third of the left leg and ankle, with exposed bone less than 25 cm^2. Dermal substitute (Pelnac) is used for coverage. A, Intraoperative photograph of defect after debridement. B, Dermal substitute application. C, STSG applied. D, Appearance at 9-month follow-up.

perforator flaps. However, it is notable that the article did not provide a definitive plan or a structured algorithmic approach with specific indications for utilizing each modality.[12]

Our study's results substantiate the efficacy of employing dermal substitutes and negative pressure wound therapy (NPWT) across diverse scenarios. The benefits of using dermal substitutes and NPWT include the following: (a) postponing conclusive decisions until the wound bed is adequately prepared for definitive coverage; (b) in multitrauma patients with critical injuries, NPWT can be used temporarily if no vital structures are exposed, or with dermal substitutes for exposed structures, allowing time for stabilizing the general condition; (c) in the case of complex wounds with multiple leg injuries, we can extend the timeline for definitive coverage until a multidisciplinary team meeting is convened for thorough planning; (d) in cases of compromised limb vascularity where vascular repair is uncertain, avoiding the implementation of invasive reconstructive procedures till limb vascularity is ensured; and (e) for major defects amenable to free tissue transfer, executing the procedure on a more stable patient, reducing operative time and allowing thorough preoperative planning.

The algorithm proposed in this study aims to produce a comprehensive and clear plan of management, considering the complexity of wounds, the general condition of patients, and the local wound/limb condition. The size of exposed structures within complex defects is a crucial consideration in selecting the most appropriate and optimal coverage option. Notably, the study incorporates different modalities for soft tissue coverage, such as dermal substitutes and NPWT, emphasizing their optimal use for the best outcomes in patients.

CONCLUSIONS

We believe that this algorithm offers a safe and effective approach for the management of traumatic lower third leg and ankle defects, demonstrating an overall success rate of 98.1% in soft tissue coverage. We also advise the proper allocation of using dermal substitutes in defects with exposed structures not exceeding 25 cm^2 to achieve optimal coverage. The algorithm is straightforward, safe to apply, and can serve as a comprehensive guide for specialized trauma centers. Our algorithm is specific to the lower third of the leg and ankle regions; it does not give a guide for the management of the rest of the leg. Nevertheless, it is recommended to conduct additional studies to define precise parameters for the effective utilization of dermal substitutes in covering exposed vital structures, and to optimize the selection of flaps for this specific zone, taking into account factors such as defect size and other relevant criteria.

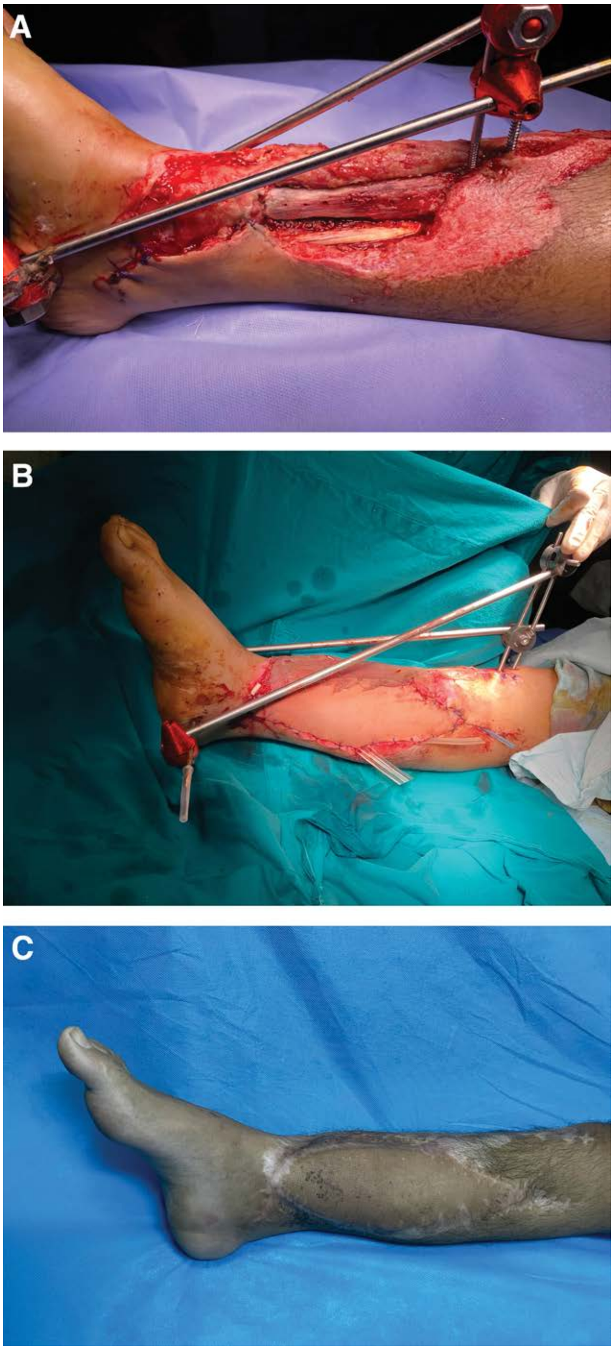

Fig. 4. Patient presenting with a post-traumatic defect over the lower third of the left leg with exposed lower third of the tibia. A free latissimus dorsi flap is done for coverage. A, Intraoperative photograph of defect after debridement. B, Free latissimus dorsi flap inset with complementary skin grafting. C, Appearance at 9-month follow-up.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

ETHICAL APPROVAL

This work was approved by our institute ethical committee (approval no. MD-90-2021).

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