ISSN 1948-9358 (online)

# World Journal of *Diabetes*

Monthly Volume 16 Number 1 January 15, 2025

Published by Baishideng Publishing Group Inc

World Journal of
Diabetes

Contents

Monthly Volume 16 Number 1 January 15, 2025

World Journal of Diabetes

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# Contents

*World Journal of Diabetes*

Monthly Volume 16 Number 1 January 15, 2025

## Contents

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**NAME OF JOURNAL**
*World Journal of Diabetes*

**ISSN**
ISSN 1948-9358 (online)

**LAUNCH DATE**
June 15, 2010

**FREQUENCY**
Monthly

**EDITORS-IN-CHIEF**
Lu Cai, Md. Shahidul Islam, Michael Horowitz

**EDITORIAL BOARD MEMBERS**
https://www.wjgnet.com/1948-9358/editorialboard.htm

**PUBLICATION DATE**
January 15, 2025



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World Journal of
Diabetes

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World J Diabetes 2025 January 15; 16(1): 100597

DOI: 10.4239/wjd.v16.i1.100597

ISSN 1948-9358 (online)

EDITORIAL

# Acellular fish skin grafts in diabetic foot ulcer care: Advances and clinical insights

Yu Zhao, Quan-Quan Shen

**Specialty type:** Endocrinology and metabolism

**Provenance and peer review:** Invited article; Externally peer reviewed.

**Peer-review model:** Single blind

**Peer-review report's classification**
**Scientific Quality:** Grade B
**Novelty:** Grade B
**Creativity or Innovation:** Grade B
**Scientific Significance:** Grade B

**P-Reviewer:** Wang K

**Received:** August 21, 2024
**Revised:** October 23, 2024
**Accepted:** November 13, 2024
**Published online:** January 15, 2025
**Processing time:** 100 Days and 22.8 Hours

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## Abstract

Diabetic foot ulcers (DFUs) represents a significant public health issue, with a rising global prevalence and severe potential complications including amputation. Traditional treatments often fall short due to various limitations such as high recurrence rates and extensive resource utilization. This editorial explores the innovative use of acellular fish skin grafts as a transformative approach in DFU management. Recent studies and a detailed case report highlight the efficacy of acellular fish skin grafts in accelerating wound closure, reducing dressing changes, and enhancing patient outcomes with a lower socio-economic burden. Despite their promise, challenges such as limited availability, patient acceptance, and the need for further research persist. Addressing these through more extensive randomized controlled trials and fostering a multidisciplinary treatment approach may optimize DFU care and reduce the global health burden associated with these complex wounds.

**Key Words:** Diabetic foot ulcer; Acellular matrix tissues; Acellular fish skin grafts; Wound healing; Bioengineered materials

**Core Tip:** This editorial explores the innovative use of acellular fish skin grafts (AFSGs) in the management of diabetic foot ulcers (DFUs). It introduces AFSGs as a bioengineered alternative that mimics the natural extracellular matrix, enhancing healing by promoting cell migration and tissue integration. The unique properties of AFSGs include reducing dressing changes, enhancing healing rates, and minimizing patient discomfort. This article calls for further randomized controlled trials to validate the effectiveness of AFSGs in diverse DFU cases and stresses the importance of a multidisciplinary approach in DFU management.

**Citation:** Zhao Y, Shen QQ. Acellular fish skin grafts in diabetic foot ulcer care: Advances and clinical insights. *World J Diabetes* 2025; 16(1): 100597
**URL:** https://www.wjgnet.com/1948-9358/full/v16/i1/100597.htm
**DOI:** https://dx.doi.org/10.4239/wjd.v16.i1.100597

## INTRODUCTION

Diabetic foot ulcers (DFUs) represents a significant and growing public health challenge[1]. According to the International Diabetes Foundation, the global prevalence of DFUs has significantly increased, with current estimates ranging from 40 to 60 million people, compared to the 2015 estimates of 9 to 26 million[2]. As a common complication of diabetes mellitus, DFUs can lead to severe outcomes, including infection, prolonged hospitalization, and even lower limb amputation[3-5]. The prevalence of DFUs is on the rise, with estimates suggesting that 12%-34% of patients with diabetes will develop a foot ulcer in their lifetime[6,7]. This not only imposes a substantial burden on healthcare systems but also profoundly impacts the quality of life of affected individuals.

Effective management of DFUs requires a comprehensive approach that addresses underlying factors such as glycemic control, infection, arterial disease, and mechanical stress[8]. Traditional treatment modalities, including surgical interventions and negative pressure wound therapy, have long been the cornerstone of DFU management[9-11]. Debridement, a critical step in DFU management, often necessitates subsequent tissue grafting. However, the use of autografts, while effective, can lead to additional pain and trauma for the patient due to the harvesting of tissue from donor sites, which are limited[12]. Furthermore, allografts have constraints due to the risks of immune rejection and disease transmission, complicating their use[13].

The emerging use of bioengineered materials and biological dressings has shifted the landscape of DFU treatment. Among these innovations, fish skin grafts have garnered attention due to their unique biological properties that can enhance the healing process[14]. This editorial aims to explore the promising advancements in DFU treatment, focusing on the application of fish skin grafts, as highlighted in a recent case report involving a challenging DFU. By reviewing the current state of knowledge and the potential clinical implications, we hope to provide valuable insights into how these novel approaches can shape the future of diabetic foot care.

## EMERGENCE OF AFSGS IN DFU CARE

In the past few years, the field of wound care has seen significant advancements with the introduction of acellular matrix tissues (AMTs)[15]. These bioengineered materials are designed to facilitate the healing process by providing a scaffold that mimics the natural extracellular matrix of the skin, promoting cell migration and tissue integration[16]. Among various AMTs, acellular fish skin grafts (AFSGs) have attracted particular attention due to their unique composition, which includes essential fatty acids and proteins that are critical for wound healing[17].

AFSGs are xenogenic skin substitutes derived from species such as North Atlantic cod or Nile Tilapi. During their production, these grafts are lyophilized, decellularized, and sterilized, preserving the extracellular dermal structure and their native bioactive lipid components[18]. This structural similarity to human skin, which includes three basic layers - epidermis, dermis, and hypodermis - allows AFSGs to integrate compatibly with human tissue, promoting cellular proliferation without triggering hypersensitivity reactions[19].

The presence of collagen in fish skin provides a structural framework that supports skin regeneration and tissue repair by promoting cellular attachment and critical migration processes during the proliferation phase of wound healing. Moreover, fish skin's hydration-retaining properties help create an optimal moist environment, accelerating the process of epithelialization[19]. Enriched with soluble molecules and natural omega-3 fatty acids, AFSGs play a proactive role in host defense, inflammation reduction, tissue remodeling, and pain mitigation[20-22].

Unlike mammalian-derived products, AFSGs carry no risk of viral transmission to humans and no cultural or religious barriers to use[23,24]. Their unique properties enable effective adherence to the wound bed, reducing the frequency of dressing changes needed and facilitating quicker, more comprehensive healing[25,26]. These advantages position AFSGs as a favorable option in wound management, supported by various clinical studies. For instance, retrospective studies have indicated that treating DFUs with AFSGs can transition wounds from a chronic, hard-to-heal state to an acute, pro-inflammatory state that promotes faster healing[27].

Meta-analyses of randomized controlled trials (RCTs) have shown that AFSGs are more effective in achieving complete ulcer healing compared to conventional treatments such as collagen alginate dressings[28]. In the management of burn wounds, studies comparing AFSGs with treatments such as 1% silver sulfadiazine cream have demonstrated that AFSGs can accelerate wound healing, reduce analgesic requirements, and decrease the frequency of dressing changes[29,30]. In a double-blind RCT, AFSGs have been found to heal wounds faster and at a lower cost compared to dehydrated human amnion/chorion membrane[25]. Preclinical trials comparing AFSGs with fetal bovine dermis grafts for deep partial thickness burn wounds revealed that wounds treated with AFSGs showed faster epithelialization and contraction[31]. A retrospective case-control study has also indicated that AFSGs can hasten epithelialization in burn wounds, improve skin elasticity, and even enhance aesthetic outcomes compared to synthetic skin substitutes and autologous split thickness skin grafts[32].

Recently, this journal published a case report entitled "Treatment of severe non-healing diabetic foot ulcer using topical fish skin graft: A case report"[33]. In this case, a 39-year-old male patient who had type 1 diabetes since the age of 15 years experienced significant therapeutic success with the application of an intact fish skin graft. The patient initially presented with a DFU on the dorsum of his left foot involving muscle and tendon, and conventional treatments including intensive diabetes control, surgical interventions, infection management, and negative pressure therapy, yielded only limited improvements. Faced with the prospect of amputation due to persistent infection and lack of healing, the application of AFSGs marked a turning point in the patient's recovery. The AFSGs were derived from the skin of North Atlantic cod and received approval from the United States Food and Drug Authority in 2013 (Kerecis® Omega3 Wound™, Kerecis, Iceland). The AFSGs application was performed once per week for a period of 10 weeks, leading to complete epithelialization of the ulcer within 10 weeks - a notably rapid recovery for a wound of such severity.

This case underscores the efficacy of AFSGs in treating deep, infection-prone DFU, providing a viable alternative to more invasive procedures such as amputation. The successful outcome highlights the graft's role not only in closing the ulcer but also in significantly enhancing the patient's quality of life. The integration of fish skin grafts into the therapeutic regimen for DFUs, especially those at high risk of complications, promises a new frontier in diabetic wound care, aligning with contemporary strategies aimed at preserving tissue and function while minimizing surgical interventions.

However, several limitations should be noted in this case. First, as a single case report, the results cannot be generalized to a broader population, particularly given the complexity and variability of DFUs. Individual patient factors, such as the extent of tissue involvement and overall health status, can significantly influence outcomes. Second, the follow-up period was relatively short, and long-term efficacy, including the potential for ulcer recurrence or complications, remains unexamined. Moreover, the case lacks a control comparison, making it difficult to definitively attribute the successful outcome solely to the use of the AFSGs. Finally, further RCTs with larger patient populations are needed to validate these findings and determine the specific contexts in which AFSGs is most effective. These limitations underscore the importance of more comprehensive studies to establish the long-term benefits and general applicability of AFSGs in DFU treatment.

## CHALLENGES AND CONSIDERATIONS IN THE USE OF AFSGS IN DFU TREATMENT

Although the use of AFSGs in treating DFUs presents several advantages, it does have some challenges that may affect broader clinical application. Firstly, there are currently too few mature products on the market, and the availability of these grafts can be limited. Secondly, some patients may have reservations due to the origin of the grafts. Moreover, the long-term efficacy of AFSGs in DFU treatment remains under-explored. Prolonged follow-up studies are necessary to establish the durability of healing outcomes and the potential for recurrence of ulcers.

Current research into AFSGs for DFUs demonstrates promising results but also reveals substantial heterogeneity in study designs, which can complicate the interpretation of outcomes. There is a notable scarcity of large-scale RCTs, and existing studies often suffer from small sample sizes and lack diversity in patient populations. In the future, we recommend designing multi-center RCTs to enhance the generalizability and statistical power of the findings. Furthermore, DFUs vary widely in severity and type, yet many studies do not adequately stratify patients based on these characteristics, potentially obscuring the specific contexts in which AFSGs are most effective. Future research should prioritize subgroup analyses to ascertain the efficacy of AFSGs across different severities and stages of DFUs, including chronic *vs* acute wounds and moderate *vs* severe cases.

Another principal challenge in clinical trials for AFSGs is achieving effective blinding[34]. The distinct nature of these treatments makes it difficult to conceal whether patients are receiving the experimental intervention or a control, which could introduce bias and affect the reliability of the results. To mitigate this issue, we suggest utilizing more sophisticated blinding techniques and possibly involving independent assessors to validate outcomes.

Additionally, long-term follow-up studies should be conducted to evaluate the durability of healing outcomes and recurrence of ulcers. Assessing a wide range of clinical indicators including healing time, healing rates, complication rates, and quality of life measures, will provide more comprehensive insights into the effectiveness of this treatment. By addressing these challenges and incorporating a multidisciplinary approach, which includes input from diabetologists, surgeons, wound care specialists, and patient care coordinators, the effectiveness of AFSGs and other advanced treatments could be maximized[35]. This collaborative model facilitates comprehensive care that addresses all aspects of DFU management, from metabolic control to local wound care. The effectiveness of AFSGs and other advanced treatments could be maximized within such frameworks, suggesting that future research and clinical protocols should continue to emphasize and explore the dynamics of multidisciplinary care.

## CONCLUSION

While AFSGs represent a significant advance in the treatment of DFUs, their integration into standard care protocols requires a concerted effort to overcome existing barriers and fully understand their long-term benefits and limitations. With continued research and collaborative care approaches, AFSGs have the potential to become a cornerstone in the evolving landscape of diabetic wound management, offering new hope for patients suffering from this severe complication of diabetes.

## FOOTNOTES

**Author contributions:** Zhao Y drafted the manuscript; Shen QQ designed and revised the manuscript; both authors have read and approved the final manuscript.

**Supported by** the Zhejiang Medical Technology Project, No. 2022RC009 and No. 2024KY645.

**Conflict-of-interest statement:** All the authors report no relevant conflicts of interest for this article.



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**S-Editor:** Li L
**L-Editor:** A
**P-Editor:** Xu ZH

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