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Hyperbaric Oxygen Therapy as an Effective Adjunctive Treatment in the Reconstruction of Tissue Defects With Graft in Diabetic Foot Patients: A Retrospective Cohort Study

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ABSTRACT

Diabetic foot patients frequently experience delayed wound healing due to compromised vascularity and oxygenation, which increases the risk of graft failure. Hyperbaric oxygen therapy (HBOT) has demonstrated potential in enhancing graft survival and accelerating wound healing in these patients. This study aimed to assess the efficacy of HBOT in improving graft success and wound healing rates in diabetic foot patients undergoing foot graft reconstruction. Forty-five diabetic patients with tissue defects requiring graft procedures were included. Among these, 28 patients received HBOT (2.4 ATA for 120 min daily), and 17 served as controls. Wound healing was assessed based on milestones of wound closure (25%, 50%, 75% and complete healing). The control group consisted of patients with adequate graft nutrition who did not require HBOT or were unable to undergo HBOT for other reasons. Statistical analyses were performed to compare healing times and graft retention rates between the two groups. Patients in the HBOT group exhibited significantly faster healing, with a median time to 50% healing of 18 days compared to 30.5 days in the control group ($p < 0.05$). A moderate negative correlation was observed between graft retention rates and time to complete healing ($p < 0.05$), indicating that higher graft retention was associated with shorter healing times. Despite higher HbA1c levels in the HBOT group, favourable healing outcomes were achieved. No adverse effects were reported in the HBOT group. HBOT significantly enhances graft survival and accelerates wound healing in diabetic foot patients, even in cases with poor glycaemic control. HBOT emerges as a valuable adjunctive treatment for patients with compromised vascular beds and hypoxic tissues. Future randomised controlled trials are needed to validate these results.

1 | Introduction

The lifetime risk of foot ulceration in diabetic patients is alarmingly high, estimated at approximately 34% [1]. Key risk factors

for developing diabetic foot ulcers include sensory loss from peripheral neuropathy, prior ulcers or amputations, foot deformities, trauma, infection and chronic ischemia due to peripheral arterial disease (PAH) [1]. Diabetic foot ulcers contribute

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Summary

- Keypoints
 - HBOT significantly reduces the median time to achieve 50% and complete wound healing in diabetic foot patients undergoing skin graft reconstruction, even in cases with poor glycemic control.
 - Patients treated with HBOT exhibited higher graft retention rates compared to the control group, demonstrating its efficacy in enhancing graft viability and reducing failure rates.
 - By enhancing tissue oxygenation, promoting angiogenesis and reducing hypoxia-induced complications, HBOT serves as an effective adjunctive treatment for compromised vascular beds in diabetic foot patients.
 - HBOT minimises the need for repeat grafting and further surgical interventions, thereby reducing morbidity associated with graft failure. HBOT was well-tolerated with no reported adverse effects in this study. While not all patients are eligible for hyperbaric oxygen therapy, those who can undergo treatment may significantly benefit from its adjunctive use in diabetic foot patients with delayed wound healing and high-risk tissue conditions.

significantly to morbidity, representing over two-thirds of non-traumatic amputations in the United States, and are responsible for about 25% of hospitalisations among individuals with diabetes [2, 3]. These findings highlight the need for timely and appropriate treatment of diabetic foot ulcers. Wound healing in diabetic patients is notably delayed, with standard wound care achieving only 24%–30% healing within 12–20 weeks, underscoring the need for effective adjunctive therapies [4].

The viability and vascularization of grafts are largely dependent on the condition of the recipient bed. Consequently, the success of graft reconstruction and the prevention of graft failure are contingent upon the adequate preparation of the wound bed. While ensuring an optimal recipient bed is the most effective strategy to prevent graft loss, there are instances where the bed's condition may be insufficiently addressed, or the harvested graft may exceed the recipient bed's capacity to sustain it. In diabetic foot, macro- and microangiopathy lead to reduced vascularity and tissue oxygenation, contributing to hypoxia and increased risk of graft failure. In cases of compromised perfusion, HBOT has demonstrated substantial efficacy in the salvage of compromised grafts [5]. HBOT not only optimises graft viability by enhancing oxygenation during neovascularization but also decreases the need for repeat grafting and further surgical interventions [6].

HBOT has been shown to significantly enhance wound healing and decrease the risk of amputation [6]. The literature supports the use of standard wound care in conjunction with HBOT for nonhealing wounds [7]. While HBOT is not routinely recommended or utilised following graft or flap surgery, it should be considered as a primary treatment modality in cases where the affected area is exposed to hypoxia or reduced perfusion due to factors such as radiotherapy, trauma or vascular injury [8]. Administering HBOT to appropriately selected patients with

clear indications can mitigate hypoxia-induced microvascular damage surrounding the wound and address the factors impeding normal healing. Moreover, HBOT promotes angiogenesis, controls oedema and infection, and supports the regeneration of connective tissue, all of which contribute to wound healing and reinforce its rationale as an adjunctive treatment in cases of compromised skin grafts and flaps [9].

This study evaluates HBOT's efficacy in diabetic foot patients undergoing graft reconstruction. We analysed the impact of HBOT on graft success and healing rate, along with factors such as HbA1c levels, the presence of osteomyelitis (OM) and vascular intervention outcomes.

2 | Materials and Methods

In this retrospective cohort study, all diabetic foot patients who underwent graft (Split-thickness Skin Grafts) reconstruction at the General Surgery Clinic were included, with Ethics Committee approval (Project/Decision No: 2022/256). Patients meeting the criteria for HBOT were assigned to the HBOT group, while patients with adequate graft nutrition and vascularity, who did not require HBOT, formed the control group. Graft healing and success rates were compared between groups. Patients under 18 years of age and those with incomplete data were excluded.

In both graft groups, split-thickness skin grafts were harvested from the lateral aspect of the thigh, fenestrated and applied to the ulcer site. A multilayer dressing was applied to both the recipient area and the graft site in all patients. This dressing consisted of paraffin gauze, moistened sterile gauze and a roll bandage. For standardisation purposes, the first dressing change was performed on postoperative Day 3 in both groups. Subsequent dressings were carried out every 2 days until complete epithelialisation was achieved. For dorsal foot wounds, no specific offloading device was used; patient mobilisation was encouraged, but the use of standard daily footwear was not permitted. For plantar foot wounds, partial offloading casts or devices were employed based on wound location, ensuring that the graft site remained exposed.

Patients' demographics, comorbidities, vascular intervention status, defect sizes, HbA1c levels and surgical success rates were documented. The healing progress of the graft site was meticulously tracked. The day on which 25% of the wound had healed was recorded as the 25% healing time, while 50% and 75% healing times were similarly documented when the respective proportions of the wound had healed. The time of complete healing was defined as the day when the wound was fully epithelialised and closed. For wounds that did not fully close, the day when the wound reached its best possible condition was recorded as the time of maximum healing. The relationships between these healing milestones were then analysed and compared.

2.1 | HBOT Procedure

HBOT was administered in a multiplace hyperbaric chamber (Zyron 12, 2008, Hipertech, Istanbul, Turkey) at the Gulhane

Training and Research Hospital, Clinic of Underwater and Hyperbaric Medicine. Treatment was conducted once daily, lasting 120 min at a pressure of 2.4 ATA. Patients descended to 45 ft over 15 min, followed by three 30-min oxygen breathing periods, with two 5-min air breaks between them. The session concluded with a 15-min ascent.

The control group included patients who either could not undergo HBOT or declined treatment due to risks such as claustrophobia.

Statistical analyses were performed using SPSS Statistics (IBM Corp., version 21, Armonk, NY). The normality of variable distributions was assessed both visually (using histograms and probability plots) and analytically (via the Kolmogorov–Smirnov and Shapiro–Wilk tests). Categorical variables that did not follow a normal distribution were presented as *n* (%), while continuous variables not conforming to normal distribution were expressed as median (interquartile range). Nonnormal distributions were analysed with the Mann–Whitney U test, and correlations were assessed using Spearman's rank correlation test. A $p < 0.05$ was considered statistically significant.

3 | Results

Forty-five patients who underwent graft procedures for the closure of tissue defects caused by diabetic foot were included in this study. Of these, 28 patients (62.2%) were in the HBOT group, while 17 patients (37.8%) comprised the control group. The demographic characteristics of the patients are presented in Table 1, showing no significant differences in age, gender, comorbidities, wound size, HbA1c levels or vascular intervention status. The median HbA1c was higher in the HBOT group (9.1%) than in the control group (7.6%). OM presence and worse overall health were more common in the HBOT group, but these differences were not statistically significant. Although these differences were not statistically significant, patients in the HBOT group generally exhibited worse overall health in terms of comorbidities, clinical performance and general condition.

The healing rate of the graft site was analysed from the date of the surgical procedure across five distinct groups (Table 2). Comparison of wound healing rates indicated that patients receiving HBOT consistently exhibited faster healing in all groups. Specifically, the median time to achieve 50% wound healing was 30.5 days in the control group and 18 days in the HBOT group (Figure 1), demonstrating a statistically significant difference ($p < 0.05$).

Table 3 presents the correlation between graft retention rate and healing times. The analysis revealed a moderate negative correlation between graft retention rate and complete healing time (Spearman's $r = -0.418$, $p < 0.05$), indicating that shorter healing times were associated with higher graft retention rates. Additionally, a statistically significant correlation was found between the 75% healing time, time to maximum healing and time to complete healing ($p < 0.01$, $r = 0.873$; $p < 0.01$, $r = 0.979$, respectively).

Table 4 outlines the data for patients who underwent successful interventional procedures, compared to those with unsuccessful

outcomes, after excluding patients who did not receive angioplasty. A statistically significant difference in graft retention rates was observed between these two groups ($p < 0.05$). Notably, although patients with successful angioplasty had significantly higher HbA1c levels, their graft retention rates were also higher.

In the HBOT group, hyperbaric oxygen therapy (HBOT) began an average of 31.5 days (IQR 14.2–40) prior to grafting. During this period, patients received 29 sessions (IQR 18–36) of HBOT at 2.4 ATA for 120 min each. No side effects or complications requiring notification were reported in the HBOT group, and all patients successfully completed the treatment regimen without interruption.

4 | Discussion

The study's primary finding is the significantly faster healing observed in the HBOT group across all milestones. Specifically, the time to 50% healing was significantly shorter in the HBOT group, at 18 days, compared to 30.5 days in the control group ($p < 0.05$). This difference is clinically important, as each day that diabetic foot patients do not achieve complete healing through epithelialisation, they remain at increased risk of resistant infection, biofilm formation and reinfection.

Another noteworthy result was that, despite the significantly higher HbA1c levels in the HBOT group compared to the control group, the desired wound healing times were still achieved. These healing outcomes should be considered in the context of elevated HbA1c levels, which are known to increase Wagner/PEDIS stages, disease severity and associated tissue loss in diabetic foot patients [10].

The primary goal of diabetic foot treatment is to prevent major amputation and preserve a functional foot. Patients who undergo major amputation experience increased morbidity and mortality. The expected mobility and prosthesis use rates within the 1st year after major amputation are notably low, with only 50%–60% of patients being able to mobilise with a prosthesis [11, 12]. In patients who are unable to mobilise, the resulting metabolic imbalance can lead to life-threatening cardiovascular complications and may result in long-term dependency on care. Mortality within the 1st year following major amputation is estimated to be between 20.8% and 35% [13].

Reamputation rates are particularly high in patients undergoing diabetic foot surgery. Anwander et al. identified several risk factors for reamputation, including the presence of multiple ulcers, PAH, CRP levels above 100, peripheral neuropathy and nonpalpable foot pulses. As the number of risk factors increases, the success rate at any given level of amputation decreases. Among patients with diabetic foot disease, approximately one in four requires further surgical intervention [14].

Van der Wal et al. reported wound healing failure rates of 20% following Lisfranc amputation, 28% after modified Chopart amputation and 46% after conventional Chopart amputation [15]. Re-amputation is a common outcome after these surgeries. In clinical practice, particularly in cases of infected diabetic foot, guillotine and irregular amputations are frequently

TABLE 1 | Demographic and clinical characteristics of patients.

Characteristics	Control group (N=17)	HBOT group (N=28)	Total (N=45)	<i>p</i>
Age (median, IQR)	61 (56–65)	56 (49.8–65.2)	58 (53–65)	0.241
Gender				
Male (%)	11 (64.7)	23 (82.1)	34 (75.6)	0.336
Female (%)	6 (35.3)	5 (17.9)	11 (24.4)	
Graft retention rate (%)	100 (80–100)	100 (87.5–100)	100 (80–100)	0.531
Graft retention percentage				0.504
< 50%	1 (5.9)	3 (10.7)	4 (8.9)	
51%–75%	3 (17.6)	2 (7.1)	5 (11.1)	
> 76%	13 (76.5)	23 (82.1)	36 (80)	
HbA1c(%) (median, IQR)	7.6 (6.4–9.5)	9.1 (7.9–11.2)	8.8 (6.9–10.7)	0.117
Wound size (cm ²)	12 (9–18)	15 (8.8–29.2)	12 (9–20)	0.353
Duration of wound formation (months)	4 (3–7)	3 (2–6)	3 (2–6)	0.427
Presence of osteomyelitis	5 (29.4)	17 (60.7)	22 (48.9)	0.084
Peripheral arterial disease (PAD)	14 (82.4)	21 (75.0)	35 (77.8)	0.837
Vascular intervention status	12 (70.6)	20 (71.4)	32 (71.1)	1.000
Angioplasty outcome				0.998
Successful (%)	9 (52.9)	15 (53.6)	24 (53.3)	
Unsuccessful (%)	3 (17.6)	5 (17.9)	8 (17.8)	
No intervention (%)	5 (29.4)	8 (28.6)	13 (28.9)	
Smoking status				0.618
Yes (%)	10 (58.8)	13 (46.4)	23 (51.1)	
No (%)	7 (41.2)	15 (53.6)	22 (48.9)	
Hypertension	8 (47.1)	11 (39.3)	19 (42.2)	0.841
Asthma, COPD	3 (17.6)	2 (7.1)	5 (11.1)	0.550
Amputation type				0.604
None	7 (41.2)	8 (28.6)	15 (33.3)	
Minor	9 (52.9)	19 (67.9)	28 (62.2)	
Below knee	1 (5.9)	1 (3.6)	2 (4.4)	
Wagner grade				0.156
Grade 2	7 (41.2)	5 (17.9)	12 (26.7)	
Grade 3	3 (17.6)	11 (39.2)	14 (31.1)	
Grade 4	7 (41.2)	12 (42.9)	19 (42.2)	
Wound location				0.134
Plantar	6 (35.3)	6 (21.4)	12 (26.7)	
Dorsal	6 (35.3)	5 (17.8)	11 (24.4)	
Irregular	5 (29.4)	17 (60.8)	22 (48.9)	

employed to rapidly eliminate infection and avoid creating a closed space. The primary advantage of these amputations is the preservation of foot surface area and the creation of a

functional stump capable of supporting short-distance ambulation without the need for a prosthesis. However, in cases where both bone and soft tissue are amputated at the same

TABLE 2 | Wound healing times (days).

Healing milestone	Control group (median, IQR)	HBOT group (median, IQR)	Total (median, IQR)	p
25% healing time	11 (7–14)	7 (6–11.5)	8 (7–13)	0.181
50% healing time	30.5 (22.8–43.5)	18 (14.5–34.5)	24 (15.5–39)	0.038.
75% healing time	46 (42.5–79.5)	41 (28–69)	45 (30–76.5)	0.175
Maximum healing time	85 (48–101)	56 (40.5–95.8)	67 (44–98)	0.198
Complete healing time	103.5 (65.5–145.8)	70 (45–123.2)	79.5 (47.8–133.2)	0.371

Note: Bold indicates statistically significant results ($p < 0.05$).

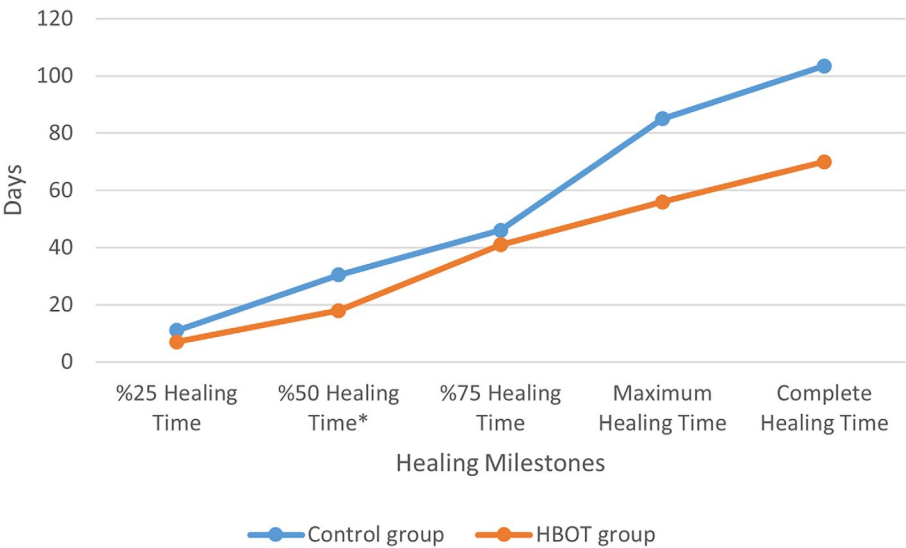


FIGURE 1 | Comparison of wound healing timelines between control and HBOT groups.

TABLE 3 | Correlation between graft retention rate and healing times.

Healing time milestone	Complete healing time (Spearman's ρ)	Graft retention rate (Spearman's ρ)	p
25% healing time	0.213	−0.192	0.242, 0.213
50% healing time	0.603	−0.283	<0.001 , 0.066
75% healing time	0.873	−0.137	<0.001 , 0.399
Maximum healing rate	0.979	0.165	<0.001 , 0.278

Note: Bold indicates statistically significant results ($p < 0.05$).

TABLE 4 | Graft retention rate by angioplasty success.

Angioplasty outcome	Graft retention rate (median, IQR)	HbA1c (median, IQR)	p
Successful (N=24)	100 (90–100)	9.3 (7.5–11.4)	0.037
Unsuccessful (N=8)	80 (80–85)	6.4 (6.2–8.3)	0.041

Note: Bold indicates statistically significant results ($p < 0.05$).

level, or following irregular amputations, grafting becomes necessary once granulation tissue forms in the defect area. In such situations, split-thickness skin grafts provide a valuable treatment option, particularly in diabetic foot patients who experience delayed healing with conventional methods [16]. In our study, split-thickness skin grafts were applied to all patients following both regular and irregular amputations, with a high success rate achieved. Below-knee amputation occurred in 3.6% ($n = 1$) of patients in the HBOT group and 5.9% ($n = 1$) in the control group.

Studies on compromised flaps and grafts treated with HBOT have consistently shown highly positive outcomes [8]. The

therapeutic effects of HBOT are attributed to enhanced oxygenation, improved fibroblast function, neovascularization and the mitigation of ischaemia–reperfusion injury [17].

In animal models, the effects of HBOT on both injured and noninjured wound beds have been experimentally examined. Researchers demonstrated that HBOT at 2 atm absolute pressure (ATA) did not affect the healing rate of uninjured open wounds with intact blood flow [8]. However, in wounds where the edges were deprived of their vascular supply, HBOT significantly increased healing rates compared to control groups [18]. Shulman and Krohn, in their study on full-thickness and partial-thickness wounds, also found that HBOT significantly reduced healing time. Additionally, when combined with repeated skin grafting, HBOT cut the healing time of partial-thickness wounds in half compared to untreated control groups [19]. Notably, wound sterilisation was not performed during these procedures, and while superficial contamination was observed in all animals, no infections occurred in the HBOT-treated groups.

In our study, graft healing time was similarly found to be shorter in patients receiving HBOT, with a statistically significant difference observed at the 50% healing time. This aligns with previous findings, such as those from a rabbit ear study, demonstrating the efficacy of HBOT in enhancing wound healing. Similarly, in animal studies on rabbit ears, HBOT was shown to significantly enhance the survival of composite skin grafts, with a statistically significant difference observed compared to the control group [20, 21].

The evaluation of the benefits of HBOT in problematic flaps and grafts with vascularity issues dates back to a seminal study published in 1966, which was the first to demonstrate the effectiveness of HBOT in ischemic skin flaps [22]. In a subsequent randomised controlled trial by the same research group, 48 patients were divided, with half receiving HBOT at a pressure of 2.0 ATA twice daily for 3 days [23]. In the HBOT group, 64% of grafts fully healed, compared to just 17% in the control group [22]. These results indicated that HBOT significantly improved healing in compromised grafts. This remains the only randomised controlled trial with Level I evidence evaluating the effect of HBOT on grafts.

In our study, the median graft retention rate was 100% in both the HBOT and control groups. Due to the nonnormal distribution of the data, mean values were not provided. However, despite the HBOT group presenting with worse baseline conditions regarding vascular bed quality, patient performance and glycaemic regulation, these factors improved more rapidly in this group. Furthermore, when patients with good vascular status who did not require vascular interventions were excluded, the graft retention rate was found to be statistically significantly higher in those who underwent successful interventional procedures.

In a retrospective study with Level II level of evidence published by Roje et al. in 2008, the effects of HBOT in the treatment of combat injuries were analysed. 388 patients were evaluated; 99 patients in the HBOT group and 289 patients in the control group. Skin graft loss was 23% in the HBOT group and 52% in the control group ($p < 0.001$). Similarly, flap necrosis was 15%

in the HBOT group and 51% in the control group [24]. In our study, graft success was quite high in both the study and control groups. Graft retention below 50%, which can be considered as unsuccessful, was seen in only four (8.9%) patients in total, while there were five (11.1%) patients with graft survival between 51% and 75%. Of these five patients, three were in the control group and two were in the HBOT group. There was no statistically significant difference between the groups. There were a total of 36 patients (80%) with graft survival of 76% and above, and successful results were obtained in the majority of patients.

There are numerous favourable case reports demonstrating the success of HBOT in posttraumatic nasal reconstruction involving mixed grafts of skin, subcutaneous tissue and cartilage [25, 26]. Zhou and colleagues conducted the largest review on this topic, analysing 20 years of data from China [27]. In a total of 23 clinical trials, 957 patients treated with HBOT were compared to 583 control patients. The reported survival rates ranged from 62.5% to 100% in the HBOT group, compared to 35.0%–86.5% in the control group [27]. These studies, which involved various graft and flap types, utilised different treatment durations and protocols. However, they consistently demonstrated that HBOT significantly enhances graft and flap survival. The success of HBOT is attributed to its ability to prevent graft and flap necrosis by reducing hypoxia, supporting fibroblast and collagen synthesis, promoting neovascularization and improving microcirculation [28–31].

The timing of HBOT administration is critically important in maximising the survival chances of a flap or graft. The literature suggests that initiating HBOT early in hypoxic or poorly perfused tissues reduces the need for re-grafting or additional surgical interventions, thereby lowering patient morbidity [8]. In our study, the majority of patients received HBOT prior to the grafting procedure. Many had underlying conditions such as OM, deep tissue infections or poor vascular status, which necessitated preoperative HBOT. As a result, the area designated for graft placement became more oxygenated and vascularised by the time of surgery. This approach underscores the benefit of starting HBOT as early as possible in patients at risk of graft rejection, enhancing the chances of graft success.

The standard treatment approach for compromised grafts or flaps typically involves local wound care, surgical debridement and repeated reconstruction. These modalities are associated with hospital stays, additional costs, loss of workforce, the need for reoperation, increased morbidity and psychosocial impacts. Failed grafts and flaps present significant challenges for both the patient and the surgeon. HBOT can aid in salvaging skin grafts, composite grafts and flaps, potentially reducing or eliminating the need for further surgical interventions and the search for new donor sites. This, in turn, can alleviate financial, physical and psychological burdens. Despite its potential to address these issues, HBOT is often overlooked as a valuable tool. Animal studies have demonstrated the benefits of HBOT in treating damaged tissues, and clinical studies support these findings, though they are mostly limited to case reports and series [17].

Graft loss remains a significant clinical challenge in the management of diabetic foot wounds. The use of negative pressure

wound therapy (NPWT) over skin grafts has been reported to enhance graft survival [32]. In our clinical practice, we excluded this technique from the study to ensure standardisation, although we routinely apply it over grafts. For patients who are not eligible for HBOT, topical oxygen therapy may serve as an effective alternative to improve skin graft survival [33].

Although the 2023 update of the IWDGF (International Working Group on the Diabetic Foot) guidelines now includes more moderate recommendations for the use of HBOT in diabetic foot cases, HBOT remains effective in improving graft retention and reducing wound healing time in graft reconstructions [34]. This conservative view likely reflects the IWDGF's overall cautious approach to diabetic foot surgery. While the group has softened its stance on NPWT, it has yet to update its position on epidermal growth factor applications.

5 | Limitations

The limitations of this study include its retrospective nature. Our control group consisted of individuals with fewer comorbidities and better vascular health, who did not require HBOT. Patients with a well-prepared wound bed and good graft condition were not included in the HBO group due to the lack of indication. Since HBOT was recommended for all clinically worse-off patients, creating a similar control group and randomisation was not ethically appropriate. The control group included patients who were eligible for HBOT but declined treatment due to reasons such as claustrophobia. Therefore, randomisation could not be achieved, but the study results still provided statistical significance.

6 | Conclusions

This study demonstrates that HBOT significantly improves graft survival and accelerates healing in diabetic foot patients undergoing tissue reconstruction. Despite higher HbA1c levels and worse baseline clinical status, patients in the HBOT group achieved faster healing, underscoring HBOT's efficacy in compromised vascular beds. HBOT emerges as a valuable adjunctive treatment, reducing the need for additional surgical interventions and lowering the risk of complications associated with graft failure. Given its safety and effectiveness, HBOT should be considered for diabetic foot patients with impaired wound healing, especially those with ischaemic or hypoxic tissue. Further randomised controlled studies are needed to consolidate these findings.

Ethics Statement

In this retrospective cohort study, all diabetic foot patients who underwent graft (Split-thickness Skin Grafts) reconstruction at the General Surgery Clinic were included, with Ethics Committee approval (Project/Decision No: 2022/256).

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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