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Impact of Endovascular Pedal Arch Angioplasty on Wound Healing in Patients with Lower Limb Ischemia

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Abstract

Background: Peripheral artery disease (PAD) is the second most prevalent manifestation of atherosclerosis, impacting more than two hundred million individuals. The aim of this work was to evaluate the outcome of pedal arch angioplasty in patients with critical lower limb ischemia (LLI) on healing of tissue loss (ulcers - raw areas post-surgical debridement), time to healing, follow-up clinical improvement (rest pain) and duplex assessment of arterial system and ankle brachial index (ABI) post intervention. **Methods:** This prospective randomized cohort study was carried out on 40 patients aged from 30 to 80 years old, both sexes, with chronic limb threatening ischemia of Lower Limb. All patients were subjected duplex scanning and computed tomography angiography of LLs. **Results:** Wound condition after 1 month of follow up, three months & six months of monitoring among studied cases were statistically significant

(p value less than 0.05) as percentage of cases with complete wound healing increased from 5% after 1 month to 30% following three months & then to 65% following six months of monitoring. Regarding Technical success among studied cases, the cases that had complete pedal arch revascularization with percentage of 35%, then 45% had incomplete pedal arch, while only 20% had failed pedal arch angioplasty. **Conclusions:** Our results showed that pedal arch angioplasty showed statistical improvement in total wound healing over follow-up periods shortening the duration of healing in Ischemic patients, improving limb salvage and quality of life.

1. Introduction:

Critical limb ischemia (CLI) is an adverse clinical outcome of peripheral artery disease (PAD) that leads to mortality, amputation and diminished quality of life (QOL) [1].

PAD impacts over 202 million individuals worldwide and has a significant illness cost on society [2]. About one-third of people with peripheral artery disorder presents with isolated infra-popliteal illness. In the remaining two-thirds, they are presented with femoro-popliteal and infra-popliteal disorders together [3].

Numerous clinical research has indicated that pedal artery illness leads to impaired wound healing as well as suggested supplementary methods for pedal arch revascularization to enhance the wound healing rate [4].

The pedal arch is the connection between the posterior and anterior circulations of the foot and serves as the primary source of blood to the forefoot [5].

Since the onset of this century, there has been a growing focus on pedal arch patency in both diabetic and non-diabetic individuals with CLI [6].

CLTI is not usually a candidate for surgery like bypass because of advanced age, associated comorbidities, for example, smoking, hypertension, or diabetes and the nature of atherosclerotic pathology characterized by diffuse vessel involvement and high rates of restenosis and multilevel occlusion [7].

Conversely, endovascular intervention, utilizing new specialized instruments, innovative methodologies and improving clinical expertise, is essential for ensuring sufficient blood flow to the wound, particularly when the limb is at risk [4].

Progress in endovascular methodologies and apparatus facilitates the intervention of distal pedal outflow arteries commonly compromised in cases with diabetes with CLI, hence permitting the restoration of in-line flow to the pedal wound bed [8] .

The objective of revascularization for cases with CLI and tissue loss isn't the long-term patency of target arteries, but rather the provision of sufficient blood flow to wounds to facilitate complete recovery [9].

Within one year of a PAD diagnosis, twenty-five percent of cases get high level of amputation, while another twenty-five percent die due to co-morbid diseases [10].

The aim of this work was to evaluate the outcome of pedal arch angioplasty in patients with critical lower limb ischemia (LLI) on healing of tissue loss (ulcers - raw areas post-surgical debridement), time to healing, follow-up clinical improvement (rest pain) and duplex assessment of arterial system and Ankle - Brachial Index post intervention.

2. Patients and Methods:

This prospective randomized cohort study was carried out on 40 patients aged from 30 to 80 years old, both sexes, with CLTI ischemia with tissue loss, rest pain, gangrene and infra popliteal lesion with or without associated lesion. The study was

done from March 2023 to December 2023 after approval from the Ethical Committee Beni-Suef University hospital, Beni-Suef, Egypt (FM-BSU REC) with approval No. **FMBSUREC/05032023**. An informed written consent was obtained from the patients.

Inclusion criteria include: Patients Age 30-80 years, Sex: both males and females, presenting with CLTI with tissue loss, rest pain and gangrene. Patient has an infra popliteal lesion with or without associated lesion

Exclusion criteria include: patient with iliac or superficial femoral artery (SFA) lesion without infra popliteal disease, renal impairment, heart failure presenting with orthopnea, patient can't lay on table for a long time, stiffness of knee joint causing limitation of its movement and hypersensitivity to the dye.

All patients were subjected to complete history taking, physical examinations, laboratory investigations [complete blood count (CBC), erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), serum creatinine, prothrombin time (PT), partial thromboplastin time (PTT) and international normalized ratio (INR)] and radiological investigations [duplex scanning and computed tomography angiography (CTA) of LLs].

Possible complications written in the consent were:

puncture site related complications: bleeding, hematoma, pseudo aneurysm, or areterio-venous fistula, contrast related complications: allergy to the contrast, acute tubular necrosis, and contrast nephropathy, procedure related complications: failure of procedure, arterial dissection, thrombosis, acute ischemia, perforation, recurrence and minor or major amputation.

Surgical technique

The procedure has been conducted in the operating room using a mobile C-arm with vascular imaging capabilities and a comprehensive aseptic technique. Supine position and local anesthesia. A single-piece eighteen-gauge needle has been

utilized to penetrate the common femoral artery on the ipsilateral or contralateral side. Eleven centimeters long, 6-F Terumo introducer sheath has been inserted following the selective cabling of the SFA. When the procedure lasted for more than one hour, half of the prescribed dose of heparin fifty international unit per kilogram was administered intravenously. Baseline angiography has been conducted to acquire images of the femoro-popliteal tract, as well as the vessels below the knee and the foot. A 0.018-inch hydrophilic guidewire has been advanced into the occluded pedal arch with the support of a microcatheter. The typical balloon size for foot vessels and plantar arch is two ± 0.5 millimeters It is crucial to utilize a dedicated balloon catheter to guide the wire through tortuous vessels. The duration of inflation should be between sixty and 180 seconds. The treatment of any related femoral, popliteal and tibial vascular lesions was carried out as well. Following inflation, the balloon has been retrieved while maintaining the guidewire to do digital subtraction angiography and evaluate the outcomes of post-percutaneous transluminal angioplasty (PTA). Upon confirmation of angiographic success, the guidewire has been removed, a final control angiography has been conducted. Homeostasis has been achieved by manually compressing the puncture site that was accessible following the procedure (ten to twenty minutes) and a compressive bandage has been utilized in all cases.

Figure 1

Figure 1: (A) Antegrade cannulation and protracted balloon angioplasty of the Anterior tibial artery then dorsalis pedis have been performed, with a trial to navigate a 0.014-inch wire through the pedal arch, balloon angioplasty is performed.

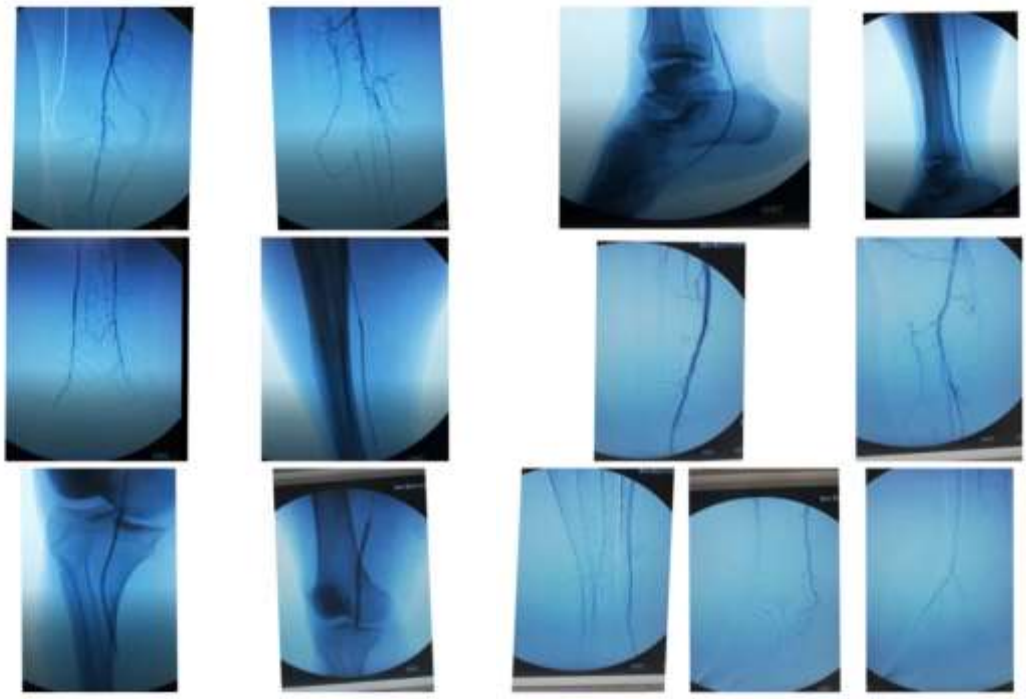

Figure (2)**:** Intraoperative angiography showing diseased ATA and PTA artery. Balloon angioplasty was done continuous with foot arch Angioplasty.

Through the first 24 hours post procedural, patients were seen in the ward twice and check the following: inspection and palpation of the compression bandage over puncture site to exclude the presence of puncture site complication (hematoma or pseudoaneurysm). Palpation of the

pedal pulse, check the handheld Doppler signals, measurement of post-procedural ABI. Confirmation of the patient decubitus (lying flat on bed with no straining or movement). All patients were given IV 500 ml normal saline slowly postoperative (except those with cardiac disease or renal failure, to avoid volume overload). All patients were given Acetylcysteine 600 every 8 hours for 3 days to guard against contrast induced nephropathy (CIN). All patients started oral clopidogrel (75 mg tabs, once per day and immediately after procedure). First and third day postoperative kidney function tests were taken from all patients to exclude the presence of CIN. After revascularization, we assessed the foot wounds for all patients, and we categorized them into infected wet gangrenous toes for urgent minor amputation, or infected foot ulcer for urgent surgical debridement to remove infected necrotic ischemic tissues, or dry gangrenous toes for elective minor toe amputation.

A male patient, 47 years old presented to us with infected big toe and no distal pulsation is detected, investigations done showing infrapopliteal disease, Angioplasty of infrapopliteal lesion and dilatation of pedal arch. Then amputation of big toe due to osteomyelitis was carried out and **Fig. (3)** Shows the follow up.

Figure (3): The stump of Big toe amputation, post angioplasty the result of follow up post 1 month , 3 months duration.

A female patient, 58 years old presented to us with infected 3rd toe and no distal pulsation is detected, investigations were done showing infrapopliteal disease, Angioplasty of infrapopliteal lesion and dilatation of pedal arch. Then amputation of 3rd toe due to osteomyelitis was carried out and **Fig. (4)** Shows the follow up.

Figure (4): The stump of 3rd toe amputation, post angioplasty the result of follow up post 1 month , 3 months duration.

Outcome Measurements and Follow-up

Patient was followed up every 2 weeks till improvement of the condition through: Wound condition: assessment of wound during the follow up visits, examination of wound, checking for any pus discharge, abscess pocket, necrotic tissues or awful offensive odor .Time to heal: surveillance continued until the wound totally healed, as healing of wound has been defined as complete epithelialization of the tissue defect by secondary intention or after any additional local wound operation. Pulses: palpation of peripheral pulses and assessment of pedal pulsation. Laboratory: Serum creatinine. Duplex assessment: assessment of arterial patency during the follow up visits (ABI measurement and checking handheld doppler signals).

Sample Size Calculation:

Using Open Epi Version 3, open-source calculator—SSPropor, print from the browser with ctrl-P, the sample size is calculated as at least 40 patients. The sample size calculated by the following criteria: allocation ratio for a power 80% and confidence level 95% and effect size, Population size (for finite population correction factor or fpc) was 50 and hypothesized % frequency of outcome factor in the population was 86%. Sample size equation was n = [DEFF*Np(1-p)]/ [(d2/Z21-α/2*(N-1) +p*(1-p)].

Statistical analysis

Statistical analysis was done by SPSS v26 (IBM Inc., Chicago, IL, USA). Quantitative variables were presented as mean and standard deviation (SD) and compared between the three groups utilizing ANOVA (F) test with post hoc test (Tukey). Qualitative variables were presented as frequency and percentage (%) and were analyzed utilizing the Chi-square test. Roc curve was used for evaluation of diagnostic performance sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). A two tailed P value < 0.05 was considered statistically significant.

3. Results:

Demographic data, comorbidities, clinical presentation, duplex investigation, technical success, complication and amputation as an intervention post angioplasty were enumerated in this table. **Table 1**

Table 1: Demographic data, comorbidities, clinical presentation, duplex investigation, technical success, complication and amputation as an intervention post angioplasty of the studied patients

		N=40
Age (years)		65.5±8.3
Sex	**Male**	24(60.0%)
	Female	16(40.0%)
Comorbidities	**DM**	40(100.0%)
	HTN	22(55.0%)
	Smoking	14(35.0%)
	Coronary artery disease	20(50.0%)
	Obesity	8(20.0%)
Clinical presentation	**Infection**	30(75.0%)
	Presence of gangrene	22(55.0%)
	Presence of ulcer	6(15.0%)
Duplex investigation		
Infra popliteal disease	**ATA and PTA monophasic**	40(100.0%)
Associated lesion	**SFA lesion**	14(35.0%)
	Common femoral artery lesion	2(5.0%)
	External iliac artery lesion	2(5.0%)
ABI		0.42±0.07
Technical success	**Complete pedal arch revascularization**	14(35.0%)
	Incomplete pedal arch revascularization	18(45.0%)
	Failed pedal arch angioplasty	8(20.0%)
Complication	**Perforation**	0(0.0%)
	Dissection	0(0.0%)
	Groin hematoma	4(10.0%)
	Ecchymosis	12(30.0%)
Amputation as an intervention post angioplasty		
Major	**BKA**	4(10.0%)
Minor	**Big toe**	10(25.0%)
	Little toe	0(0.0%)
	Second toe	2(5.0%)
	Third toe	4(10.0%)
	Fourth toe	6(15.0%)
	Debridement	18(45.0%)

Data are presented as mean ± SD or frequency (%). DM: diabetes millets, HTN: hypertension, ATA: anterior tibial artery, PTA: below-the-ankle, ABI: ankle brachial index, BKA: below-knee amputation, IPA: incomplete pedal arch, CPA: complete pedal arch, SFA: superficial femoral artery.

Follow up after one, three and six months were enumerated in this table. **Table 2**

Table 2: Follow up after one, three and six months between the studied patients

		After1month	After 3 months	After 6 months
Wound condition	**Complete healing**	2(5.0%)	12(30.0%)	26(65.0%)
	Incomplete healing	22(55.0%)	18(45.0%)	10(25.0%)
	Not healed	16(40.0%)	6(15.0%)	0(0.0%)
Pulses				
	Dorsalis pedis	26(65.0%)	22(55.0%)	22(55.0%)
	Posterior tibial	8(20.0%)	6(15.0%)	6(15.0%)
	Absent pedal pulsation	6(15.0%)	8(20.0%)	8(20.0%)
Duplex assessment	**Monophasic and restenosis**	8(20.0%)	8(20.0%)	8(20.0%)
	Biphasic	--	2(5.0%)	2(5.0%)
	Triphasic	32(80.0%)	26(65.0%)	26(65.0%)
ABI		0.97±0.14	0.85±0.27	0.85±0.27

Data are presented as mean ± SD or frequency (%). ABI: ankle brachial index.

Wound condition, pulses and duplex assessment at follow up after one, three and six months were significantly different between studied groups (P<0.05). ABI after one, three and six months of follow up was significantly higher in CPA group than IPA and APA (P<0.05). **Table 3**

Table 3: Comparison of follow up results after one, three and six months according to technical success

		Technical success			P
		CPA (n=14)	IPA (n=18)	APA (n=8)	
After one month					
Wound condition	**Complete healing**	2(14.3%)	0(0.0%)	0(0.0%)	**<0.001***
	Incomplete healing	10(71.5%)	10(55.5%)	2(25.0%)	
	Not healed	2(14.3%)	8(44.5%)	6(75.0%)	
Pulses					**<0.001***
	Dorsalis pedis	14(100.0%)	10(55.5%)	0(0.0%)	
	Posterior tibial	0(0.0%)	8(44.5%)	2(25.0%)	
	Absent pedal pulsation	0(0.0%)	0(0.0%)	6(75.0%)	
Duplex assessment	**Monophasic and restenosis**	0(0.0%)	2(11.1%)	6(75.0%)	**<0.001***
	Triphasic	14(100.0%)	16(88.9%)	2(25.0%)	
ABI		1.03±0.7[(b)]	1.02±0.13[(c)]	0.71±0.02	**<0.001***
After three months					
Wound condition	**Complete healing**	8(57.2%)	4(22.2%)	0(0.0%)	**0.02***
	Incomplete healing	6(42.8%)	8(44.4%)	4(50.0%)	
	Not healed	0(0.0%)	4(22.2%)	2(25.0%)	
Pulses					
	Dorsalis pedis	14(100.0%)	8(44.5%)	0(0.0%)	
	Posterior tibial	0(0.0%)	6(33.3%)	0(0.0%)	
	Absent pedal pulsation	0(0.0%)	2(11.1%)	6(75.0%)	
Duplex assessment	**Monophasic**	(0.0%)	2(11.1%)	6(100.0%)	**<0.001***
	Biphasic	0(0.0%)	4(22.2%)	0(0.0%)	
	Triphasic	14(100.0%)	12(66.6%)	0(0.0%)	

ABI		0.98±0.06[(a), (b)]	0.78±0.37	0.66±0.05	**0.01***
After six months					
Wound condition	**Complete healing**	12(85.7%)	12(66.6%)	2(25.0%)	
	Incomplete healing	2(14.3%)	4(22.2%)	4(50.0%)	**0.05***
Pulses					
	Dorsalis pedis	14(100.0%)	8(44.4%)	0(0.0%)	
	Posterior tibial	0(0.0%)	6(33.3%)	0(0.0%)	
	Absent pedal pulsation	0(0.0%)	2(11.1%)	6(75.0%)	
Duplex assessment	**Monophasic**	0(0.0%)	2(12.5%)	6(75.0%)	
	Biphasic	0(0.0%)	10(62.5%)	0(0.0%)	**<0.001***
	Triphasic	14(88.9%)	12(12.5%)	0(0.0%)	
ABI		0.98±0.06[(a), (b)]	0.78±0.37	0.66±0.05	**0.01***

Data are presented as mean ± SD or frequency (%). * Significant P value <0.05. CPA: complete pedal arch, IPA: incomplete pedal arch, APA: absent pedal arch, ABI: ankle brachial index.

Wound condition and duplex assessment were significantly different between after one, three and six months (P<0.001). **Table 4**

Table 4: Comparison of wound condition and duplex assessment after one month of follow up, following three and six months of monitoring

		After 1 month	**After 3 months**	**After 6 months**	**P**
Wound condition	**Complete healing**	2(5.0%)	12(30.0%)	26(65.0%)	
	Incomplete healing	22(55.0%)	18(45.0%)	10(25.0%)	**<0.001***
	Not healed	16(40.0%)	6(15.0%)	0(0.0%)	
Duplex Assessment	**Triphasic**	32(80.0%)	26(65.0%)	26(65.0%)	
	Biphasic	22 (55.0%)	2(5.0%)	2(5.0%)	**<0.001***
	Mono phasic	8(20.0%)	8(20.0%)	8(20.0%)	

Data is presented as frequency (%). * Significant P value <0.05.

4. Discussion:

PAD is the 2nd most prevalent manifestation of atherosclerosis in the US and globally, impacting more than two hundred million individuals [11].

Regarding Duplex investigation among studied cases, all cases had ATA, PTA monophasic, more than one half (55%) had no associated lesions and the remaining 45% had associated lesion either in Superficial femoral artery (35%), Common femoral artery (5%) or External iliac artery (5%). In agreement with our result about, Troisi et al. [12] reported that lesion was in SFA (32.6%), deep femoral artery (0.7%) and external iliac artery (2%). As well with Kobayashi et al. [4] reported that the lesion in femoropopliteal was (8%), infrapopliteal was (56%), and aortoiliac + femoropopliteal was (1%).

Regarding Technical success among studied cases, the percentage of patients with complete pedal arches 35%, then 45% had incomplete pedal arch, while only 20% had failed pedal arch angioplasty. Soliman et al. [13] reported that as 21 cases (24%) in

CPA , 49 cases(56%) in IPA and 18 cases (20%) in APA. Troisi et al. [6] reported that the presence of complete pedal arch was in 42 cases(30.7%) patients, 60(43.8%) patients had incomplete pedal arch, while only 35 cases (25.5%) patients had failed pedal arch angioplasty.

In agreement with our result about follow up results after one , three and six months , Chaudhari et al. [15] indicated that the mean ABI after one month was 0.90±0.11 in the single vessel group and 0.93±0.08 in the multiple vessel group. Kobayashi et al. [14] reported that at 3 month follow up, the wound healing rates were 51% in Toe wounds (T) group, 12% in Heel wounds (H) group, and 0% in Extensive wounds (E) group, however reported that duplex values suggested restenosis. Nakama et al. [18] investigated the clinical effects of pedal artery angioplasty for cases with critical limb ischemia, reporting a wound healing rate of 24.8 percent & an amputation-free survival rate of 89.1 percent after three months.

Regarding Follow up results after 6 months among studied cases, it was found that all cases had some degrees of healing, 20% had delayed wound healing and 70% had totally healed wound, For pulse, the majority had Dorsalis pedis (55%) and only 15% had Posterior tibial pulse and 20% had absent pedal pulse.

Meyer et al. [16] reported that a wound-healing rate of 22% after 6 months (6 of 25 remaining patients). As well with Chaudhari et al. [15] reported that after 6 months the wound healing rate 70.12% in single vessel group vs. 62.79% in multiple vessel (MV) group, also the mean Ankle brachial index was 0.92±0.06 in single vessel (SV) group & was 0.90±0.10 in multiple vessel (MV) group. Moreover, Kobayashi et al. [17] reported that at 6 months, wound healing rates were 64% in Toe wounds (T) group, 36% in Heel wounds (H) group, and 5% in Extensive wounds (E). Furthermore Nakama et al. [18] reported that at 6 months the wound healing rate was (37.5%) and amputation free survival rate was (82.9%).

Regarding comparison of baseline data, clinical presentation and duplex results according to technical success, it was found that, there was non-significant difference regarding age, comorbidities, presence of infection, associated lesion and Ankle brachial. Higashimori et al. [17] concluded that there was insignificant distinction in comorbidities, age, presence of infection, or sex among cases with and without a pedal arch.

Regarding comparison of complication and intervention post angioplasty according to technical success, it was found that, there is non-significant difference regarding complication either perforation, dissection,

Groin hematoma and Ecchymosis. As well as Nakama et al.[18] reported that there was no significant difference regarding the incidence of complications between the studied groups.

Regarding comparison of 1 month follow up results according to technical success, it was found that, there was significant difference regarding wound condition, pulse, duplex assessment, serum creatinine and ABI as mean ABI was significantly higher among cases with CPA and IPA than among cases with failed pedal arch angioplasty. Our results could be supported with Soliman et al. [13] reported that there was significant regarding wound condition, and patency among the studied groups.

Regarding comparison of 3 month follow up results according to technical success, it was found that, there is significant difference regarding wound condition, pulse, duplex assessment and ABI as mean ABI was significantly higher among cases with CPA than among cases with IPA and APA. Our findings corroborate those of Troisi et al. [6] indicated that healing occurred within three months post-procedure in twenty-one (fifty percent) cases with CPA, 17 (28.3 percent) cases with IPA, and seven (twenty percent) cases with APA, with a significant distinction.

Regarding comparison of 6 month follow up results according to technical success, it was found that, there is significant difference regarding wound condition, pulse, duplex assessment and ABI as higher percentage of cases with CPA had wound totally healed (88.9%) than among cases with IPA and failed pedal angioplasty (50% and 66.7% respectively), also, the mean ABI was significantly higher among cases with CPA (0.98) than among cases with IPA and absent pedal arch (0.78 and 0.66 respectively). Our findings corroborate those of Troisi et al. [6] indicated that over a follow-up period of 7.4 ± 4.6 months, complete healing of lesions was attained in thirty-five (83.3 percent) cases with CPA, thirty-four (56.7%) cases with IPA and thirteen (37.1 percent) cases with APA, with a statistically significant distinction.

Regarding comparison of wound condition after 1 month of follow up, after 3 months and after 6 months of follow up among studied cases, the results were significant as percentage of cases with totally healed wound increased from 5% after 1 month to 30% after 3 months and then to 65% after 6 months of follow up.

Limitations of the study included that the sample size was relatively small. The follow up of patients was limited for relatively short period.

5. Conclusion:

Pedal arch angioplasty significantly enhanced overall wound healing throughout follow-up periods, reducing

healing length in ischemic cases, and enhancing limb salvage and quality of life.

Recommendations:

Further studies with larger sample size are needed to confirm the current results. To accurately assess long-term outcomes, studies should have a longer follow-up period. We recommended that future research should include multicenter studies to validate our findings.

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