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Original Article

Factors Influencing the Recovery of Wounds in Individuals with Peripheral Artery Disease Undergoing Below-the-knee Interventions

Gülden Güven,[1] Ertan Ural,[2] Burak Acar[2]

[1]Department of Cardiology, Başakşehir Çam ve Sakura City Hospital, İstanbul, Türkiye
[2]Department of Cardiology, Kocaeli University, Kocaeli, Türkiye

Abstract

Objectives: This study aimed to explore the elements that impact the healing of wounds in patients suffering from lower limb peripheral arterial disease due to various risk factors who underwent endovascular interventions.

Methods: Conducted at the Cardiology Department of Kocaeli University from January 2015 to August 2019, the study involved 200 patients referred for endovascular revascularization due to stenosis or blockage in the infrapopliteal arteries. A retrospective analysis of medical records was performed. Patients with Burger's disease were excluded from the study, resulting in 192 participants. Angiography and angioplasty results were reviewed, focusing on vessel conditions and outcomes of the procedures. Wound healing was assessed through follow-up records, and additional information was gathered through phone interviews with patients lacking complete data. Healing assessments occurred at least 3 months post-procedure, categorizing patients based on their healing outcomes.

Results: A comparative analysis of patient demographics and procedural details indicated that factors such as male gender, chronic kidney disease (CKD), smoking history, and lack of flow in the tibialis anterior post-procedure were significantly associated with non-healing outcomes. Multivariate analysis identified CKD, Rutherford class 6 classification, and absence of tibialis anterior flow as negative predictors for healing.

Conclusion: The study highlights that CKD, classification as Rutherford 6 before intervention, and impaired tibialis anterior flow post-procedure are significant negative indicators for wound healing in patients undergoing peripheral interventions.

Keywords: Percutaneous transluminal angioplasty; periperipheral artery disease; wound healing.

Diz Altı Perkutan Girişim Yapılan Periferik Arter Hastalarında Yara İyileşmesini Etkileyen Faktörler

Özet

Amaç: Bu çalışmada çeşitli risk faktörlerine bağlı olarak alt ekstremite periferik arter hastalığı (PAH) gelişen ve endovasküler girişim uygulanan hastalarda yara iyileşmesine etki eden unsurların araştırılması amaçlandı.

Gereç ve Yöntem: Kocaeli Üniversitesi Kardiyoloji Anabilim Dalı'nda Ocak 2015-Ağustos 2019 tarihleri arasında gerçekleştirilen çalışmaya, infrapopliteal arterlerdeki darlık veya tıkanıklık nedeniyle endovasküler revaskülarizasyon için başvuran 200 hasta dahil edildi. Tıbbi kayıtların geriye dönük analizi yapıldı. Burger hastalığı olan hastalar hariç tutularak 192 katılımcı elde edildi. Anjiyografi ve anjiyoplasti sonuçları damar koşullarına ve prosedürlerin sonuçlarına odaklanılarak gözden geçirildi. Yara iyileşmesi takip kayıtları aracılığıyla değerlendirildi ve tam verileri olmayan hastalarla yapılan telefon görüşmeleri yoluyla ek bilgiler toplandı. İyileşme değerlendirmeleri işlemden en az üç ay sonra yapıldı ve hastalar iyileşme sonuçlarına göre sınıflandırıldı.

Bulgular: Hasta demografisi ve prosedür ayrıntılarının karşılaştırmalı bir analizi, erkek cinsiyeti, kronik böbrek hastalığı, sigara içme öyküsü ve işlem sonrası tibialis anteriorunda akış eksikliği gibi faktörlerin iyileşmeyen sonuçlarla önemli ölçüde ilişkili olduğunu gösterdi. Çok değişkenli analiz, kronik böbrek hastalığını, Rutherford sınıf 6 sınıflandırmasını ve tibialis anterior akışının yokluğunu iyileşmenin negatif belirleyicileri olarak tanımladı.

Sonuç: Çalışma, periferik girişim uygulanan hastalarda kronik böbrek hastalığının, müdahale öncesi Rutherford 6 olarak sınıflandırılmasının ve işlem sonrası bozulmuş tibialis anterior akımının yara iyileşmesi açısından önemli olumsuz göstergeler olduğunu vurgulamaktadır.

Anahtar sözcükler: Perkütan translüminal anjiyoplasti; periferik arter hastalığı; yara iyileşmesi.

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Address for Correspondence: Gülden Güven

Department of Cardiology, Başakşehir Çam ve Sakura City Hospital, İstanbul, Türkiye

E-mail: gldngvn89@gmail.com

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Introduction

Atherosclerotic diseases are the leading cause of death and disability worldwide, creating a significant economic burden for countries.[1] Coronary artery disease (CAD) is the most common cause of death, but peripheral artery disease (PAD), kidney failure, and cerebrovascular accidents also contribute notably to morbidity and mortality.[2] PAD is among the most widespread conditions, with over 200 million cases globally.[3] Pad refers to a condition affecting blood vessels outside the heart, brain, and other isolated organs. It is characterized by the narrowing of arteries, which reduces blood flow to both the upper and lower limbs. In the lower limbs, PAD becomes an occlusive disease due to thrombosis and thromboembolic events in arteries beyond the aortic bifurcation.[4] PAD is a progressive disorder that can severely affect quality of life, increase the need for prolonged hospital stays, result in amputations, raise mortality rates, and elevate healthcare costs.[5] It is also linked to a higher incidence of cardiovascular events and deaths compared to the general population.[6] PAD is more common in older individuals and those with a greater risk for heart disease. The presence of additional risk factors, such as diabetes, hypertension (HT), high cholesterol, chronic kidney disease (CKD), and smoking, is a significant predictor of development.[5,7–9]

The key event in atherosclerosis involves thickening of the arterial wall and lipid accumulation, which leads to the formation of an atheroma. This process can result in the narrowing or blockage of the blood vessels, disrupting blood flow to vital organs. Ischemia, caused by stenosis and occlusion in arteries supplying the lower extremities, can result in intermittent claudication (pain in the legs that forces the person to stop walking), rest pain, muscle cramps, coldness, pale skin, weakened or absent pulses, numbness, weakness, a burning sensation, nail changes, ulcers, and eventually gangrene in advanced stages.[7–11] Two primary systems are used to classify the severity of PAD and guide treatment decisions. The Fontaine and Rutherford classifications (Table 1) assess how well patients can function, while the Trans-Atlantic Inter-Society Consensus (TASC) classification is used to determine the location and complexity of lesions.[2,7,12] In the 2000 and 2007 TASC I and II guidelines, lesions in the aortoiliac and femoropopliteal regions were categorized from simple to complex (TASC A, B, C, D), with endovascular treatment recommended for types A and B, and open surgery for types C and D. After 2007, advancements in imaging and angioplasty technology, along with increased clinical experience, have enabled many medical centers to treat complex lesions with endovascular procedures instead of traditional surgery. Risk factors for PAD are similar to those for CAD and atherosclerotic diseases, including smoking, dyslipidemia, diabetes, CKD, and HT. However, there is limited evidence to suggest that these risk factors have a distinct impact on specific peripheral arterial regions. Further research is needed to determine the specific factors influencing the development of disease in various areas.[13] Thus, our study aims to identify factors that affect wound healing in patients with lower-extremity peripheral arterial disease who also have risk factors and underwent endovascular treatment.

Materials and Methods

Patient Group Characteristics

Approval for this study was obtained from the Clinical Research Ethics Committee of Kocaeli University Faculty of Medicine on May 10, 2019, with project number 2019/126. The study was conducted on 200 patients who presented to the Cardiology Department of Kocaeli University between January 2015 and August 2019 with intermittent claudication (leg pain during physical activity) and critical limb ischemia (leg discomfort at rest or tissue loss) due to peripheral artery disease. These patients underwent endovascular revascularization using standard or drug-coated balloon angioplasty for narrowing or blockage in their below-knee arteries. Patient records were analyzed retrospectively. Individuals with Buerger's disease were excluded from the study. After excluding eight patients based on exclusion criteria, 192 patients were included in the study.

We retrospectively reviewed the records of patients admitted to our hospital between January 2015 and August 2019 with lower extremity peripheral artery disease who underwent balloon angioplasty. Patients who underwent peripheral endovascular intervention in our center are routinely followed up in outpatient clinics at the 1st, 3rd, 6th, and 12th months. Follow-up records were accessed from the nucleus system archive, and wound healing progress was evaluated. Patients with incomplete information were contacted by phone to assess post-procedure wound healing. Wound healing status was checked at least 3 months after the procedures. Patients were divided into two groups based on their wound healing status after the procedure. Those who underwent early amputation post-procedure were classified as the non-healing group. Demographic data, lesion characteristics, procedural details, and follow-up outcomes were obtained from the hospital registry system. Angiography and balloon angioplasty images of the patients were recorded from the Picture Archiving and Communication System archive system. This included re-evaluating the narrowing and/or blockage in the vessels, identifying which vessels were affected, the number of vessels involved, which vessels were treated, and the success of the balloon angioplasty procedure. TASC classification was performed using all these data. Clinical evaluation during hospitalization was conducted by examining data identified and recorded according to the Rutherford classification.

Table 1. Rutherford and Fontaine classifications

Rutherford stage	Fontaine stage	Description/definition
0	I	Asymptomatic
1	IIa	Mild claudication
2	IIb	Moderate claudication
3	IIb	Severe claudication
4	III	Rest pain
5	IV	Ischemic ulcers of the digits of the foot (minor tissue loss)
6	IV	Severe ischemic ulcers or gangrene (major tissue loss)

Procedure Characteristics

In 182 patients, the same-side common femoral artery was used as the access site, while in 10 patients, the opposite-side common femoral artery was utilized. Before the procedure, each patient underwent a detailed medical history and complete physical examination, baseline laboratory tests were conducted, and an electrocardiogram was performed. Body mass index could not be calculated due to incomplete data in the archive system. Patients were administered 300 mg of clopidogrel and 300 mg of acetylsalicylic acid the day before the procedure. Maintenance therapy continued with 75 mg of clopidogrel and 100 mg of acetylsalicylic acid tablets in the following days. Individuals with CKD received isotonic fluid at a dose of 1 cc/kg of body weight 24 h before the procedure, and treatment continued for at least 24 h afterward. In diagnostic images obtained by catheterizing the femoral vascular sheath or popliteal artery and injecting iodinated contrast material with the help of a pump, stenoses of 50% or more were considered significant. Percutaneous transluminal angioplasty (PTA), with or without atherectomy, was performed in cases with significant stenosis and in occluded below-knee main arterial structures whose distal section could be visualized, depending on the lesion structure. After the procedure, control angiographies were performed to evaluate lumen patency. Technical success was defined as a maximum of 30% residual stenosis after the procedure with increased blood flow. During the treatment, the catheter access site was frequently checked for hemorrhagic complications. After the procedure, patients with foot ulcers received meticulous care, regular foot dressings were performed, and medical treatment was organized.

Definitions

CAD was identified in individuals with at least 50% narrowing of the heart's blood vessels, as determined by previous coronary imaging for any indication. Hyperlipidemia (HL) was defined as a low-density lipoprotein cholesterol level exceeding 100 mg/dL or the use of cholesterol-lowering therapy. A family history of CAD was defined by the presence of the condition in first-degree female relatives younger than 65 years or first-degree male relatives younger than 55 years. Diabetes mellitus (DM) was characterized by either treatment with insulin or oral glucose-lowering agents or a fasting blood sugar level above 126 mg/dL. CKD was identified by a glomerular filtration rate (GFR) below 60 mg/dL or routine dialysis treatment. The GFR calculation was performed using the Modification of Diet in Renal Disease formula. Body mass index was calculated by dividing body weight (kg) by the square of height (m^2). Tobacco exposure was categorized into current smokers, former smokers, individuals who had quit, and those exposed to secondhand smoke. HT was defined as a clinic-measured blood pressure above 140/90 mmHg or ongoing antihypertensive therapy.

Statistical Analysis

Data evaluation was conducted using IBM SPSS 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean±standard deviation, while categorical variables were summarized as frequencies and percentages. The normality of numerical data distribution was assessed using the Shapiro–Wilk test. The relationship between categorical variables was determined through chi-square analysis. The Student's t-test was applied to compare normally distributed continuous variables. Univariate regression analysis was initially performed to identify factors independently influencing wound recovery. Variables with a p-value below 0.1 in the univariate model were included in the multivariate regression analysis. A $p<0.05$ was considered statistically significant for two-tailed hypothesis testing.

The study was conducted in accordance wıth the declaratıon of 31 Helsinki.

We did not use artificial intelligence–assisted technologies (such as large language models, chatbots, or image creators) in the production of submitted work.

Results

Patient Group Characteristics

A total of 192 individuals with severe leg ischemia were treated with angioplasty (with or without atherectomy) for critical narrowing in the below-knee arterial region. The distribution of patients was as follows: 38.5% (74) were female, and 61.5% (118) were male. The mean age was 67 years, ranging from 32 to 93 years. Among the patients, 80 (41.7%) were active smokers. Diabetes was present in 134 individuals (69.8%), HT in 119 patients (62%), HL in 25 patients (13%), and CAD in 96 patients (50%). CKD was identified in 52 patients (27.1%). The functional classification of patients was based on the Rutherford scale, with 149 individuals (77.6%) categorized as Rutherford 5 and 43 patients (22.4%) classified as Rutherford 6.

When comparing the two subgroups based on demographic factors, statistically significant differences were observed in male prevalence (52.2% vs. 70%, p=0.01), CKD occurrence (16.3% vs. 37%, p=0.01), and tobacco exposure (32.6% vs. 50%, p=0.01). Detailed wound recovery characteristics and subgroup demographic data are presented in (Table 2).

Procedure and Post-treatment Monitoring

During the examination of vascular blockages, it was observed that blood circulation was absent in the popliteal artery in 105 individuals (54.7%), in the anterior tibial artery in 171 cases (89.1%), in the posterior tibial artery in 173 subjects (90.1%), in the peroneal artery in 148 patients (77.1%), and in the distal segments in 164 cases (85.4%). Among these, 78 individuals (40.6%) exhibited a complete absence of blood supply in all lower leg arteries. The anatomical assessment was conducted following the TASC classification, identifying 10 cases (5.2%) as TASC-C and 182 cases (94.8%) as TASC-D.

Further evaluation of endovascular interventions and treatment sites revealed no significant statistical variations concerning blockage location, TASC categorization, clot removal, balloon dilation, or stent placement, and full occlusions in the infrapopliteal region. However, a notable difference was iden-

Table 2. Demographic characteristics of the patients

	Wound in remission (92)		Wound no improvement (100)		p
	n	%	n	%	
Age (mean±standard deviation)	66.4±11.9		64.4±11.4		0.22
Male gender,	8	52.2	70	70	0.01
Smoking	30	32.6	50	50	0.01
Coronary artery disease	43	46.7	53	53	0.38
Diabetes mellitus	60	65.2	74	74	0.18
Hypertension	59	64.1	60	60	0.55
Hyperlipidemia	8	8.7	17	17	0.08
Chronic kidney disease	15	16.3	37	37	0.01
Rutherford classification					
Rutherford 5	80	87	69	69	0.003
Rutherford 6	12	13	31	31	0.003

Table 3. Target lesion and procedure characteristics

Location of the lesion	Wound healing which is		Wound healing non-existent		p
	n	%	n	%	
Popliteal	49	53.3	56	56	0.70
Tibialis anterior	80	87	91	91	0.37
Tibialis posterior	84	91.3	89	89	0.59
Peroneal	68	73.9	80	80	0.31
Distal	78	84.8	86	86	0.81
Total infrapopliteal occlusion in the entire infrapopliteal region	38	41.3	40	40	0.85
TASC classification					
TASC C	7	7.6	3	3	0.15
TASC D	85	92.4	97	97	0.15
Endovascular procedure type					
Atherectomy+angioplasty					
Popliteal	23	25	34	34	0.17
Tibialis anterior	14	15.2	26	26	0.06
Tibialis posterior	9	9.8	23	23	0.01
Peroneal	19	20.7	13	13	0.15
Distal	3	3.3	0	0	0.06
Anjiyoplasti					
Popliteal	54	58.7	68	68	0.76
Tibialis anterior	55	59.8	58	58	0.80
Tibialis posterior	38	41.3	51	51	0.17
Peroneal	48	52.2	41	41	0.12
Distal	17	18.5	12	12	0.21
Thrombus aspiration	5	5.4	4	4	0.63

tified in the wound recovery rate in individuals undergoing vessel scraping (atherectomy) and balloon-assisted widening in the posterior tibial artery (Table 3).

In follow-up imaging conducted through peripheral angiography, persistent vessel blockage was noted in 7 individuals (7%) in the popliteal artery, 52 cases (52%) in the anterior tibial artery, 63 patients (63%) in the posterior tibial artery, 40 cases (40%) in the peroneal artery, and 44 individuals (44%) in the dorsalis pedis among those who exhibited no wound improvement. A comparative evaluation was performed between individuals whose wounds healed and those who did not. No significant disparities were found apart from the anterior tibial artery findings (Table 4).

A detailed statistical model (multivariate regression) was applied to factors with $p<0.1$ in the initial single-variable analysis. In this advanced analysis, CKD, Rutherford stage 6 classification, and the absence of blood supply in the anterior tibial artery following the vascular intervention were identified as independent risk factors negatively impacting wound recovery (Table 5).

Discussion

Performing endovascular procedures on the infrapopliteal region in patients with peripheral arterial disease (PAD) presents significant challenges for interventional cardiologists. The presence of extensive calcifications, the involvement of multiple ar-

Table 4. Post-procedure evaluation

	With wound healing (92)		No wound healing (100)		p
	n	%	n	%	
Lack of flow after the procedure					
Popliteal	4	4.3	7	7	0.43
Tibialis anterior	31	33.7	52	52	0.01
Tibialis posterior	60	65.2	63	63	0.74
Peroneal	31	33.7	40	40	0.36
Distal	42	45.7	44	44	0.81

Table 5. Multivariate analysis table of factors affecting wound healing after endovascular intervention

	OR	CI 95%	p	OR	CI 95%	p
Male	0.46	0.25–0.84	**0.01**			
Atherectomy	0.51	0.28–0.91	**0.02**			
DM	0.65	0.35–1.22	0.18			
HT	1.19	0.66–2.13	0.55			
KAH	0.77	0.44–1.37	0.38			
KBH	0.33	0.16–0.65	**0.02**	0.36	0.13-0.61	**0.02**
HL	0.46	0.19–1.13	**0.09**			
Cigarette exposure	0.48	0.26–0.87	**0.01**			
Thrombus aspiration	1.37	0.35–5.30	0.64			
Rutherford classification						
Rutherford 5	2.99	1.42–6.27	**0.004**			
Rutherford 6	0.33	0.15–0.70	**0.004**	0.32	0.14-0.75	**0.009**
Angioplasty						
Popliteal	0.66	0.37–1.20	0.18			
Anterior	1.07	0.60–1.91	0.80			
Posterior	0.67	0.38–1.19	0.17			
Peroneal	1.57	0.88–2.77	0.12			
Distal	1.66	0.74–3.70	0.21			
Atherectomy+angioplasty						
Popliteal	0.64	0.34–1.21	0.17			
Anterior	0.51	0.24–1.05	**0.06**			
Posterior	0.36	0.15–0.83	**0.01**			
Peroneal	1.74	0.80–3.76	0.15			
Distal	0.98	0.73–1.67	0.94			
Post-procedure flow absence of						
Popliteal	0.60	0.17–2.13	0.43			
Anterior	0.46	0.26–0.84	**0.01**	0.33	0.16-0.66	**0.02**
Posterior	1.10	0.61–1.98	0.74			
Peroneal	0.76	0.42–1.37	0.36			
Distal	1.06	0.60–1.88	0.81			

OR: Odds ratio; CI: Confidence interval; DM: Diabetes mellitus; HT: Hypertension; HL: Hyperlipidemia; CKD: Chronic kidney disease.

teries, a higher incidence of complete blockages compared to narrowing, difficulties in vascular access (particularly in more proximal obstructions), and other anatomical complexities all contribute to the difficulty of these interventions.[14] Advances in guidewire and balloon technologies have facilitated the ability to reach and restore blood flow in these small-caliber vessels. However, despite these advancements, the outcomes may not always be favorable for all individuals.

Peripheral artery disease necessitates close monitoring both during and after treatment, requiring careful management by both patients and physicians. In this retrospective study, factors influencing post-procedural wound healing in individuals with intermittent claudication and critical limb ischemia were analyzed. These patients underwent endovascular revascularization to address blockages or complete occlusions in the arteries below the knee. Our findings indicated that the presence of CKD (classified as Rutherford stage 6) and the absence of blood flow in the anterior tibial artery following PTA were independent predictors of poor wound healing.

The risk factors for PAD align with those of other atherosclerotic conditions, including HT, dyslipidemia, diabetes, and kidney dysfunction, in addition to unchangeable variables such as aging

and male sex.[11,14,15] A systematic review by Mustapha et al.,[16] which analyzed 52 studies published between 2005 and 2015, found that among patients undergoing PTA for infrapopliteal disease, 75% had diabetes, 75% had high blood pressure, 53% had elevated cholesterol levels, and 34% had kidney impairment.

In this study, a comparison was made between individuals with successful wound healing and those without. The average age in the group with impaired wound recovery was 64.3 years, and 70% were male. Although the differences were not statistically significant, diabetes, HT, HL, and CAD were more prevalent in the non-healing group. A single-center study by Conrad et al.[17] involving 407 individuals found that diabetes was a predictor of shorter limb survival and that kidney disease requiring dialysis was associated with worse outcomes. Similarly, our study identified CKD as an independent determinant of delayed wound healing, supporting the findings of previous research.

Pre-procedural assessments indicated that individuals classified as Rutherford stage 6 had a poorer prognosis for wound healing compared to those classified as Rutherford stage 5, suggesting that the extent of tissue involvement negatively impacts the healing process. Chronic wounds are frequently located in the lower limbs, which can be attributed to relatively slower blood circulation in these regions compared to other parts of the body. Our findings also highlighted that the absence of blood flow in the anterior tibial artery post-intervention had a detrimental impact on wound healing, likely due to the vascular supply this artery provides to critical regions of the foot.

Smoking is a known vasospastic agent that exacerbates atherosclerosis, a relationship well-documented in the Framingham study. This research indicated that smokers have a threefold higher risk of developing peripheral artery disease compared to non-smokers. A meta-analysis of 30 studies conducted by Romiti et al. and another meta-analysis by Mustapha et al.[16–18] found that smoking history was present in 50% and 40% of individuals undergoing. PTA for infrapopliteal disease, respectively. In our study, smoking prevalence was significantly higher among those with poor wound healing. Although smoking was a significant factor in univariate regression analysis, it did not remain statistically significant in the multivariate model.

A study by Kok et al.[19] involving 112 individuals found that at a 3-year follow-up, major amputations were more common in individuals with a history of smoking, stroke, and cardiovascular disease. In our study, 100 patients (52.1%) experienced impaired wound healing post-procedure. Using the updated 2015 TASC II classification, the majority of our patient population consisted of TASC C and D lesions with multiple medical comorbidities. However, no significant difference in wound healing was found between different TASC classifications. Given that most individuals fell within the TASC D category, direct comparisons between groups were somewhat limited. In addition, due to an insufficient number of records, we could not definitively assess the relationship between procedural success and amputation rates. Amputations were identified through an in-depth review of imaging records and categorized as cases with delayed wound healing.

Minimally invasive endovascular techniques offer benefits such as shorter hospital stays, lower morbidity, and reduced mortality. However, procedural success is often limited by long-segment occlusions, extensive calcifications, and multi-level arterial involvement. While newer techniques such as atherectomy, cryoplasty, specialized cutting balloons, and laser angioplasty have been introduced for below-the-knee interventions, studies indicate that these approaches do not provide superior results compared to conventional methods and tend to be more expensive.[20–23] Drug-coated balloons have also been explored in recent years, yet their effectiveness compared to standard balloon angioplasty remains uncertain. In our study, atherectomy combined with PTA did not demonstrate a significant positive effect on wound healing.

Limitations of the Study

The primary limitation of this study is the relatively small sample size. In addition, data regarding the timing of amputations and the extent of wound healing following peripheral endovascular intervention were insufficient. As a result, larger-scale studies are necessary to validate and expand upon these findings.

Conclusion

In summary, an evaluation of factors influencing wound healing after peripheral endovascular intervention identified CKD, a pre-procedural clinical classification of Rutherford stage 6, and the absence of blood flow in the anterior tibial artery following PTA as negative predictors of wound healing.

Disclosures

Ethics Committee Approval: The study was approved by the Kocaeli University Faculty of Medicine Clinical Research Ethics Committee (no: 2019/126, date: 10/05/2019).

Informed Consent: Informed consent was obtained from all participants.

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