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Original Article

Comparison of PTFE sutures with polypropylene sutures in suprapopliteal femoropopliteal bypass with PTFE grafts

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Abstract

Aim: Infrainguinal bypass surgery stands as the predominant open surgical procedure for lower limb revascularization and is reserved for cases of intermittent claudication (IC) that have proven unresponsive to maximal medical management. Polypropylene monofilament sutures have been widely used for peripheral vascular surgery operations. Aim of this study is comparing this new type of suture with propylene sutures.

Material and Methods: Between January 2022 and December 2022, two cohorts who underwent suprapopliteal femoropopliteal bypass surgery, each comprising 15 patients were included in the study. In Group I (polytetrafluoroethylene (PTFE) Group), PTFE served as the suture material, whereas in Group 2 (Non PTFE Group), polypropylene sutures were employed. All preoperative demographics, perioperative and postoperative data were collected carefully.

Results: All patients underwent surgical interventions due to either rest pain or ischemic ulcers. Among the 30 patients, 11 fell into Fontaine class 4, while 19 were categorized as Fontaine class 3. Out of the 30 patients, 18 received cilostazol treatment. The mean age of the patient cohort was 66.97±7.4 years, with a mean body mass index of 29.03±6.2. When we compared the two groups, no statistically significant difference was found between groups according to demographic data. In the evaluation of intraoperative data, the mean operation time was 88.7±9.37 minutes, and the mean hemostasis time was 5.8±2.8 minutes. Group I (PTFE group) exhibited significantly lower hemostasis time and drainage levels on the first and second postoperative days ($p<0.0001$, $p=0.03$, and $p=0.017$, respectively). The use of absorbable hemostats were significantly less in PTFE suture group.

Conclusion: The selection of sutures significantly influences the achievement of soft tissue approximation, reduced inflammation, suture hole leakage and capsule formation.

Keywords: Peripheral artery disease, infrainguinal bypass, expanded polytetrafluoroethylene sutures

INTRODUCTION

Incidence of peripheral artery disease (PAD) is 13% over the age of 50. Also the incidence of symptomatic PAD between 55-74 is 5% [1]. Lower limb ischemia is separated into two groups: intermittent claudication (IC) and critical limb ischemia (CLI). IC is characterized by exertional pain without limb-threatening ischemia. For IC diagnosis, physical examination, walking test, ankle-brachial index, doppler ultrasound, magnetic resonance angiography, computer tomography angiography and gold standard conventional angiography can be used [1].

The primary approach to IC treatment is medical management, encompassing smoking cessation, administration of antiplatelet agents, statin therapy, diabetes control, hypertension management, and the implementation of a structured exercise regimen.

Infrainguinal bypass surgery stands as the predominant open surgical procedure for lower limb revascularization and is reserved for cases of IC that have proven unresponsive to

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maximal medical management.

While autologous vein grafts are widely regarded as the gold standard due to their superior patency, limb salvage rates, and long-term survival outcomes, they may not always be available or suitable for above-knee revascularization [2-5].

Expanded polytetrafluoroethylene (ePTFE) grafts have emerged as an acceptable prosthetic alternative to autologous veins for infrainguinal arterial reconstructions [3-5].

The reason for using high-quality suture is prevention of complications such as mechanical failures of implanted grafts, pseudoaneurysm, and infections. The ideal characteristics for a vascular suture include maintaining its tensile strength while minimizing any significant “foreign body” reaction [5,6].

Contemporary surgical anastomotic interventions for cardiovascular reconstructions typically employ a monofilament suture, such as polypropylene, in either an interrupted or continuous technique for vascular bypass. However, the use of these suture materials inevitably introduces foreign material at the blood-graft interface, potentially leading to direct intimal damage and exposing thrombogenic extracellular matrix to turbulent blood flow [6-8].

Polypropylene monofilament sutures have shown all the features that a surgical suture should have and have long ago surpassed polyfilament sutures and become the first choice in this type of surgery. Aim of this study is comparing this new type of suture with propylene sutures.

Expanded polytetrafluoroethylene (PTFE) has been employed longer than any other material in various grafts for vascular repair [9]. Surgical sutures crafted from ePTFE are primarily utilized in vascular and cardiac surgery. The pores within ePTFE sutures become intertwined with soft tissues and vessels, resulting in their permanent incorporation within the body.

Suture hole bleeding presents a significant concern in vascular reconstructive procedures using PTFE grafts [6,8]. Traditionally, this issue is managed through compression with surgical swabs and heparin reversal. Alternative methods, such as the application of oxidized cellulose, gelatin sponge, various forms of collagen, and adhesives, have also been attempted, yielding varying degrees of success.

MATERIAL AND METHODS

Between January 2022 and December 2022, we conducted a study aimed at comparing the effects of employing PTFE sutures in infrainguinal bypass procedures where PTFE grafts were used as conduits in the suprapopliteal position. The use of autologous vein grafts was precluded due to prior surgical procedures, instances of thrombophlebitis, or inadequate vein diameter.

To achieve this objective, we established two cohorts, each comprising 15 consecutive patients. In Group I (PTFE Group), PTFE served as the suture material (DOĞSAN Surgical suture and medical device Company, Rize cad 91 A, Trabzon, Türkiye 61220), whereas in Group 2 (Non PTFE Group), polypropylene sutures (DOĞSAN Surgical suture and medical device Company, Rize cad 91 A, Trabzon, Türkiye 61220) were employed. In our clinic we perform approximately 30 suprapopliteal femoropopliteal bypass surgeries annually. When we conferred with Department of Statistics, it was concluded that the number of 30 patients would be sufficient to have an idea to evaluate the two different sutures in suprapopliteal femoropopliteal bypass with PTFE grafts.

Preoperative and intraoperative data including age, body mass index (BMI), gender, previous smoking history, coronary artery disease (CAD), diabetes mellitus (DM), fontain classification of patients, the use of absorbable hemostats (oxidized regenerated cellulose), time to hemostasis, drainage, time spent in the intensive care unit, the necessity for surgical revision, postoperative hematoma occurrence, and hospitalization duration, were meticulously recorded. Hemostasis was defined as the point at which the wound achieved complete dryness or sufficient dryness to permit the completion of the operation without additional suturing in the anastomosis area. During this period, heated sponges were applied to the area to mitigate needle hole bleeding, and the specific duration was documented. If the area did not attain adequate dryness, surgery was applied before replacing the drainage system.

This study received approval from the local review board (with the reference number KA 21/405). All surgical procedures were conducted by the same surgical team, employing a uniform operative technique. Anti-platelet medications were not withheld preoperatively. Standard end-to-side anastomoses were established using grafts measuring 7 mm and 8 mm in diameter, with a reinforced ring used in most cases. The use of suture material was depending on the decision of surgeon however only 5/0 and 6/0 sutures were used

All patients were subjected to a nine-month follow-up period, including physical examinations, inspections, pulse assessments, ankle-brachial index (ABI) measurements, and duplex ultrasonography evaluations to determine the presence of graft thrombosis and primary patency.

Statistical Analysis

Statistical analysis was conducted utilizing IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Descriptive characteristics of the study population were presented as means with standard deviations or as counts with percentages. A specific table was formed for arithmetic mean, standard deviation, and associated confidence interval. Pearson's chi-square test was applied for categorical data comparisons (such as gender, previous smoking history, CAD, DM, fontain classification of patients, the use of absorbable hemostats (oxidized regenerated

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cellulose), the necessity for surgical revision, postoperative hematoma occurrence, while independent sample T-tests were used for numerical data comparisons (Such as operation time, hemostasis time, amount of drainage) with specific test locations indicated where relevant. A significance level of $p<0.05$ was deemed statistically significant.

RESULT

All patients underwent surgical interventions due to either rest pain or ischemic ulcers. Among the 30 patients, 11 fell into Fontaine class 4, while 19 were categorized as Fontaine class 3. Out of the 30 patients, 18 received cilostazol treatment. The mean age of the patient cohort was 66.97±7.4 years, with a mean body mass index of 29.03±6.2. Detailed demographic parameters are summarized in Table 1 and numeric values are shown in Table 2 (arithmetic mean, standard deviation, and associated confidence interval.

In PTFE group, 6 (40%) of the patients were in fontaine class 3 and 9 (60%) were in class 4; in non PTFE group, 5 (33.3%) of the patients were in fontaine class 3 and 10 (66.6%) were in class 4. There was no statistically significant difference between groups ($p>0.05$).

In the evaluation of intraoperative data, the mean operation time was 88.7±9.37 minutes, and the mean hemostasis time was 5.8±2.8 minutes. Group I (PTFE group) exhibited significantly lower hemostasis time and drainage levels on the first and second postoperative days ($p<0.0001$, $p=0.03$, and $p=0.017$, respectively). Total numbers and descriptive datas are presented in Table 2. Intraoperative and postoperative data are presented in Table 3. Notably, two patients in Group 2 required blood transfusions, and neither group necessitated surgical revisions or secondary interventions during the initial nine-month follow-up period. Pictures show before and after blood exposure of ePTFE sutures (Figures 1 and 2).

Table 1. Demographic parameters

	PTFE group	Non-PTFE group	P value
Age (year)	67.33±5.86	66.6±8.90	>0.05
Gender (male)	10 (66.6%)	10 (66.6%)	>0.05
BMI	29±6.27	28.78±6.40	>0.05
DM+	13 (86.67%)	13 (86.67%)	>0.05
CAD+	10 (66.6%)	10 (66.6%)	>0.05
Smoking	13 (86.67%)	13 (86.67%)	>0.05

Table 2. Total numbers and descriptive data

	BMI	Age	Operation time	Homeostasis time	Bleeding postoperative day 1	Bleeding postoperative day 2
Number/missing	30/0	30/0	30/0	30/0	30/0	30/0
Mean	29.0333	66.97	88.70	5.6000	76.6667	33.6667
Standart error of mean	1.13801	1.353	1.711	.51551	5.34625	2.28606
Mean	27.8000	67.00	88.00	5.0000	80.0000	35.0000
Standart deviation	6.23312	7.411	9.370	2.82355	29.28261	12.52125
Varaince	38.852	54.930	87.803	7.972	857.471	156.782
skewnwss	.981	-.593	.522	.124	.252	-.268
Std error of skewness	.427	.427	.427	.427	.427	.427
Range	23.10	31	36	8.00	100.00	40.00
Minimum	21.20	47	74	2.00	40.00	10.00
Maximum	44.30	78	110	10.00	140.00	50.00

BMI: body mass index

Table 3. Intraoperative and postoperative data

	PTFE group	Non-PTFE group	P value
Operation time (min)	88.80±9.87	88.60±9.20	0.57
Hemostasis time (min)	3.07±0.96	8.13±1.36	0.0001
Postop first day drainage (ml)	61.67±24.83	91.67±26.02	0.03
Postop second day drainage (ml)	28.33±12.34	39.00±10.56	0.017
The use of absorbable hemostats	3 (20%)	15 (100%)	0.0001

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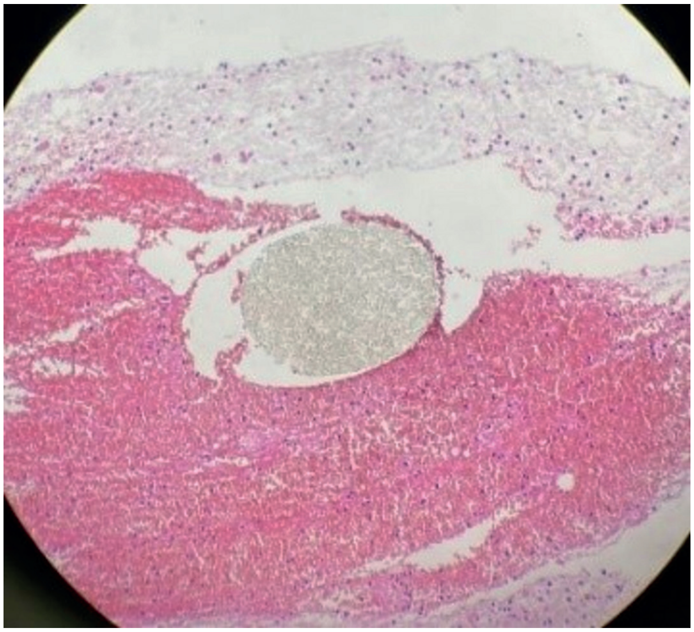

Figure 1. Electron microscpic images of PTFE sutures before blood exposure

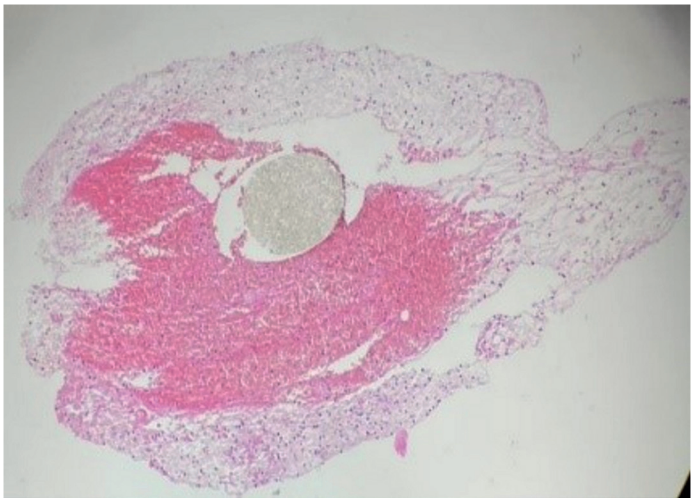

Figure 2. Electron microscpic images of PTFE sutures after blood exposure

DISCUSSION

The selection of sutures significantly influences the achievement of optimal soft tissue approximation, particularly when considering reduced capsule formation, inflammation, and suture hole leakage. The porous microstructure of ePTFE sutures allows for tissue attachment, while ePTFE's inertness and biocompatibility result in a benign tissue response to the suture [9]. Consequently, the use of ePTFE sutures leads to reduced capsule formation and inflammation when compared to polypropylene and polyester sutures (Gore Medical, Gore-Tex® Suture, www.goremedical.com/la/suture) [9-11].

Although polyester represents another biomaterial commonly employed in medical applications, PTFE offers several advantages over polyester. PTFE's surface exhibits lower thrombogenicity (causing less blood coagulation) than woven polyester [9]. In terms of tissue reaction, PTFE is preferred over polyester because, while PTFE may induce a low-grade tissue reaction, polyester more readily triggers an inflammatory tissue reaction and granulation. Regarding dimensional stability, PTFE surpasses polyester, as the latter tends to dilate more extensively than PTFE [9]. However, despite the advantages claimed for ePTFE, studies on abrasion resistance reveal significantly lower resistance in ePTFE fabrics when compared with polyethylene terephthalate grafts [9-11].

For comparing two sutures, electron microscopy measurements were taken from 3 different sites of the sutures. After making the measurements of the inflammatory reaction thickness in anastomosis area, statistical analysis was performed. Both sutures' inflammatory reaction was minimal and there was no statistically significant difference between the two sutures according to Student's T- test (p=NS). In the authors' opinion, ePTFE is a good alternative for propylene suture in cardiovascular surgery [3,8,9,11].

The primary constraint of this investigation lies in its retrospective nature, its confinement to a single-center setting, and its reliance on a relatively limited sample size. Notwithstanding the modest number of subjects included, the current study has demonstrated a noteworthy finding: the utilization of PTFE sutures leads to a statistically significant reduction in the time required to achieve hemostasis and decreased use of absorbable hemostat. Despite the aforementioned limitations we may conclude that PTFE sutures can be used safely in suprapopliteal femoropoplital bypass surgery with PTFE grafts. Further studies with larger group of patients will give more information about this subject.

CONCLUSION

After blood exposure ePTFE sutures expanded and becuse of this reason these suture more secure for bleeding then propylene suture. ePTFE can be a good alternative for propylene suture in cardiovascular surgery operation

Ethics Committee Approval: Ethical approved taken from Başkent University Ethical Commitee with KA21/405.

Patient Consent for Publication: Since the study was retrospective and did not contain personal information or pictures of the patients, it was not required by the ethics committee.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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