Composite Grafts as an Alternative Conduit to Prosthetic Grafts in Below Knee Femoro-popliteal Bypass in Patients of Chronic Lower Limb Ischemia

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Abstract

Background: Chronic limb threatening lower limb ischaemia (CLTI) gives high limb loss and mortality. Infra-genicular Femoro-popliteal bypass offers in-line flow to target vessels. When vein not available, composite and prosthetic grafts are used.

Aim of the work: Comparing composite vs synthetic femoro-popliteal bypass conduits in treatment of CLTI.

Patients and methods: 20 adult patients were included in this prospective study from July 2020 to July 2021 having CLTI requiring below knee femoro-popliteal bypass, no suitable vein conduit. Ten had composite grafts bypass (group A) and 10 patients had synthetic graft (group B), and followed for 6 months.

Results: Improved clinical manifestations in both groups and significant increase of ankle brachial index. 6 months 1ry and 2ry patency were 90% and 100% in group A, and 67% and 78% in group B. Limb salvage were 100% in group A and 89% in group B. No significant difference between groups' outcome, complications, and ABI.

Conclusion: Both types of conduit showed acceptable feasibility and outcome.

Key words: Infragenicular bypass, femoro-popliteal, composite graft, synthetic graft.

Introduction

Chronic limb threatening lower limb ischaemia (CLTI) is an important health problem with an impact on both patients and health service providers. This serious condition got its significance from being associated with high incidence of limb loss and significant all-cause mortality as well.[1,2]

As an effective treatment option of such condition, infra-genicular bypass is considered one of the major lower-extremity arterial reconstruction, which aims to guarantee in-line flow to target vessels below the knee level. Common femoral artery is a common inflow site rendering femoro-popliteal bypass a common form of arterial reconstruction. However, other inflow sites may also be used including iliac segment, profunda-femoris artery, superficial femoral, and popliteal arteries.[3]

Infra-genicular bypass is commonly done for CLTI as a primary indication.[4] However, it can be used to treat patients suffering aneurysmal disease and traumatic arterial injuries.[5] The bypass conduit is preferably an autogenous vein, commonly the great saphenous vein. Moreover, short saphenous, superficial femoral, and arm veins can be used as well. Whenever not available, composite (Vein + prosthetic), and prosthetic arterial grafts can be used.[6,7]

Synthetic grafts have multiple graft materials and configurations.[8] However, all prosthetic conduits have similar patency in the infra-popliteal position which proved to be inferior to autogenous veins.[6] Thus, synthetic conduit should be kept only for patients lacking suitable vein grafts and those with high operative risk to shorten their operative time. The composite option can be used when vein conduit length in not sufficient to complete the bypass down lower than knee level. In such situation the vein segment is used to cross the knee joint while the rest of the graft length is replaced by the synthetic part making natural and synthetic parts complementary to each other.

For an infra-genicular bypass, contraindications include: Severe debilitating disease, inadequate run off target artery, severe knee contractures and non-ambulatory patient.[8,9]

The distal target artery must be confirmed to be the dominant vessel to the foot. Tissue distribution of the outflow vessels must correlate with the operative indication. For example, whereas revascularization of the pedal arteries will aid in healing of ischemic foot ulcers, it will not improve calf claudication.[10]

Aim of the work

The aim of this work was to compare clinical outcome of composite vs synthetic graft as below

knee femoro-popliteal bypass conduits in treatment of CLTI.

Patients

Institutional Review Board (IRB) ethical approval and patient consents were obtained in Alexandria University Faculty of Medicine. 20 adult patients were included in this prospective study from 1st July 2020 to 31st July 2021. They presented with critical chronic lower limb ischemia which required below knee femoro-popliteal bypass surgery. They were admitted to Alexandria Main University Hospitals. Ten patients had bypass with synthetic graft and 10 patients were treated using composite grafts formed partially of a long saphenous vein segment harvested and sutured to a plain polytetrafluoroethylene (PTFE) graft.

Inclusion criteria

1. Patients presenting with Rutherford Category 4 or 5.[11]
2. Trans-Atlantic Inter-Society Consensus (TASC II) Class C or D fem-pop lesion.[1]

Exclusion Criteria

1. High risk of anaesthesia.
2. Patients presenting with Rutherford category 6.[11] Indicated for major amputation.
3. Life threatening limb infection indicated for life-saving amputation.
4. Redo revascularization surgery.
5. Patient has an appropriate autogenous vein suitable for below the knee (BTK) bypass.
6. Patients without appropriate popliteal artery run-off in angiogram.
7. Patients with acute ischaemia.
8. Extensive tibial arteries calcification making objective ABI measurement and follow up not feasible.

Methods

All included patient had:

- **History taking:**
  - A. Personal history.
  - B. Medical history.
  - C. Surgical history.
  - D. Special habits (e.g, smoking).
- **Clinical examination:**
  - A. General examination.
  - B. Vital signs.
  - C. Local examination of the affected limb including preoperative ankle-brachial index (ABI) measurement.
- **Investigations**

A. Laboratory Investigations (e.g, CBC, Coagulation profile, Renal functions, lipid profile, Hb A1c level).

B. Imaging:

- Arterial duplex ultrasound: for patency of below knee vessels and its heamodynamics and type of inflow and outflow arteries.
- Saphenous vein duplex mapping and marking: to be used as a conduit, vein less than 3 mm, Calcified, sclerotic or varicose is considered not suitable.
- MDCT angiography of abdominal aorta and both lower limbs: for inflow and outflow evaluation.

Operative procedure

After signing an informed consent and under spinal, general or epidural anaesthesia. Included patients had infra-genicular femoro-popliteal bypass surgery using a composite (6mm plain PTFE sutured to a reversed segment of great saphenous vein) graft in 10 patients (group A). The vein part of the composite graft were used to cross the knee joint and for the outflow anastomosis to the popliteal artery. This kept the vein-to-PTFE anastomosis always in the mid-to-lower thigh level **(Figure 1)**. The remaining 10 patients were offered infragenicular femoro-popliteal bypass using ringed (externally supported) 6mm PTFE graft (group B) **(Figure 2)**. This was done due to lack of suitable long saphenous vein segment to be incorporated in a composite graft in this patients'group.

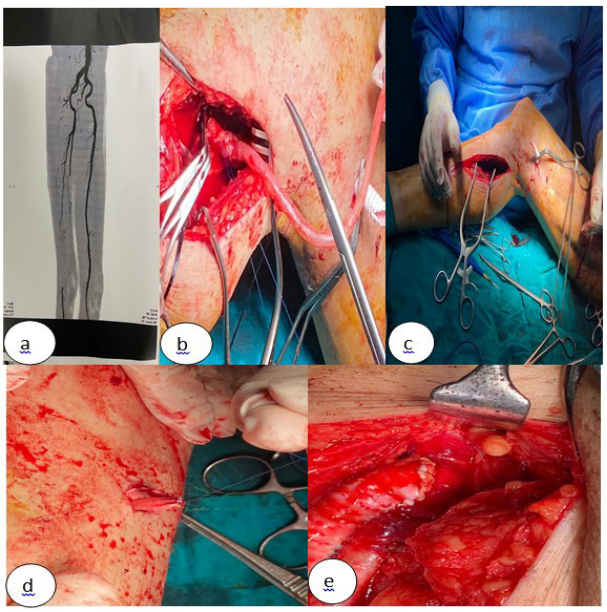

Fig 1: Composite infragenicular femoro-popliteal graft: a: CTA. b: Distal vein anastomosis to popliteal artery. c: Synthetic part in place. d: Synthetic-vein anastomosis. e: Proximal synthetic part anastomosed to common femoral artery.

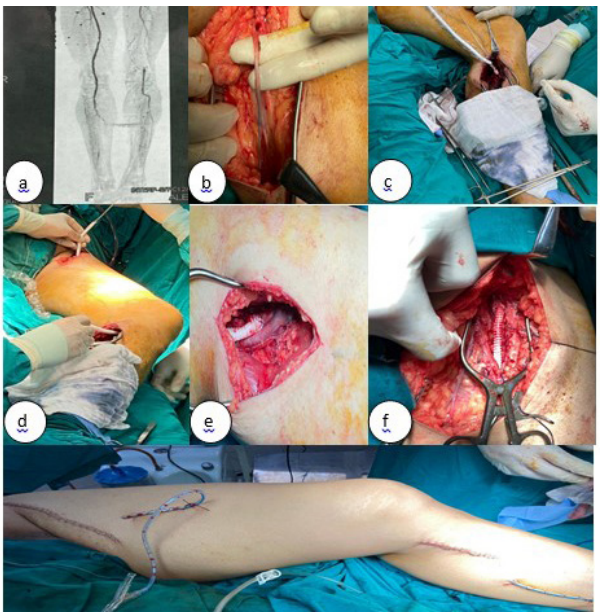

Fig 2: Synthetic infragenicular femoro-popliteal graft. a: CTA. b: Unsuitable, bifurcated long saphenous vein. c: Constructing popliteal anastomosis. d: Tunneling. e: Distal anastomosis. f: Proximal anastomosis. g: Wounds closed with drainage.

Follow up

Included patients were followed for 6 months for:

A. Clinical outcome including examination of distal pulses, healing of the ischemic ulcers, improvement of the rest pain and ABI measurements.

B. Color duplex ultrasound (CDU) (Graft Surveillance) at 3 and 6 months procedure to follow up the graft patency (Peak Systolic Velocity PSV) and if there are any stenotic segments.

C. Complications including:

- Graft occlusion.
- Graft infection and removal.
- Major amputation.
- Mortality.

Statistical analysis of the data

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. Shapiro-Wilk test .was used to verify the normality of distribution Quantitative data were described using range (Minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

Results

20 patients (20 limbs) presented who had CLTI of the lower limb were included in this study and treated by below the knee (BTK) bypass surgery; 10 patients had composite graft (group A) and 10 patients had synthetic grafts (group B). They were 11 (55%) males, and 9 (45%) females. Their ages ranged from 45 to 76 years, with a mean age of 61 years ±7 (SD).

Patients' co-morbidities including diabetes, hypertension, smoking and ischaemic heart disease showed differences between the two groups **(Table 1).**

Regarding the clinical presentations, the majority of patients had minor ishaemic tissue loss (60%) in the form of toe gangrene, forefoot gangrene, and ishaemic ulcer while 40% presented by ischaemic rest pain. No difference were observed in clinical presentation between the two groups **(Table 2).**

No operative mortality was reported or intraoperative bleeding complication. Smooth postoperative recovery with 100% technical success except one patient in group (A) who developed early postoperative bleeding (10%) and one patient in group (B) (10%) due to anticoagulation and both were treated conservatively.

Both patients' groups showed no marked difference regarding the preoperative ABI. However, statistically significant increase of ABI was reported in all study patients when measured immediately postoperative and compared to the pre-operative values ($p<0.001$). Comparing the pre and post-operative ABI in each group separately resulted in significant rise in each patients' group ($p=0.005$) **(Table 3).**

Comparing the ABI changes in both patients' groups revealed significant difference in ABI rise in favour of the composite graft group (group A) in immediate postoperative period ($p=0.019$). However, the rise in ABI showed no significant change between the two patients' groups and they became statistically matching 3 months post-operatively ($p=0.270$) and after 6 months follow up ($p=0.364$) **(Table 4) (Figure 3).**

During follow up, only one patient mortality was reported (10%) in group (B) due to myocardial infarction. During the 6 months follow up, graft occlusion occurred in one patient of group (A). He was treated by graft thrombectomy rendering a 6-months 1ry and 2ry patency 90% and 100% respectively, in this group. On the other hand, 2 patients of group (B) (22.2%) developed graft thrombosis. One of them had non salvageable limb due to extensive foot infection. He had a major

amputation. The other one was treated by hybrid graft thrombectomy and para-anastomotic balloon dilatation **(Figure 4).** Moreover, another graft loss was reported in this group (group B) due to late graft infection treated by graft removal and arterial ligation in one patient (11%) that continued on conservative treatment. These rendered the group (B) primary patency to be 66.7% and a 2ry patency to be 77.8%. **(Table 5)**.

In group-A, 100% clinical improvement was reported in the form of ischaemic lesion healing in 6 patients (60%) and rest pain relief in 4 (40%) while in group-B, lesion healing was reported in 4 patients (44.4%) and rest pain relief in 4 (44.4%). This renders a 6-months limb salvage rate of 100% in group-A and 89% in group-B) **(Table 5).**

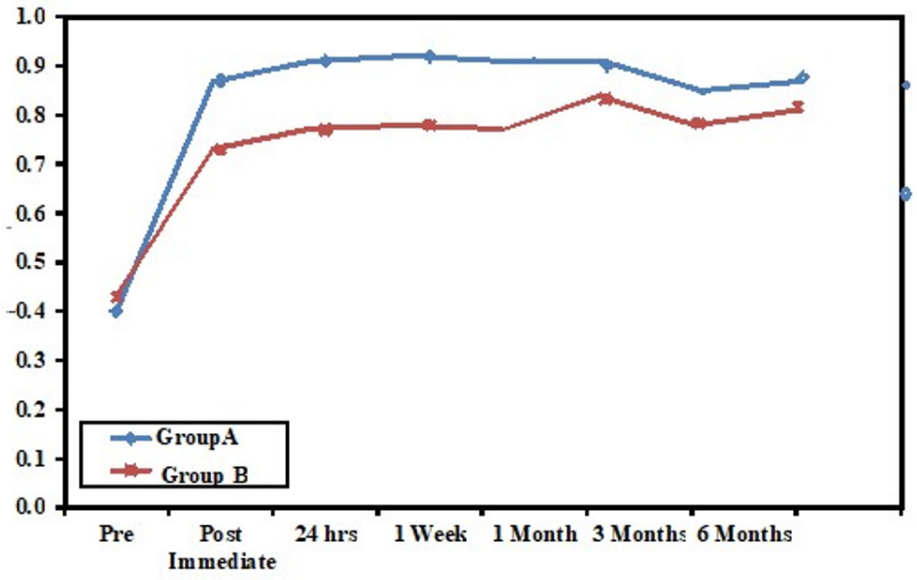

Fig 3: Comparison between the two studied groups according to ABI.

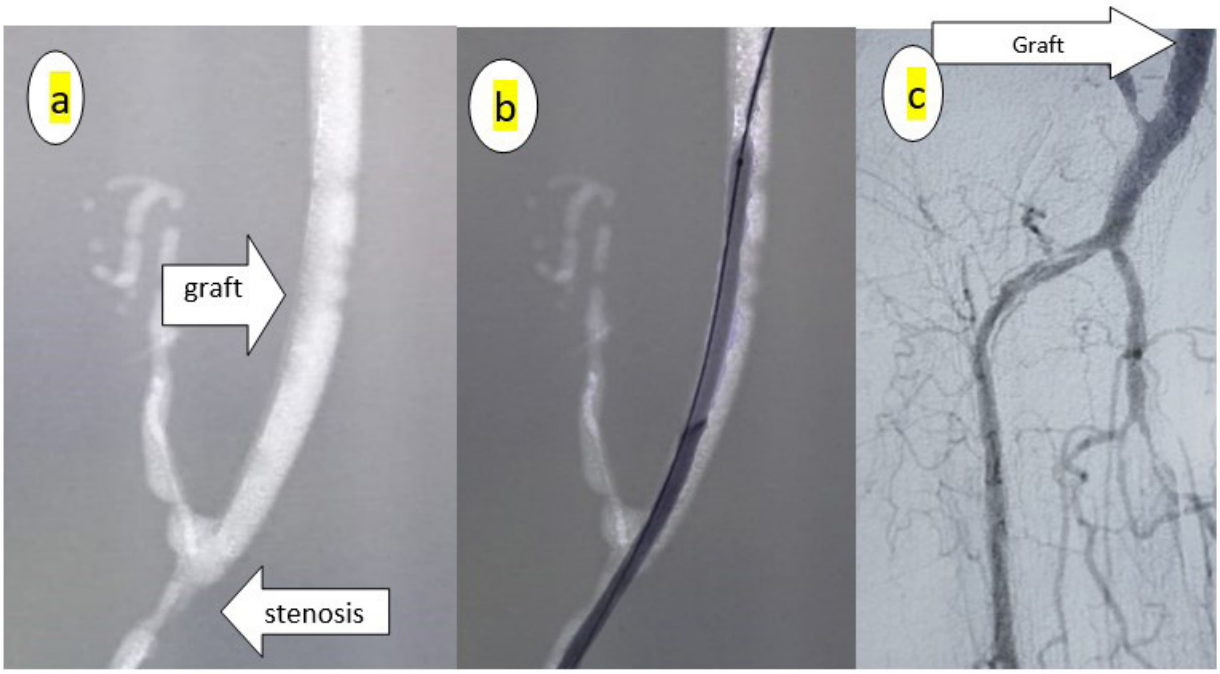

Fig 4: Para-anastomotic balloon dilatation after graft thrombectomy. a: Angiography after graft thrombus removal. b: Anastomotic and para-anastomotic balloon dilatation. c: Control angiogram after dilatation.

Table 1: Patients' co-morbidities and their differences between the two groups

Risk factors	Patients' group				Total (n=20)	
	Group A (n=10)		Group B(n=10)			
	No.	%	No.	%	No.	%
Smoker	4	40.0	5	50.0	9	45.0
DM	6	60.0	7	70.0	13	65.0
HTN	7	70.0	8	80.0	15	75.0
Cardiac	2	20.0	5	50.0	7	35.0

Table 2: Clinical presentation (n=20)

Complain	Patients' group				Total (n=20)	
	A (n=10)		B (n=10)			
	No.	%	No.	%	No.	%
Rest Pain	4	40.0	4	40.0	8	40.0
Ischemic Ulcer	6	60.0	6	60.0	12	60.0

Table 3: Comparison between the pre and post-operative ABI

ABI	Total (n=20)	Patients' group	
		A (n=10)	B (n=10)
Pre-operative ABI:			
Min. – Max.	0.30 – 0.59	0.31 – 0.50	0.30 – 0.59
Mean ± SD.	0.42 ± 0.07	0.40 ± 0.05	0.43 ± 0.08
Median (IQR)	0.41 (0.40 – 0.45)	0.40 (0.40 – 0.41)	0.45 (0.40 – 0.45)
Early Post-operative ABI:			
Min. – Max.	0.66 – 1.0	0.70 – 1.0	0.66 – 0.85
Mean ± SD.	0.84 ± 0.11	0.91 ± 0.10	0.77 ± 0.06
Median (IQR)	0.80 (0.80 – 0.90)	0.90 (0.90 – 1.0)	0.80 (0.70 – 0.80)
Z (p)	3.923* (<0.001*)	2.809* (0.005*)	2.805*(0.005*)

IQR: Inter quartile range. SD: Standard deviation.

Z: Wilcoxon signed ranks test.

p: p value for comparing between Pre and postoperative in each group and total sample.

*: Statistically significant at p ≤ 0.05.

Table 4: Comparison between the two studied groups regarding post-operative ABI changes 3 and 6 months post-operatively

ABI	Total	Patients' group		U	p
		A	B		
3 Months	**(n=18)**	**(n=10)**	**(n=8)**		
Min. – Max.	0.45 – 1.0	0.60 – 1.0	0.45 – 1.0	23.0	0.270
Mean ± SD.	0.88 ± 0.15	0.91 ± 0.12	0.84 ± 0.18		
Median (IQR)	0.90 (0.90–1.0)	0.90 (0.90–1.0)	0.90 (0.85–0.90)		
6 Months	(n=18)	(n=10)	(n=8)		
Min. – Max.	0.40 – 1.0	0.40 – 1.0	0.40 – 1.0		
Mean ± SD.	0.82 ± 0.19	0.85 ± 0.18	0.78 ± 0.20	25.0	0.364
Median (IQR)	0.90 (0.73–0.90)	0.90 (0.80–1.0)	0.80 (0.72–0.90)		

IQR: Inter quartile range. SD: Standard deviation.

U: Mann Whitney test.

p: p value for comparing between the studied groups.

*: Statistically significant at ≤0.05.

Table 5: 6 months clinical outcome and complications

Clinical outcome and complications	Type of graft				Total (n=19)		FEc2p
	Composite (group-A) (n=10)		Synthetic (group-B) (n=9)				
	No.	%	No.	%	No.	%	
6-months Primary patency	9	90.0	6	66.7	15	78.9	1.000
6-months Secondary patency	10	100.0	7	77.8	17	89.5	–
Relief of rest pain	4	40.0	4	44.4	8	42.1	
Healing of ischemic ulcers	6	60.0	4	44.4	10	52.6	1.000
Limb salvage (6 months)	10	100	8	89	18	94.7	
Mortality	0	0.0	1	10.0	1	5.3	1.000
Graft thrombosis	1	10.0	2	22.2	3	15.8	1.000
Major amputation	0	0.0	1	11.1	1	5.3	0.474
Lymph leak	1	10.0	1	11.1	2	10.5	0.491
Graft infection	0	0.0	1	11.1	1	5.3	1.000
Bleeding & hematoma	1	10.0	1	10.0	2	10.5	0.491

χ2: Chi square test. FE: Fisher Exact test.

p: P value for comparing between the studied groups.

Discussion

For an infra-genicular femoro-popliteal bypass, the great saphenous vein is an unquestionable choice as the best conduit. Being natural, resistant to infection, non-immunogenic, and durable are factors in favor of its use in addition to be non-expensive.[1] However, this ideal conduit is not always available or suitable. Data regarding the optimal conduit for below-knee arterial bypass in the absence of a usable single segment GSV are not robust and results have been mixed.[12]

Owing to the disappointing outcome of entirely prosthetic grafts to distal arteries, the concept of a prosthetic–autogenous composite graft was first introduced by McCaughan,[13] and re-evaluated by Linton.[14] Composite conduits results were variable in different studies. They were found, either not superior to prosthetic grafts or had patency similar to that of vein grafts.[15]

In the current study, the median age of the patients was 64.0 years ranging from 60.0 to 66.0 years. Several studies found that peripheral arterial disease (PAD) is more common in age group between 50 and 70 and estimated to be in 25% of population over 80.[16-18]

In the current study, male to female ratio was 11 male to 9 female, denoting more male prevalence of infragenicular ischemic vascular disease in the patients cohort included in this study, this may be explained by the increase in male atherosclerotic disease and risk factor compared to female population. Different reports stated different gender incidence of PAD in different societies and classes. They reported prevalence of severe PAD in males.[19]

Regarding patients' co-morbidities, 65% of the current study patients were diabetics, 75% had essential hypertension, 35% had coronary heart disease, and 45% were smokers. Dyala and colleague.[20] defined risk factors affecting the outcome of bypass surgery to treat below-knee artery disease. They found that the most influencing factors were age, diabetes mellitus and heart disease.

In the current study, statistically significant differences in ABI values were reported, in each group before and after surgery. The mean ABI was 0.40 ± 0.07 for group A and 0.40 ± 0.05 for group B preoperatively. Postoperatively, there was significant increase in ABI mean values to 0.91 ± 0.10, and 0.77 ± 0.06 for group A and B respectively, with P value <0.001. This matches with the study conducted by Gamal and colleagues.[21] in 2017 to study the results of infra-genicular bypass in diabetic and non-diabetic patients with critical lower limb ischemia (CLI). They reported that the mean ankle brachial indices significantly increased after surgery (0.397 ± 0.125 versus 0.779 ± 0.137, P<0.001) in diabetic group and (0.406 ± 0.101 versus 0.786 ± 0.121, P<0.001) in non-diabetic group. Similar results were obtained by Collins et al.[22] studying infra-genicular bypass surgery. They found significant differences between the preoperative and postoperative ABI immediately after surgery and 2 months later. (0.378 ± 0.13 versus 0.699 ± 0.14).

In the current study, an early postoperative significant difference of ABI between group A and group B in favor of group A (P=0.019). This could be explained by better hemodynamics when using a vein in the distal anastomosis and this could be similar to the hemodynamics changes obtained by using a vein cuff at distal anastomosis. Despite that, no statistically significant difference was found between the 2 groups after 3 and 6 months (P=0.270 and 0.364 respectively). This can be explained by possible modulation of the hemodynamics that render both types of conduit hemodynamics equal.

In the current study comparing synthetic versus composite femoro-popliteal grafts for treating CLTI, no statistically significant difference observed between the two groups as regards 1ry patency, secondary patency, and limb salvage (p=1.000). The study reported reasonable 6 months patency and limb salvage in the two studied groups. Similar graft patency (73% in 1 year) and limb survival(76% in 1 year) were reported by Jim et al. (2017),[23] who perform 11 femoro-popliteal bypasses using composite PTFE and vein grafts between 2012 and 2016 denoting durable intermediate-term patency. Moreover, Mazzaccaro et al.[24] compared the long-term outcome of PTFE graft vs venous graft and composite graft for below knee bypass. They reported no significant difference among the three bypass groups regarding survival, primary assisted, secondary and patency rates.

Conclusions

- Infra-genicular femoro-popliteal bypass in anatomically indicated occlusive lesions is an important tool treating CLTI with excellent outcome.
- Vein graft is considered the best conduit. However, synthetic and composite synthetic-vein conduits offer an acceptable alternative in the absence of suitable vein.
- Synthetic and composite infra-genicular grafts give short-term patency and limb salvage comparable to natural one. However, long term results on large numbers of patients are lacking and strongly recommended.
- No significant differences between synthetic and composite infra-genicular grafts regarding patency, limb salvage, and complications on short-term follow up. However, the used of composite graft is still preferred owing to the malleability of its vein part on crossing the knee joint.

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