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Efficacy of the "Popliteal Compression Test" in detecting intraoperative popliteal artery transection injury during knee arthroplasty in a Tier 2 hospital in India: A rapid intra op clinical test to initiate treatment algorithm

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Abstract
Vascular injury during knee replacement surgery is a rare but a catastrophic complication. Its incidence is higher in complex primary and revision knee arthroplasties. Identification of such events at the earliest is of utmost importance to prevent long term morbidity and mortality. A simple clinical test is proposed and evaluated, while the limb is still under tourniquet; to be performed immediately before implantation; that can provide a reasonably accurate indication of such vascular transection injury. We hypothesise that the Popliteal Compression Test (PCT) accurately predicts the occurrence of any intraoperative transection vascular injury also confirmed with post operative CT angiogram thereby conferring an advantage in planning the vascular input in a tier 2 peripheral hospital within the critical revascularisation window. The test was performed on 200 consecutive knee arthroplasty patients (143- primary, 38- complex primary, 19- revision). Three patients showed a positive test of which two patients needed open vascular surgical input. The test has 100% sensitivity, 99.5% specificity, 66.7% Positive Predictive Value and 100% Negative Predictive Value. The greater proportion of high-risk patients in our cohort, a low sample size and a meticulous intraoperative procedure to detect vascular injury prevented direct comparison with literature reported incidence; even so; a χ^2 test was performed. Our limitation was the sample size in this study of only 3 predicted positive patients. The PCT represents a simple procedure that can provide an incalculable advantage in planning at a tier 2 surgical centre, where mobilising a vascular surgical team can take considerable time (up to 4 hrs). This test should be incorporated into the surgical routine of every knee arthroplasty surgeon to prevent physical morbidity to the patient and psychological burden to the surgical team.

Keywords
Knee replacement, Knee arthroplasty, Vascular injury, Clinical test, Popliteal Compression Test, Revascularization window, Arterial transection injury, Intraoperative vascular injury, Sensitivity, Specificity

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1. Introduction

Knee replacement surgery is a very common procedure that is being performed with increasing frequency in tier 2 hospitals in India (1). The incidence of vascular injury in knee replacement is rare but catastrophic. The current incidence in various studies is reported from 0.005% to 0.5% (2-7). Such an event occurs significantly more frequently in complex primary and revision knee replacements due to the altered anatomy and adhesions with synovitis (8). A tourniquet is commonly used in knee replacement surgery to obtain a bloodless field for better visibility and to allow for a good bone-to-cement interlock (9). This makes vascular injury identification difficult intraoperatively and – if found later in the post-operative phase - can lead to a catastrophic delay in planning resources especially in a peripheral hospital (10).

Current detection methods of such a vascular injury usually identify it in the post operative phase, by which time valuable time has been lost within the critical revascularisation window. This study proposes and analyzes the efficacy of a cost-effective, time saving, simple clinical test to detect popliteal arterial transection injury intraoperatively, thus giving the team a head-start in mobilising the necessary resources, if required. We hypothesise that the "Popliteal Compression test" (PCT) performed by the surgeon will serve as a sensitive, specific and a reliable test for intraoperative detection of injury to the popliteal artery during knee arthroplasty and the results of the PCT will not be affected by patient-specific variables such as age, BMI, sex, various comorbidities (diabetes, hypertension, ischemic heart disease, rheumatoid arthritis), side of surgery and type of surgery and therefore will accurately and reliably identify popliteal artery transection injury, if present, when performed during any knee arthroplasty surgery.

2. Materials and Methods

An approval was obtained from the Institutional Ethics Committee (IEC) prior to initiating the study after submitting the research plan, study design and all consent forms based on a W.H.O template (11). A prospective cohort study was performed on patients undergoing knee arthroplasty in a single hospital setting over a period of 7 months (n=200). All patients undergoing knee arthroplasty within a specific period, of all ages, sex, BMI classes, comorbidities and surgery types were included. The specific exclusion criteria are outlined in Table 1. Before enrolment in the study, participants received written study details (PIS) with a verbal explanation by the surgeon and informed consent was obtained. An approved proforma was designed to collect demographic (age, gender) and anthropometric data (height, weight, BMI). Other patient variables such as side, type, comorbidities were recorded. The result of the test (+/-), postoperative follow up score and any additional complications were recorded as well.

The PCT was performed under standardized intraoperative conditions, following a clear, reproducible procedure with defined positive and negative criteria to reduce subjectivity and ensure consistency (Figure 1). Briefly, the patient is placed in a supine position after anesthesia. The tourniquet is applied on the desired limb, with the limb elevated for 60 seconds (not exsanguinated), to empty the blood from the vessels. The tourniquet is inflated to 150 mm Hg above the patient's systolic blood pressure. Surgery begins with a midline incision, medial parapatellar approach. Femoral and tibial bone cuts are performed. Gaps are balanced for proper alignment along with trail implant. The leg is placed in full extension with extension gap clearly visible. Upper calf and lower thigh regions are emptied toward the popliteal fossa using a 'milking' maneuver. An anterior force is applied on the popliteal fossa to detect any fresh bleed in the surgical field from the back of the knee. Any fresh ooze of blood is taken as a positive result, indicating vascular injury to the popliteal artery. No fresh ooze of blood is a negative result, indicating no vascular injury to the popliteal artery. The popliteal artery, due to proximity during bone cuts, ligament releases and retractor use, increased shear stress during extreme flexion and surgical manipulation, is vulnerable to injury. The arterial wall when injured only in the anterior circumference may not reveal a bleed because of the elasticity in the adventitia which allows the torn edges to approximate, since the vessel is not under pressure due to the tourniquet. Hence some posterior pressure will allow the blood remaining in the vessel to be forced out through the rent in the vessel wall.

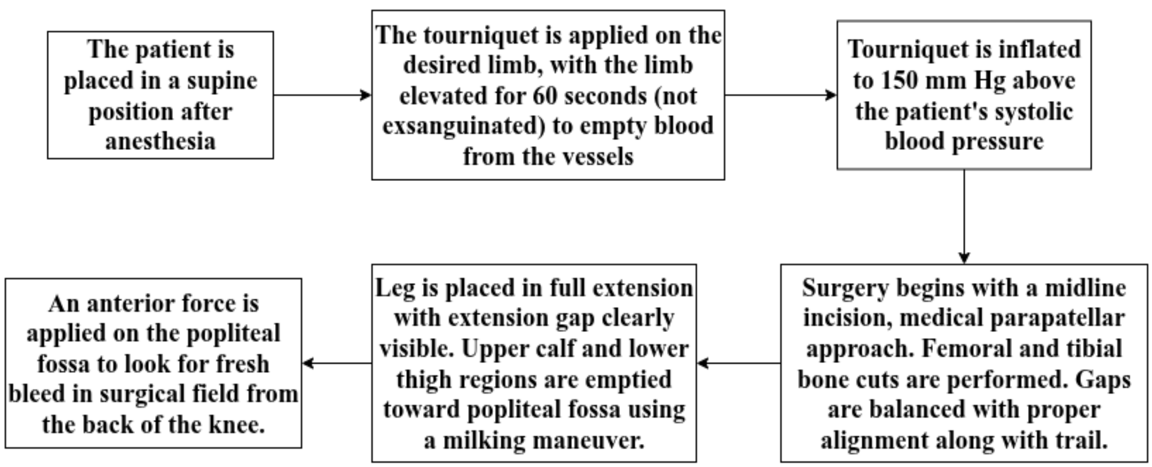

Figure 1. Flowchart showing the steps of the Popliteal Compression Test

Table 1. Patient exclusion criteria

1	Previous vascular surgery to the ipsilateral leg
2	Severe Peripheral vascular disease with ABP index < 0.9
3	Coagulopathies, or on continued anticoagulation
4	No informed consent
5	ASA grade IV and above

Statistical analysis
A χ^2 test was performed with df=1, to test the null hypothesis; i.e. that the expected positive predicted rate of transection injury during knee arthroplasty performed using the PCT (2 out of 200 patients; i.e. 1%) is not significantly different from the positive predicted rate found without using the PCT [literature values of 0.005% to 0.5% (2-7)]. Since the positive predicted rate found using the PCT was only 2 patients, a Fisher's exact test was also performed. P-values of > 0.05 in both these tests were considered insignificant. In addition, a binary logistic regression was performed using R software (15) to ascertain if any of the patient-specific demographic variables influenced the PCT test result. Firth logistic regression was used due to the extremely low number of positive outcomes. A p-value of < 0.01 in this regression was considered signficant.

3. Results

Of the total 200 patients enrolled who met the inclusion criteria, 143 were classified as primary, 38 were complex primary, and 19 were revision replacement. The Mean surgical times were 64, 85 and 110 minutes for these three categories respectively. The demographic distribution of the cohort (gender, age, BMI and co-morbidites) is presented in Figures 2 through 6.

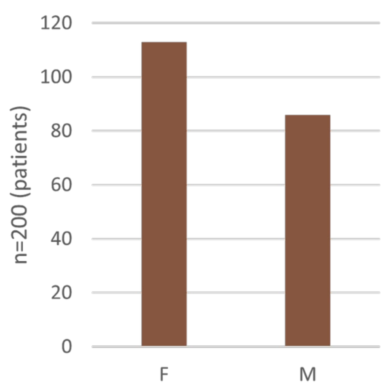

Figure 2. Gender distribution of patients

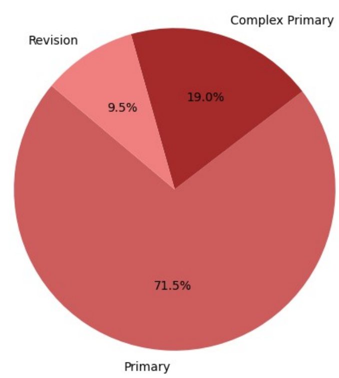

Figure 3. Type of surgery performed

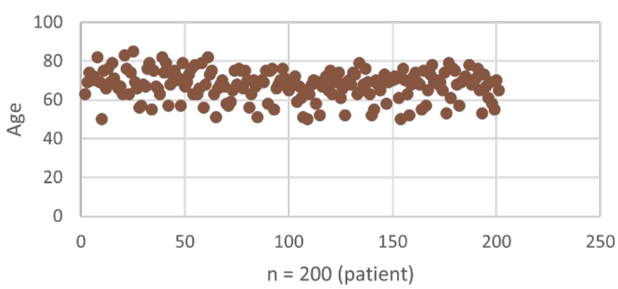

Figure 4. Age distribution of patients

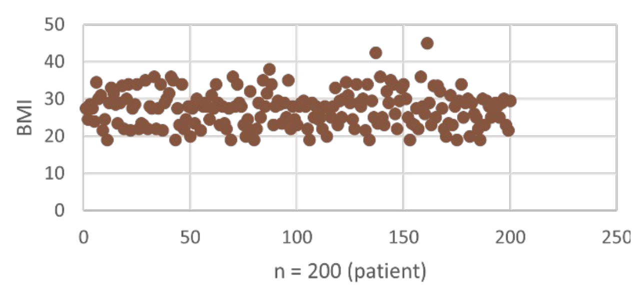

Figure 5. Body Mass Index distribution of patients

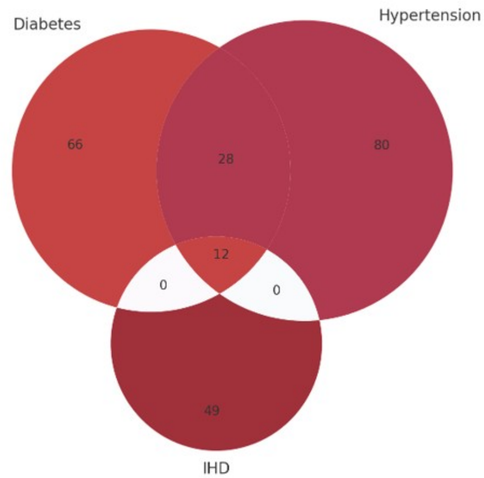

Figure 6. Comorbidities of patients (IHD; Ishemic Heart Disease)

The test was positive in 3 patients (2 in the revision category and one in the complex primary category). All three patients had CT angiography performed, which showed no significant vascular injury in one patient, a 4 mm rent in the anterior wall of the popliteal artery in the complex primary categorized patient and a complete transection of the popliteal artery in the revision knee replacement categorized patient. The vascular surgeon was involved in both of the latter cases and within 90 minutes since the index surgery, the patient was on the operating table in prone position. Through a posterior approach, the neurovascular bundle was explored, the rent was repaired with 6-0 proline in the first patient and a veinous bypass graft was performed in the second patient to avoid any tension in the repair since a segment of the vessel was lacerated. Both the patients had an uneventful recovery and have since made a fully mobile recovery. All patients of the cohort were followed up till the end of 3 months after surgery to detect any signs of chronic ischemia such as skin atrophy, loss of hair, nail atrophy and distal pulses to confirm that no cases were missed from any other causes such as occlusions, compressions or pseudoaneurysm. A functional PROM (Patient-Reported Outcome Measures) scoring was performed on the final visit at the end of 3 months of follow-up using the Oxford Knee Score (OKS-APQ) template (12).

Statistical analysis

When comparing the positive rate of 1% for the PCT versus the lower limit of 0.005% for the rate (without the PCT) in the literature, the χ^2 statistic = 40.35, with a p-value of < $1x10^{-5}$. Hence, at this literature rate, the null hypotheis was rejected. On the other hand, when the positive rate of 1% for the PCT was compared versus the upper limit of 0.5% for the rate (without the PCT) in the literature, the χ^2 statistic = 3.26, with a p-value of 0.07. Hence, at this literature rate, the null hypothesis was accepted. Since the p-value at the lower positive rate in the literature was > 3-orders-ofmagnitude lower (than 0.05) when compared to 1.4 times greater, at the upper positive rate in the literature, the null hypothesis was rejected, implying that that the expected positive predicted rate of transection injury during knee arthroplasty performed using the PCT screening was significantly greater than the positive predicted rate found without using the PCT. Since the expected counts were very low, a Fisher's Exact Test was also performed (14), which also rejected the null hypothesis when compared with the lower end of the literature value (0.005%) with a test statistic of 0.006. The incidence of vascular injury is higher when the PCT is performed, than that in the general population, since we have more than a quarter of patients in our cohort who are at a higher risk of vascular injury (complex primary or revision knee arthroplasty). Further explanation is presented in the Discussion section. Diagnostic accuracy matrices of the test are presented in Figure 7 and Table 2.

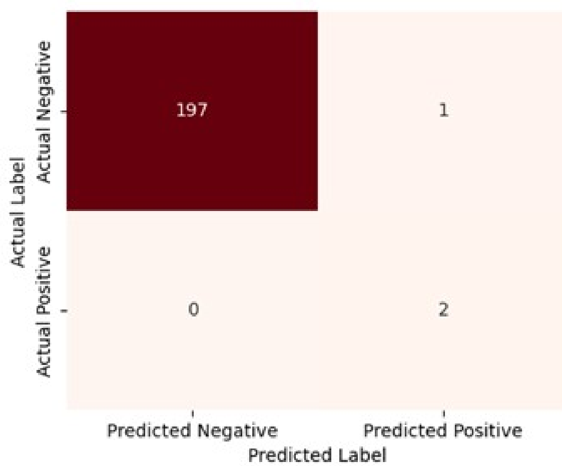

Figure 7. Confusion matrix

Table 2. Diagnostic indices of Popliteal Compression Test

Metric	Formula	Calculated values
Accuracy	TN+TP/(TN+TP+FN+FP)	99.5%
Sensitivity	TP / (TP + FN)	100%
Specificity	TN / (TN + FP)	99.5%
Precision (PPV)	TP / (TP + FP)	66.7%
F1 score	2 × (PPV × Sensitivity) / (PPV + Sensitivity)	80%

No significant associations were observed between patient specific variables and the test result (all p-values > 0.01) as shown in Table 3.

Table 3. Logistic regression analysis of comorbidities with positive PCT

Variable	Logistic Coefficient	SE	p-value (p<0.01)	Association with test result
Age	-0.20	0.089	0.06	No
Gender	1.33	1.22	0.43	No
BMI	0.20	0.10	0.08	No
Diabetes	-0.69	1.22	0.69	No
IHD	2.65	1.13	0.04	No
Hypertension	-1.42	1.15	0.36	No
Rheumatoid Arthritis	1.11	1.53	0.65	No

4. Discussion

Knee replacement surgery can cause unintended vascular insults such as occlusion, pseudoaneurysm, A-V fistula formation and outright transection (16). The focus of this article is on the direct transection of the popliteal artery for which a surgeon is directly responsible and thus has many legal implications. Hence recognition and management of such injury is crucial for the patient in terms of functional disability, for the surgeon in terms of medical liability and cost to the institution (3-5). In a Tier 2 city at a district hospital in India, as of today, there is no vascular service permanently on standby, they are stationed at least an hour away on a good day or even worse; busy in an emergency at another centre. The vascular team hence should be provided with a heads-up as early as possible to attend any other emergency. Hence the early identification of an intraoperative insult is crucial. The critical window for revascularisation for a limb for acceptable survival probability is considered to be 6 hrs (10). The clock starts ticking the moment the injury happens since all distal vascularity is compromised. In a peripheral Tier 2 hospital we do have a provision for a CT scan with the opportunity to do a CT angiography if the results of the PCT are positve. A positive PCT; which prompts a CT scan hence can provide a wealth of information to the vascular team beforehand in planning their surgical approach for such patients (8).

We usually elevate the limb for a minimum of 45 seconds instead of an Esmarch's bandage usage to exsanguinate the limb as we believe exsanguination promotes tissue trauma and thereafter causes increased post-operative discomfort (17). Hence there is some residual blood in the vessels below the tourniquet. This makes identification of a transection of the popliteal vessels easy when there is a back flow from the posterior part of the knee (this forms the basis of our clinical test). The surgeon should be patient enough to allow some time (a few minutes) for this test as it is critical to not misdianose at this stage. In revision and complex primary knee replacement, the posterior capsule along with synovitis makes it a challenge to demarcate the danger zone (11 O' clock to 3 O' clock) (8,18). Injury can occur due to the enthusiasm to clear the tissues for a better tibial bony platform preparation, or during the bony cuts themselves (especially the tibial cut / posterior femur). Hence, such injuries occur with more frequency during revisions and complex primaries than in the simple primary knee arthroplasties. Although newer endovascular advanced techniques have improved outcomes, they are still a luxury in a tier 2 city in India (19, 20).

Identification of these injuries by the PCT in a timely manner has allowed us to ask for help at the earliest, plan for a CT angiogram to confirm the injuries and prompt attendance by the single vascular surgeon in our city to attend. Hence, we propose that such a simple clinical test should be incorporated into the surgical routine procedure to avoid catastrophic delays in identifying time critical events. The fact that all the knee replacements are electives makes it even more important. The test has excellent negative predictive value meaning when the test is negative there is no injury. The one false positive case was due to a smaller genicular vessel branch bleed which needed no treatment. We strongly feel that it is better to over-investigate, than miss such a catastrophic vascular insult; which can be lifechanging for the patient.

The value of the test lies precisely in its ability to prompt this immediate, high-level consultation and objective diagnostic confirmation (CT angiogram), which is paramount in a setting where vascular expertise is not always immediately available on-site. The PCT is designed as a screening tool, not a definitive diagnostic tool. Its primary value lies in its exceptional 100% sensitivity and 100% Negative Predictive Value (NPV). The observed PPV of 66.7% means that for every three positive tests, two genuinely represent a significant vascular injury requiring intervention, while one is a false positive. We acknowledge that this implies a proportion of patients (33% of those with a positive test) will undergo an unnecessary vascular referral and subsequent CT angiogram. However, we strongly justify this approach for the following reasons; 1] The catastrophic nature of missed injury, 2] Minimal risk from a CT scan, 3] Resource optimization in context, 4] No subjective decision to exclude vascular surgeon and 5] No volume threshold (e.g., < x mL). The significantly increased positive prediction rate found using the PCT, when compared to literature PPR without using such a test could be attributed to our study focusing on a high-risk population (complex primary and revision knee arthroplasties) and the meticulous intraoperative detection method that is characteristic of this test; rather than to any differences in the skill and/or competence in performing the arthroplasty itself. Instead of trying to force our observed data to fit a general population incidence, the more appropriate interpretation for our study would be to focus on the screening performance metrics of the test within our study cohort. These values are independent of the population prevalence and accurately reflect the test's ability to identify vascular transection given that an injury occurs.

As none of the demographic characters (age, gender and BMI) or comorbidities (Diabetes, IHD, Hypertension, Rheumatoid arthritis) of the patients showed any significant correlation to a positive PCT (Table 3), the test is reproducible in any knee arthroplasty patient. Hence, by integrating this standardized test into the routine procedure of any knee arthroplasty surgery, we could transform patient outcomes globally, without adding time, complexity, or cost to the surgical procedure. This would also increase patient safety and surgical success, as well as reduce inpatient stay and hospitalisation costs. The concern of iatrogenic test-induced vascular damage to the patient will need to be addressed with a large retrospective comparison between patient outcomes with and without the test. Such a study would be challenging in terms of ethical considerations and comparison with historical cohorts. The test can be validated and its accuracy proven in a multi-centre coordinated study with multiple surgeons and a more diverse patient sample size of > 10,000 (as shown by power analysis) for authentication and optimization. After validation, this test could also be applied in other joint surgeries and in vascular surgeries, among others.

5. Conclusion

In conclusion, the "Popliteal Compression Test" is highly sensitive and specific in detecting intraoperative popliteal artery transection injury during knee arthroplasty. The results of the test are not affected by patient-specific variables, making it applicable to all knee arthroplasty patients. The immediate identification of vascular injury and non-disruption of the surgeon's natural workflow make this test very practical. It can be performed universally in any knee arthroplasty routine. This is especially so in locations with limited resources. The test has the potential to detect injury in time to save a patient's limb, and even their life.

Author contribution

While direct surgical intervention is beyond the scope of a high school student's involvement, Sadhika Arumilli was actively involved in the initial brainstorming sessions that led to the formulation of the research question during her summer volunteer time at the hospital. She participated in discussions regarding the clinical problem of vascular injury during knee arthroplasty and the need for a simple, effective diagnostic tool. Her insights helped construct the hypothesis that a straightforward clinical test could provide a timely solution, especially given the limitations of Tier 2 hospitals. Her responsibilities in the observational and data collection aspects of the study included Proforma Design and Data Entry, observation of the surgical procedure, the test performance and follow-up data collection. She organized the collected data, calculated statistical metrics such as sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) and the clinical significance. She authored the initial draft of the manuscript, including the introduction, methods, results, and discussion sections. She also authored the core narrative, the articulation of the problem, the description of the test, and the interpretation of the results.

Appendix. CT angiogram of a patient whose PCT was positive and a post operative radiograph.

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Appendix

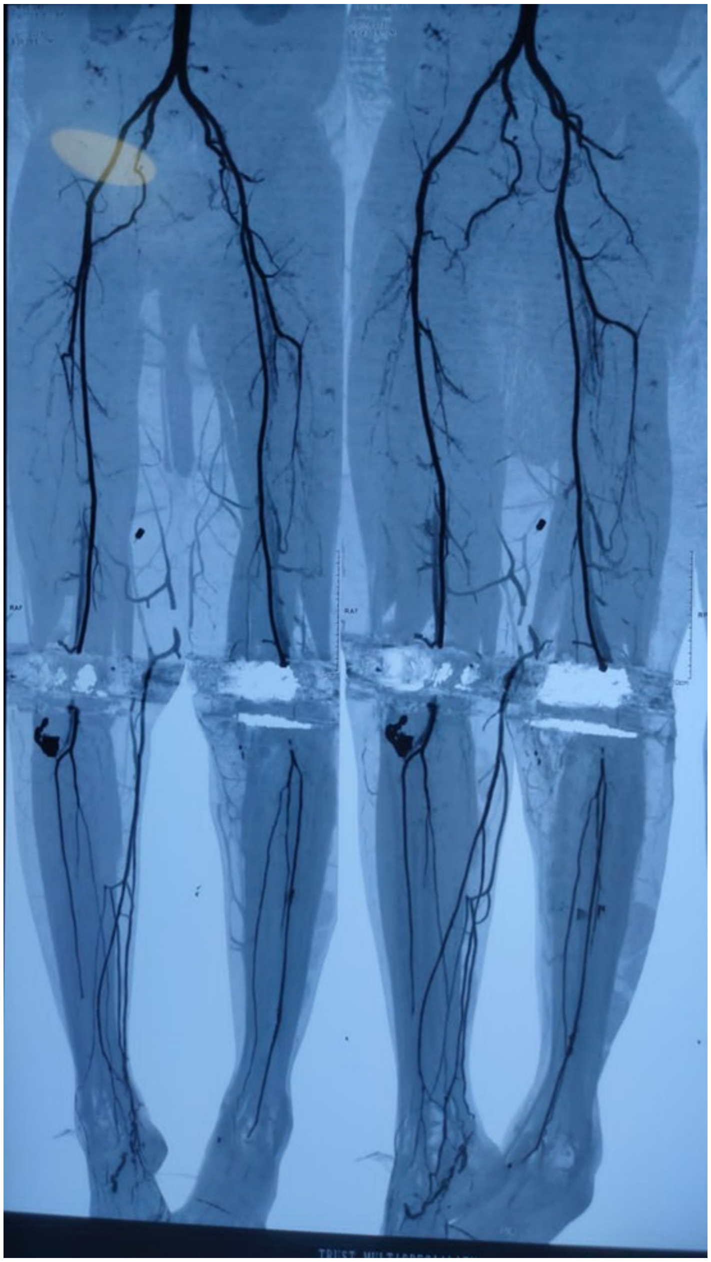

Figure A1. CT angiogram of the patient Mrs VL 53/F. The "Popliteal Compression test" was positive in this patient and an immediate CT Angiogram showed very poor distal runoff with distal saturation of toes below 80%. Immediate vascular input was sought and a veinous bypass graft was used to avoid any tension (to prevent thrombus formation) on the repair. Patient had a warm, pulsatile and vascular limb within the critical revascularisation time from the injury.

Figure A2. Post operative radiographs of the Mrs VL 53/F patient.
After complete transection of popliteal artery and subsequent venous bypass grafting- Anteroposterior and lateral views showing stable implants with a functional limb 3 months after surgery.