



PROJECT COMPLETION REPORT

1. **Project Number** : 6123
2. **Title of the Project** : PLATELET RICH FIBRIN
A study to assess the effectiveness of autologous platelet rich fibrin (PRF) therapy in secondary healing of harvest site wound in patients post coronary artery bypass grafting (CABG).
3. **Funding Agency Name** : Seed Fund of Institute
4. **Project Reference Number provided by the Funding Agency:** NA
5. **Principal Investigator (Name & Address) :** Dr Amita R Associate Professor
Department of Transfusion Medicine
SCTIMST, Trivandrum
6. **Co-Investigators (Name & Address):**
 - i. Dr Debasish Gupta
Professor and Head
Department of Transfusion Medicine
SCTIMST, Trivandrum
 - ii. Dr Varghese Panicker
Professor,
Department of Cardiovascular & Thoracic Surgery
SCTIMST, Trivandrum
7. **Implementing Institution** : SCTIMST
8. **Collaborating Institutions** : NA
9. **Date of Commencement** : 19.12.2020
10. **Duration** : 2 years
11. **Date of Completion** : 18.12.2022
12. **Objectives as approved :**

- 1) Evaluate the effectiveness of autologous PRF therapy in healing of chronic non healing saphenous harvest wounds, in terms of appearance of granulation tissue, reduction in size/ complete healing and control of infection.
- 2) Evaluate the mechanical properties of PRF membrane, including the electron microscopic appearance and tensile strength assessment.
- 3) Evaluate the feasibility of using autologous PRF in our setting, by assessing the preparation failure rate.

13. Deviation made from original objectives if any, while implementing the project and reasons thereof :

Work on electron microscopy could not be completed due to covid pandemic.

14. Field/Experimental work giving full details of summary of methods adopted, data collected supported by necessary tables, charts, diagrams and photographs :



15. Detailed analysis of results :

Study group comprised of 25 cases and 25 age and gender matched controls. 45% were males, and 55% were female. Mean age was 41 ± 8 years (range: 25–59 years). All the patients had a normal hemogram and coagulation profile pre-operatively. Preparation failure rate was 8% (4/50 PRF prepared). All were in the first sample collected. Probable reason - collection line flushed with heparin-saline prior to blood collection, residues interfered with the formation of fibrin. Complications: 4 patients in the control group with infection, required culture and sensitivity testing and antibiotics. Wound healing was achieved in all the 25 patients in the case group.

16. Summary sheet of not more than 2 pages under following heads : (Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)

Attached as separate sheet.

17. Contributions made towards increasing the state of knowledge in the subject :

The non-healing and delayed healing of harvest site wound is a cause of significant patient morbidity and hampers quality of life. The proposed platelet rich fibrin membrane is autologous product, which contains higher numbers of leucocytes and platelets. Use of PRF in wound dressing improved wound healing and control of infection with the use of this membrane. It was cost effective, with no additional risk to the patient.

18. Conclusions summarising the achievements and indication of scope for future

Based on the outcome of the study, we got a beneficial effect of autologous derived PRF membrane on wound healing, it can be used in other clinical scenarios presenting with non-healing wounds involving soft tissue or bone like surgical sternal wounds, dural closures, corneal ulcers, perforated tympanic membrane etc., to control infection and improve wound healing without any adverse effects to the patient.

The development of indigenous PRF preparation box will ensure sterility and standardization of the procedure. This will be the second in the series of autologous derived blood product after platelet rich plasma from our department to be introduced into clinical practice as part of the newly proposed regenerative medicine.

The characterization of the mechanical and biological properties of PRF obtained from patients on anticoagulants is first of a kind.

19. Science and Technology benefits accrued:

a. List of research publications with complete details:

3 manuscripts in writing, will be soon sent out for publication

b. Manpower trained on the project :

i. Research Scientists or Research Fellows : nil

ii. No. of PhD's produced : nil

iii. Other Technical Personnel trained : 3 JR and 3 PG-DBBT students trained

c. Patents taken, if any : 1 design registration number obtained

d. Products developed, if any : PRF preparation box development in progress

20. Abstract: (In 300 words for possible publication in.....Bulletin)

a. Background:

b. Materials:

c. Results:

d. Conclusion:

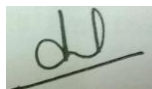
21. Procurement/Usage of Equipment:

a. Details of Equipment:

Sl. No.	Name of Equipment	Make/ Model	Cost (Rs.)	Date of Installation	Utilisation	Remarks regarding maintenance breakdown
1	TABLE TOP LAB CENTRIFUGE programmed for preparation of PRF		73447			

b. Suggestions for disposal of equipment(s):

Instrument is being used in the department for preparation of PRF for our patients with difficult to heal wounds in neurosurgery and interventional radiology.



(Name and Signature of PIs with date)

Dr Amita R

30. Nov 2023

Routing: Signed copy of "Project completion Report" by PI → root@sctimst.ac.in, rpc@sctimst.ac.in

A study to assess the effectiveness of autologous platelet rich fibrin (PRF) therapy in secondary healing of harvest site wound in patients post coronary artery bypass grafting (CABG).

Background:

This process of tissue repair involves a complex, but orderly cascade of events involving many different types of cells, which are recruited and guided by chemical mediators and homed to the damaged tissue from circulation. Most available tissue engineering scaffolds are avascular by nature, but to obtain successful clinical outcomes in terms of regeneration of either soft or hard tissues it is essential that scaffold induce the development of a vascular network. Platelet rich fibrin (PRF) was developed as a second-generation autologous platelet product, by Choukroun et al in 2001 to overcome some of the inherent disadvantages of PRP, such as additional use of anticoagulant which could delay wound healing, allergic reactions to bovine thrombin, short half-life due to rapid removal of released growth factors and cytokines and absence of a matrix to trap the platelets at the site of application. Moreover, the use of extrinsic activators like bovine thrombin can produce a massively uncontrollable but short-lived effect and even anaphylaxis like reaction.

Materials:

This is a pre and post intervention observational study, in which the same patient acts as control (pre-intervention) and test arm (post intervention). All patients, who underwent saphenous vein harvesting for coronary artery bypass grafting in our Institute, presenting with non-healing of the harvest wound and satisfying our inclusion and exclusion criteria will be enrolled in the study, after getting informed consent.

Sample size: All patients who fulfil the selection criteria will be selected.

Rationale: As this is an exploratory study, and not meant to calculate effect measures.

Sampling method: consecutive

Recruitment done from CVTS outpatient department.

Results:

Study group comprised of 25 cases. 45% were males, and 55% were female. Mean age was 41 ± 8 years (range: 25–59 years). All the patients had a normal hemogram and coagulation profile pre-operatively.

Preparation failure rate was 8% (4/50 PRF prepared). All were in the first sample collected. Probable reason - collection line flushed with heparin-saline prior to blood collection, residues interfered with the formation of fibrin. Complications: 4 patients in the control arm with infection, required culture and sensitivity testing and antibiotics. Wound healing was achieved in all the 25 patients in the case group.

Biomechanical properties:

	Dura mater	Connective tissue	PRF Membrane	Remarks
Mean elastic modulus	70 ± 44 MPa	0.1 – 2.4 MPa	0.214 MPa	Deformable
Maximum elongation (Strain at Break)	11 ± 3%	20%	140 %	Stretchable
Tensile strength (Energy to Break)	21 ± 18 N.	2.3 ± 0.1 N	3.485 N	Tensile

Conclusion:

Autologous PRF is a promising biomaterial, for promoting wound healing, preventing infection.

Easily available, with good deformability, stretchability and tensile strength.

Thus autologous platelet rich fibrin (PRF) therapy is effective in secondary healing of harvest site wound in patients post coronary artery bypass grafting (CABG).