



ESTABLISHING SKIN BANK -METHODOLOGY, FUNCTIONALITY & CHALLENGES AT A TERTIARY CARE CENTER (OSMANIA GENERAL HOSPITAL)

Plastic Surgery

Dr. Mummadi Nishanth	MS, MCh, Plastic surgery senior resident, Osmania Medical College, Hyderabad, Telangana.
Dr. N. Nagaprasad*	MS, MCh, (corresponding author) Professor & Head Of Department Of Plastic & Reconstructive Surgery, Osmania Medical College, Hyderabad, Telangana. *Corresponding Author
Dr. Madhusudhana Naik	MS, MCh, Ex- Assistant Professor, Department Of Plastic Surgery, Osmania Medical College, Hyderabad, Telangana.
Mounika Nangineedi	M.S, Senior Development Scientist, Haleon, Richmond, USA.

ABSTRACT

Introduction: There will a need for large amounts of skin graft for burns patients especially with large burn ulcers. Some of these major burns patients will have poor general condition and paucity of skin graft donor sites. Therefore, there is a constant demand for establishing skin bank in major burn centers like Osmania General Hospital (OGH) which caters to huge burns patients load from states of Telangana & adjacent states like Andhra Pradesh, Karnataka, Maharashtra. **Materials & Methods:** Detailed submission of the procedural & technical details of a model skin bank established in Osmania general hospital. Enumerating the various challenges that we encountered in establishing a skin bank in a tertiary care center & various challenges encountered while running a skin bank. **Results:** A total of about 18,100 sq. cm allograft was obtained, Out of which, about 11,000 sq. cm allograft was used for burns patients with better outcome in terms of decreasing the morbidity, hospital stay and better quality of life. **Conclusions:** Due to it's proven efficacy in saving lives as a temporary biological skin cover for extensive burn patients, the use of human skin allografts is crucial. However, there is a significant disparity between the demand and supply of these allografts. Therefore, there is a pressing need to establish more skin banks across India. This article aims to provide guidance to others interested in setting up a skin bank.

KEYWORDS

Skin banking, Skin allografts, Skin transplantation, Tissue banking.

INTRODUCTION

There will a need for large amounts of skin graft for burns patients especially with large burn ulcers. Some of these major burns patients will have poor general condition and paucity of skin graft donor sites. Therefore, there is a constant demand for establishing skin bank in major burn centers like Osmania general hospital which caters to huge burns patients load from states of Telangana & adjacent states like Andhra Pradesh, Karnataka, Maharashtra. A skin bank is an organization having sufficient structure, equipment, laboratory facilities to ensure safety and efficacy of the entire skin banking process. Skin banking is a process in which skin grafts are harvested from eligible cadaveric donor, processed and stored for future use.

The largest organ of the body is skin. A person can survive with more than 60% damage to other organs, such as liver and kidney, but loss of 40% of the skin may be fatal, unless the tissue is replaced. The skin in a major burn patient is deficient even after meshing of skin graft.

The cost of burn treatment depends also upon the type of dressing material that is being used.

Available skin substitutes such as Integra are not economical for large burn patients; skin cultures may be available in limited quantity, in few centers. In such situation, cadaveric skin graft may be the major source & effective cover of the raw area.

In case of deficient donor skin, immediate early excision and cover can be done with allograft.

This is done to protect the excised area and to prepare the wound for future allograft intake. Looking at the necessities, Osmania General Hospital along with Rotary Club Of Hyderabad East & with the contribution from Hetero drugs and National Burns Centre, Mumbai, developed skin bank in the Department of Plastic Surgery, Osmania General Hospital, Hyderabad, Telangana State.

This study is to systematically present the technical aspects of starting a skin bank and to analyze the challenges faced to establish a skin bank, & to help others to start a skin bank and the outcome of using skin allograft for patients with post burn or post trauma raw areas.

AIMS AND OBJECTIVES:

1. To systematically present the technical aspects of starting a skin bank
2. To describe the challenges faced in establishing and running a skin bank at a tertiary care centre.
3. The use of allograft and its outcomes in patients.
4. This study is to guide others to establish a skin bank

Observations

Under the guidance of national burn center Mumbai, Rotary International, and skin bank airoli, Mumbai and with the help of Rotary Club Of Hyderabad East and HETERO group of drugs, and administrative staff of OGH skin bank OGH was established on 28th June, 2021.



Challenges In Establishing A Skin Bank:

Availability of funds: As this is a government institute, there was a problem in raising funds to establish skin bank at OGH. So there as a need to take help of Non Governmental Organizations like Rotary Club Of Hyderabad East and HETERO group of drug company in getting required funds to establish skin bank at OGH.

Identifying The Space: There is a requirement of adequate space to establish a skin bank, so here we adjusted a space for skin bank beside plastic surgery operation theatre.

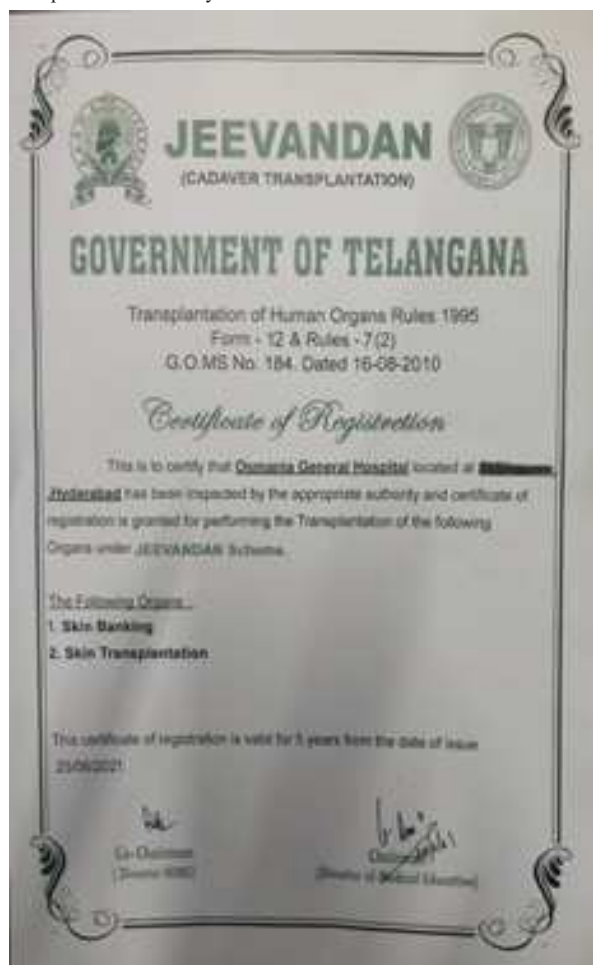
Adequate And Qualified Manpower: To run a skin bank it is a pre requisite to have adequate staff that is qualified and trained to handle, process and store skin allograft. Here, at Osmania general hospital, we have experienced faculty (five in number) and 24 MCh postgraduates, and also paramedical staff for effective functioning of skin bank with out compromising patient care.

Infrastructure Issues: As mentioned above, RCHE and HETERO provided funds to obtain required infrastructure. It is a team approach to organize & co-ordinate at each and every level of administration in getting the infrastructure for its safe delivery and installation.

Getting Permissions: To start a skin bank which handle with skin allograft from eligible donors it is mandatory to get permission from respective state governments and higher authorities.

Installation of equipment: Installation and demonstration of equipment following their procurements from standard equipment manufacturers & suppliers.

Getting Approvals: Getting approval from respective governments and concerned organizations to harvest skin from donors is another challenge. Skin bank OGH has been registered under JEEVANDAN, after the inspection of skin bank by concerned authority and approvals. "JEEVANDAN" is a Telangana state government cadaver organ transplantation authority.



Jeevandan: Skin bank, OGH is included under JEEVANDAN (A scheme for cadaver organ transplantation, in Telangana State).

Inauguration: After the exhaustive planning & execution of the skin bank project, Skin bank at OGH was inaugurated on 28th June 2021.

Training: Faculty from department of plastic surgery & microbiology department, MCh plastic surgery post graduates & technicians from Osmania General Hospital went to NBC Mumbai to get trained in skin bank related tasks and activities.

Awareness: As a part of creating awareness our team conducts awareness programmes with jeevandan coordinators at plastic surgery department regular academic activities (seminars, clinical meets, CME'S, CPD'S) Educating all the junior & senior doctors and at meetings of some communities.

Review: The guidelines shall be reviewed on a regular basis and revised as necessary to incorporate current research findings and improved clinical practice and to improve the functioning of skin bank.

Governance: The Skin Bank shall establish a governance framework to ensure compliance with existing local legislation(s), adequate coverage on all aspects of its operations to safeguard the interest of the people (donors, recipients and employees) and processes within the framework. The governance framework shall, at minimum, encompass: The organization structure; Responsibility and accountability matrix which sets the roles and responsibilities; A process for emplacing appropriately qualified persons to the skin bank; and a quality assurance programme to ensure that the product of each process is of sound quality to meet the intended use of the tissue and a process for review and improvement. There shall be adequate oversight on the recovery sites of the skin tissues, which shall be performed by competent professionals.

Personnel (Directors/ HOD/ Co-Coordinator): The Skin Bank shall have a Directors/ HOD/ Co-Ordinator with commitment to manage the administration and be responsible for all the activities performed by the Bank. The Director/ HOD/ Co-Ordinator shall be qualified by training and/or experience for the scope of activities being performed by the Skin Bank and be familiar with the local regulations governing skin banking. He/She shall be qualified by training and experience in evaluating and determining donor eligibility, particularly with regards to infectious diseases and microbiology. He/She can seek assistance from a Medical Advisory Committee, consisting of consultants to assist in these areas. The Director/ HOD/ Co-Ordinator may delegate the administrative, technical, regulatory, compliance, safety issues, financial and other general activities to suitably qualified designee(s). However, all skin banking activities shall remain the final responsibility of the Directors/ HOD/ Co-Ordinator. Skin banking activities include, but are not limited to: Approval and periodic review of all standard operating procedures (SOPs); Review and evaluation of all reports and investigation of errors, accidents, adverse reactions/outcomes and complaints; Review and notification of appropriate parties of confirmed infectious disease test results in accordance to SOPs; and Approving job descriptions, staff responsibilities, and ensuring that staff responsible for performing homograft banking activities are adequate in number, qualified for the tasks to be performed and that appropriate training is conducted for all staff. The responsibilities of a Directors/ HOD/ Co-Ordinator include: Establishing donor suitability criteria and all standard operating procedures of a medical nature prior to implementation to ensure they comply with the local laws and regulations; Reviewing and approving all policies and procedures of a medical nature in the Skin Bank. Documentation of donor suitability in a timely manner in order to qualify the tissue for preventive or therapeutic use prior to its release into the inventory for distribution; Approval of the release of each batch of skin tissue following processing; Review and evaluation of reports and investigation of errors, accidents, adverse reactions/outcomes and complaints of a medical nature. The Directors/ HOD/ Co-Ordinator shall ensure that his/her designee/s, who will provide coverage during his/her absence, shall have the relevant experience and a clear understanding of the scientific principles and techniques involved in the skin banking activities.

Technical Staff: There shall be an adequate number of qualified and trained technical personnel to supervise and perform all activities of the Skin Bank. The technical personnel shall have an educational

background, documented training and experience commensurate with their assigned duties and a thorough understanding of the procedures and activities they perform.

Quality Control: Standard Operating Procedures (SOPs) including skin tissue processing, preservation, packaging and storage, shall be validated to demonstrate the consistent effectiveness of the aseptic procedures. Instruments and equipment shall be validated and certified fit for use. Processes are in place to ensure that the instruments and equipment are operated by suitably trained personnel. Tests and procedures shall be performed periodically to measure or monitor processing, preservation and storage methods, equipment and reagents to ensure compliance with established tolerance limits. Results of all such tests or procedures shall become part of the permanent record. Environmental monitoring procedures shall be established, when appropriate, for tissue processing facilities. Biohazards and other hazardous waste items shall be disposed off in a manner that would minimize the hazards to the Skin Bank, including personnel and the environment, in accordance with all prevailing local legislation(s). Access to the Skin Bank and the tissue inventory shall be strictly limited to authorised personnel, who are appointed by the Director. Consent shall be obtained from all donors (for living donors) or their next-of-kin (for deceased donors) for the use of their tissues for specified purposes and for any necessary testing. The use of tissues from deceased donors shall be in accordance with relevant prevailing local legislation(s).

Reimbursements and Charges: Monetary compensation or payment cannot be provided to living donors or their next of kin.

MATERIAL & METHODS:

Skin banking protocol at OGH: At each step of procurement, processing and storage of skin allograft, sterile techniques are being followed to minimize the risk of contamination. Upon receiving a call from NGOs or relatives of deceased, death certificate is checked for inclusion or exclusion criteria (like known case of malignancies, HIV, HBsAg, HCV, active jaundice, STDs, Sepsis etc.) of cadaveric skin. After confirming the call, skin harvesting team is organized. The team consists of 3 – 4 members (doctors, paramedical staff). The team reaches the hospital or home with the harvesting kit and explains to the family members about the purpose of cadaveric skin collection and takes their informed written consent. After body examination, skin is disinfected with povidone-iodine and alcohol. Blood sample collected at the time of skin harvesting for serological tests. Skin is harvested (within 6 hours after death) from both the legs, thighs and back under aseptic precautions. The team harvests skin using dermatome and collects strips of skin into 50% glycerol containing antibiotics (12 lac units of inj. penicillin and 1 gram of inj. streptomycin).

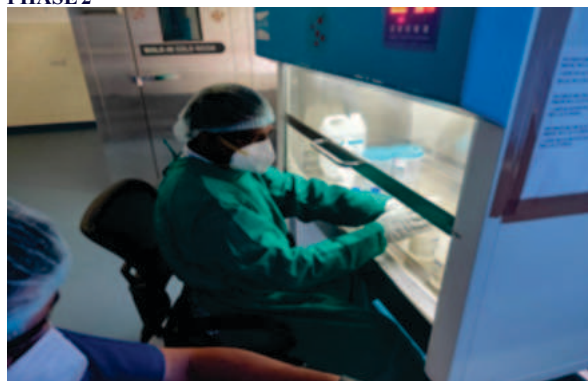
PHASE 1



Dermatome- With Which Skin Is Harvested From Donor

Glycerol preservation helps to maintain anti-microbial environment and minimizes various enzymatic and hydrolytic changes. The anatomical structure and strength is well maintained and antigenicity is also reduced. Additionally, cadaveric skin can be stored in glycerol for 5 years. It is then carried to the skin bank by the same team and kept at 4-8 degree centigrade. Within 48 hours blood reports are obtained. After getting negative blood reports for viral screening & infective pathology, within 48 hours, the skin strips are transferred to 85% glycerol containing antibiotics in the bio safety cabinet, and kept at 33 degree centigrade in shaking incubator for 3 hours, for glycerol lubrication.

PHASE 2



Biosafety Cabinet To Process (phase 2) The Harvested Skin



Shaking Incubator

Skin strips are then stored at 4-8 degree centigrade for further incubation for 3 weeks. After completion of incubation period skin is meshed and quantity is measured (**PHASE 3**) and stored at 4-8 degree centigrade. At this stage skin strips are sent to microbiology lab to rule out growth of any pathogens. After getting a negative report the skin is labeled as ready to use and it can be stored at 4-8 degree centigrade in walk in cold room.



Walk-in cold room to store skin at 4-8 degree centigrade

If it shows growth of any pathogens, the glycerol is changed and stored for 3 months to check for growth. At this stage if a negative report is obtained the skin is labeled as ready to use and it can be stored at 4-8 degree centigrade in walk in cold room as mentioned above. Up to 5th microbiological report the glycerol can be changed if the 5th report also comes positive for growth, then the skin has to be discarded.

Guidelines to be followed to change glycerol in case of infection



Documentation:

Documentation is an important part of skin banking. All the donor details are collected including medical reports and the cause of the death. The data is maintained at skin bank, OGH with a proper donor identity of each skin donated. All serological/microbiological reports are updated regularly.

Skin Donation Pledge Form

Donor card



Certificate of appreciation



Information Brochure



RESULTS:

Till now we harvested skin from 14 cadaveric donors. All are processed and being stored according to the protocol. A total of about 18,100 sq. cm allograft was obtained, Out of which, about 11,000 sq.cm allograft was used for burns patients with better outcome in terms of decreasing the morbidity, hospital stay and better quality of life.

DISCUSSION:

A total of 26 patients have received skin allograft till now. Out of which there are 13 female and 13 male patients. Among Recipients - Age of youngest patient is 18 months and that of eldest is 56yrs. Out of 14 donors, there were 13 males and 1 female. Among Donors - Maximum age was 72 years while minimum age of the donor in this study was 41years. Quantity of skin retrieved per Donor, minimum 912cm², maximum 2475cm², average 1763cm². Out of 14 recipients 13 were patients from our hospital and one is from other government hospital. Transplanted skin maximum per patient 1217.2cm², minimum 175.9cm². Out of 14 patients who received skinbank allograft 12 patients survived and 2 deaths happened with survival rate of 85.71%. In phase 1 of skin harvesting from donor, the processes needs to be streamlined with adequate manpower. In phase 2 & 3 of processing & storing the allograft, the cold chain has to be maintained & the equipment needs to be maintained properly. The selection of recipients of allograft is very important & care to be taken that the allograft is utilized properly.

CONCLUSION:

There are many challenges in establishing and running skin bank, especially at a tertiary care government hospital, and at each and every step of procurement, processing and storage of skin allograft, sterile techniques to be followed to minimize the risk of contamination.

Stored allografts are preferred over synthetic or biosynthetic based dressing material as it has the advantage of decreasing morbidity and mortality from hypovolemia, fluid and electrolyte imbalance in burns and major polytrauma patients, reduced pain, reduced risk of infection and sepsis, avoiding frequent change of dressing and is cost effective.

This paper will help in training the MCh plastic surgery postgraduates to propagate the concept of skin banking and will also help scientists/researchers dealing with similar types of procedures and equipment, to co-ordinate better with doctors and technical people dealing with skin banks for better results.

Despite all the challenges, establishing skin bank & providing allograft to massive burn and major polytrauma patients is essential.

We believe that our humble effort to document & publish all the possible practical details about skin banking will guide other institutes/doctors/scientists/researchers with similar interest to start skin bank to help the poor & needy major burns patients and major polytrauma victims.

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