SKIN SUBSTITUTES

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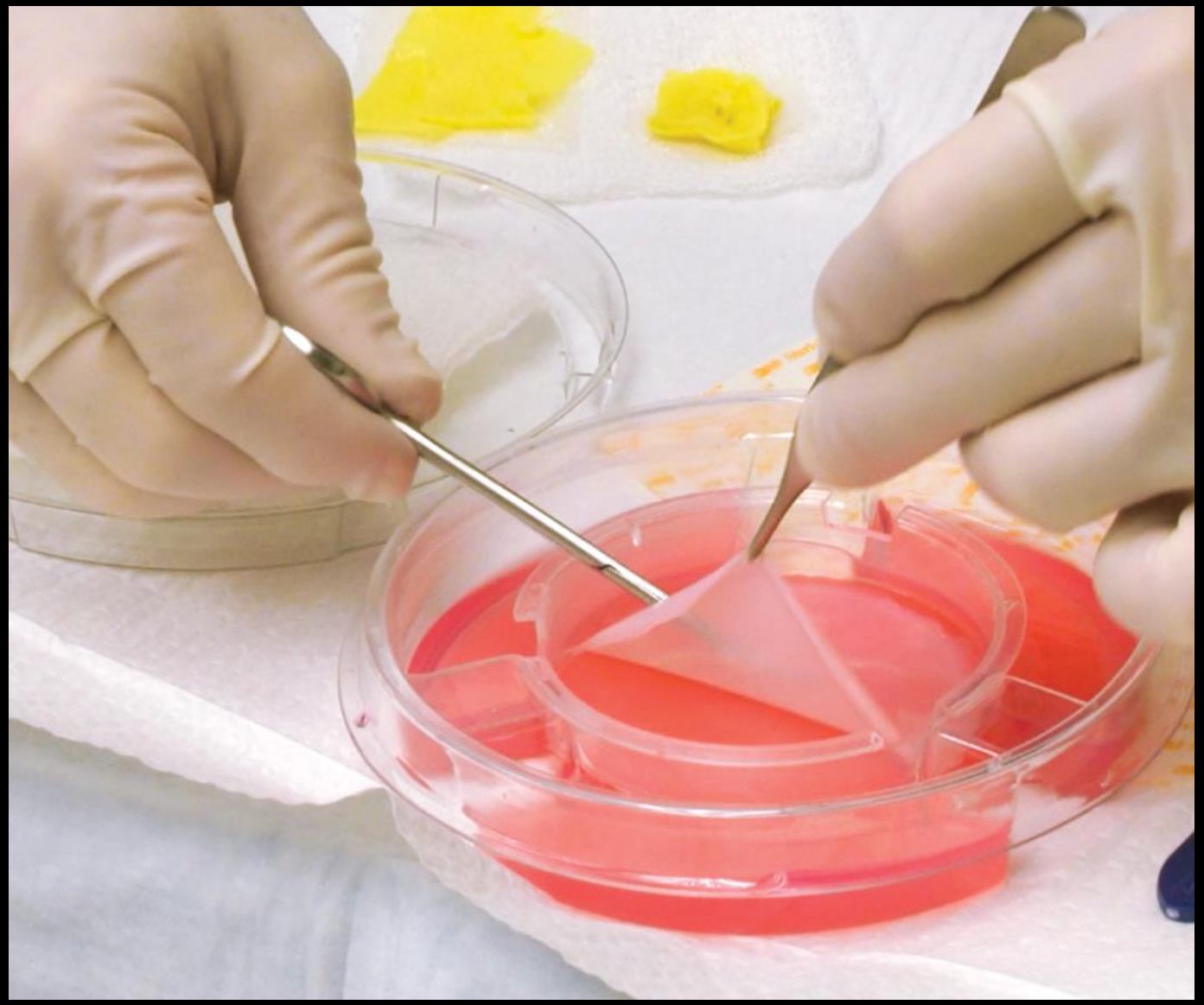
INTRODUCTION

- UNDERSTAND THE BASICS OF SKIN SUBSTITUTES AND THEIR PURPOSE IN ADVANCED WOUND CARE
- DEFINE THE MULTITUDE OF VERSIONS AVAILABLE, THEIR CONSTRUCTS, AND THEIR APPLICATIONS
- RECOGNIZE THE ADVANTAGES AND DISADVANTAGES OF SKIN SUBSTITUTES BASED ON AVAILABLE DATA AND AREAS NEEDED FOR ADDITIONAL STUDY



COMPOSITION

CLASSIFICATION

EARLIER SYSTEMS

- BALASUBRAMANI
- KUMAR
- FERRERIA
- NATHOO

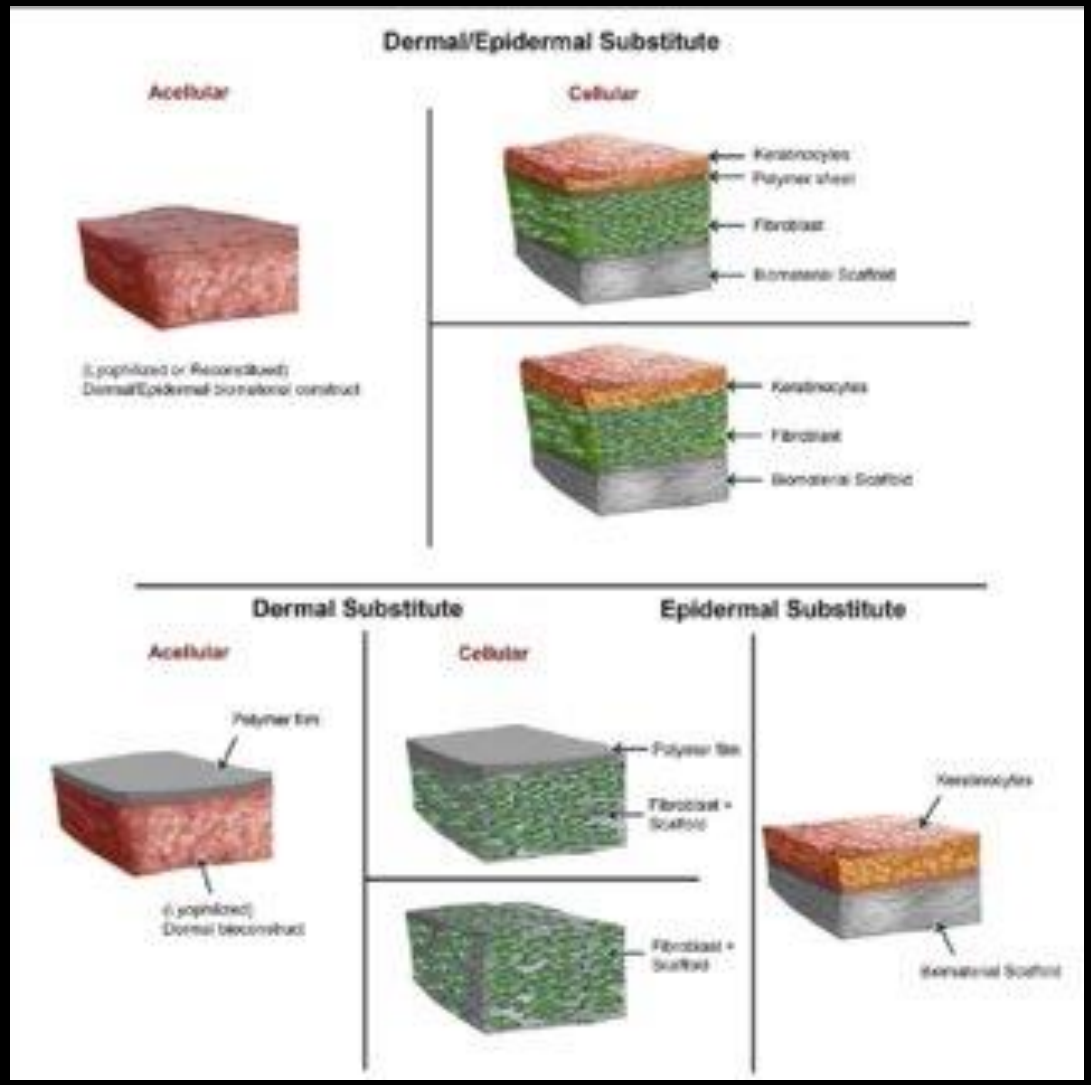
ASTM

- BIOSYNTHETIC
- BIOSYNTHETIC AND ANIMAL BASED
- NON LIVING TISSUE
  - HUMAN
  - ANIMAL
- LIVING AND BIOLOGIC
  - MINIMAL
  - CULTURED
  - CULTURED AND ANIMAL

DAVISON-KOTLER

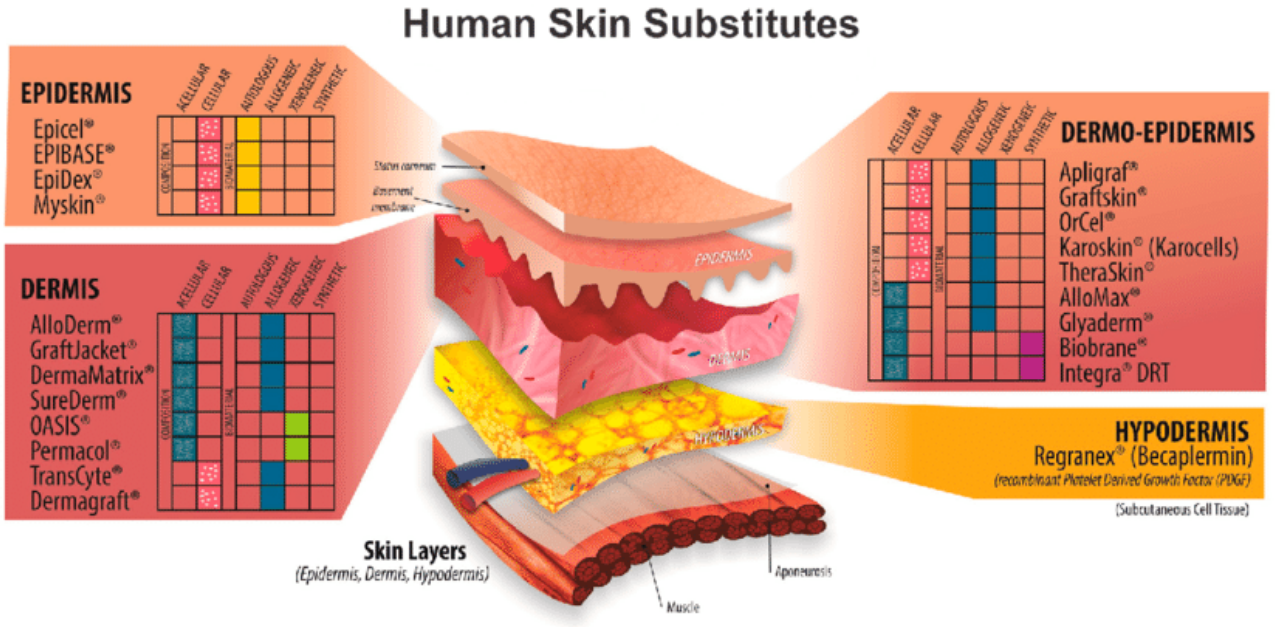
- CELLULARITY
- LAYERING
- REPLACED PORTION
- MATERIALS
- PERMANENCE

SIMPLIFIED


Dermal/Epidermal Substitute
Acellular
Cellular
Keratinocytes
Fibroblast
Keratinocytes
Fibroblast
Dermal Substitute
Epidermal Substitute
Acellular
Cellular
Fibroblast +
Fibroblast +

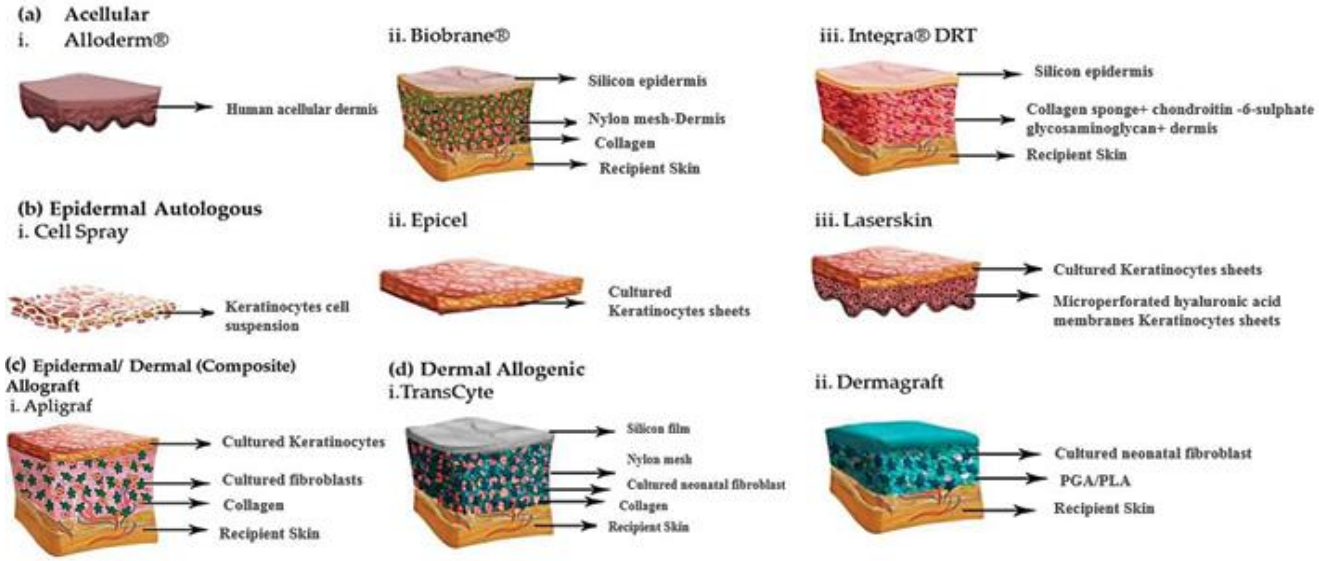
ACELLULAR

- BIOLOGIC DERMAL SUBSTITUTES MOST COMMON
- PRODUCTS
  - DECELLULARIZED HUMAN DERMIS
  - HUMAN PLACENTAL MEMBRANES
  - ANIMAL TISSUE
- NATURAL SOURCES
  - SIMILAR TO NATIVE DERMIS
- PRONE TO DEGRADATION



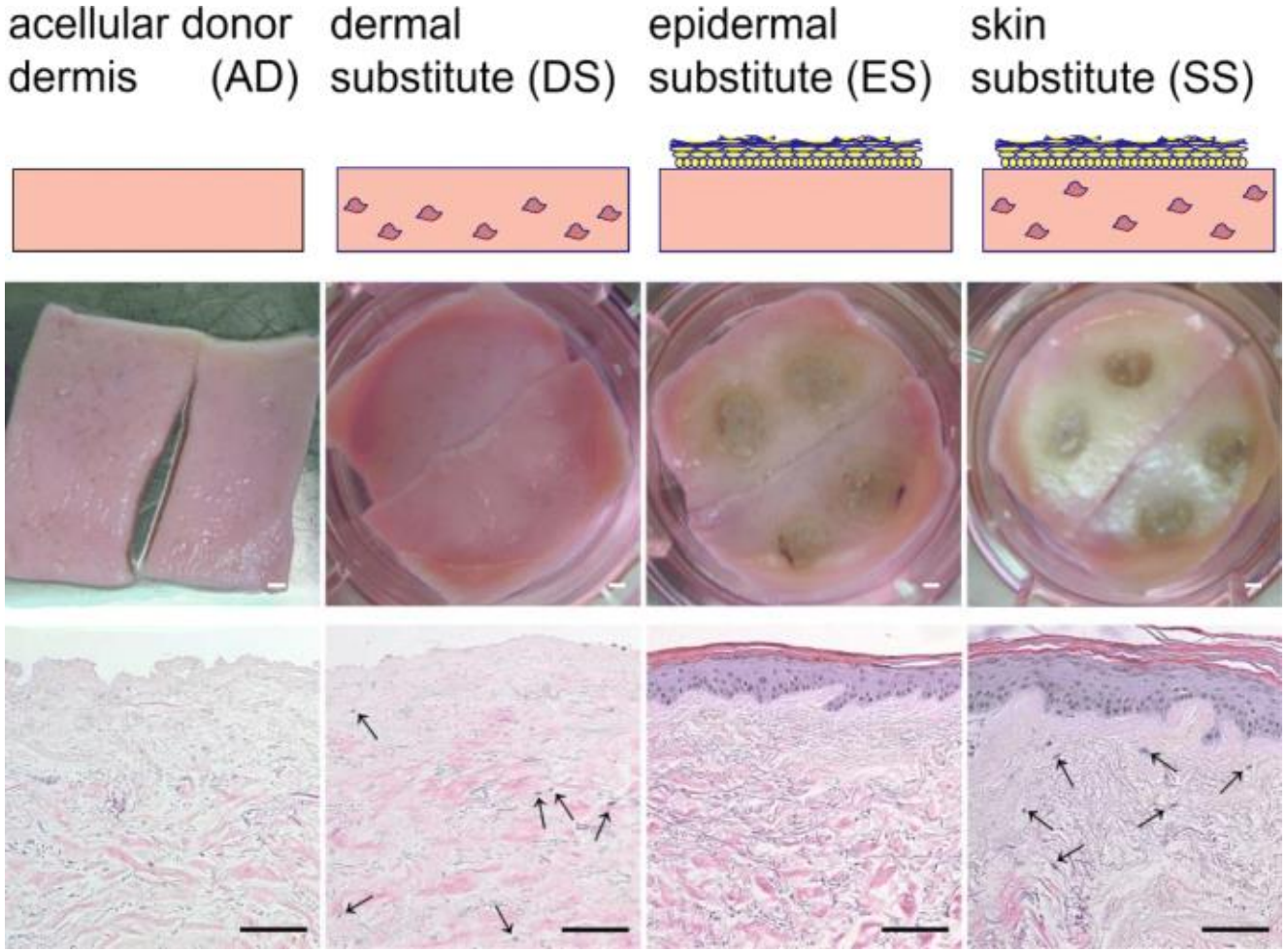
CELLULAR

- AMNIOTIC MEMBRANE PRODUCTS
- HUMAN FIBROBLAST DERMIS
- HUMAN LIVING ALLOGRAFT
- AUTOLOGOUS SKIN
- BIOENGINEERED TWO LAYER SKIN (HUMAN AND ANIMAL TISSUE)



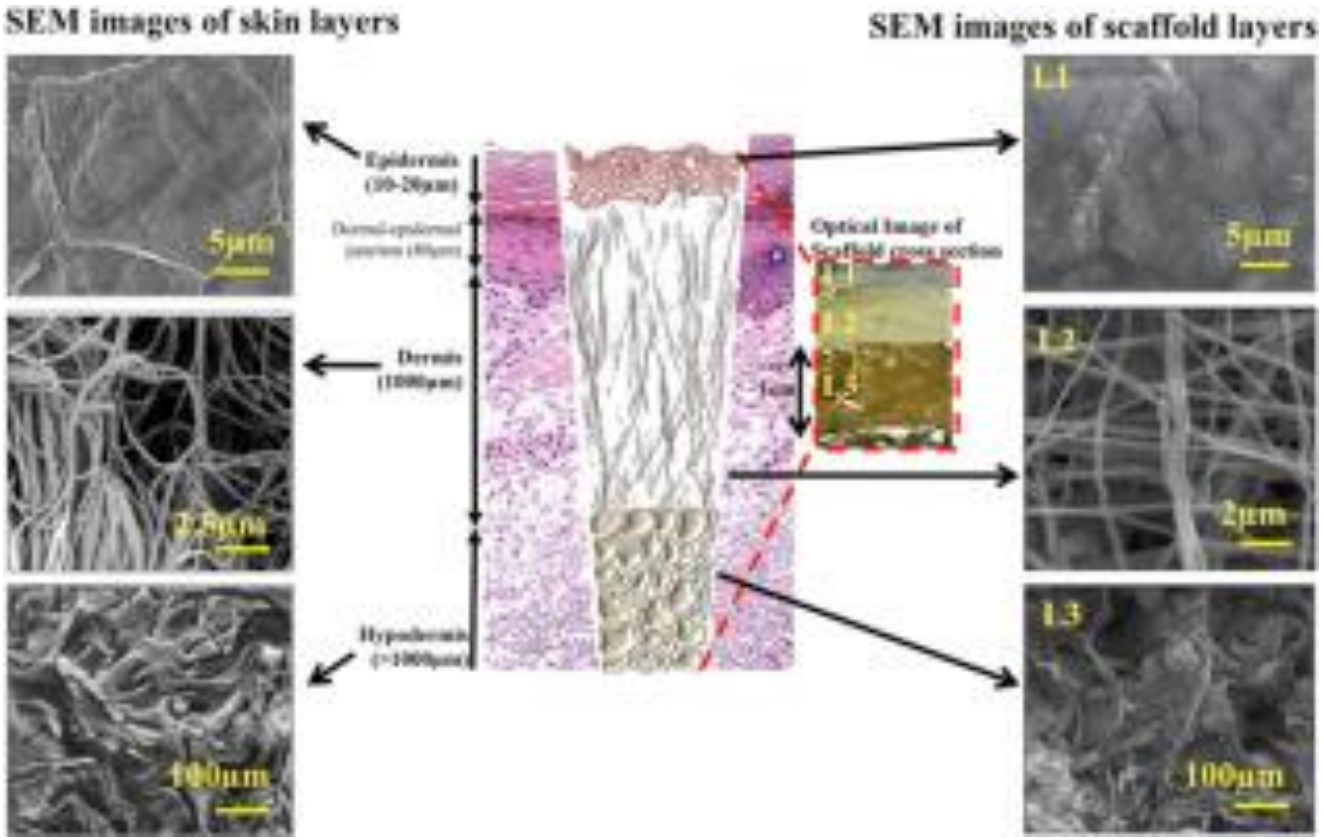
SINGLE LAYER

- EPIDERMAL SUBSTITUTES
  - CULTURED EPITHELIAL AUTOGRAFT
- DERMAL SUBSTITUTES
  - MOST ARE ACELLULAR
  - BOVINE COLLAGEN SHEET
  - PORCINE COLLAGEN SHEET
  - BOVINE DERMAL MATRIX
  - HUMAN DERMAL MATRIX



DOUBLE LAYER

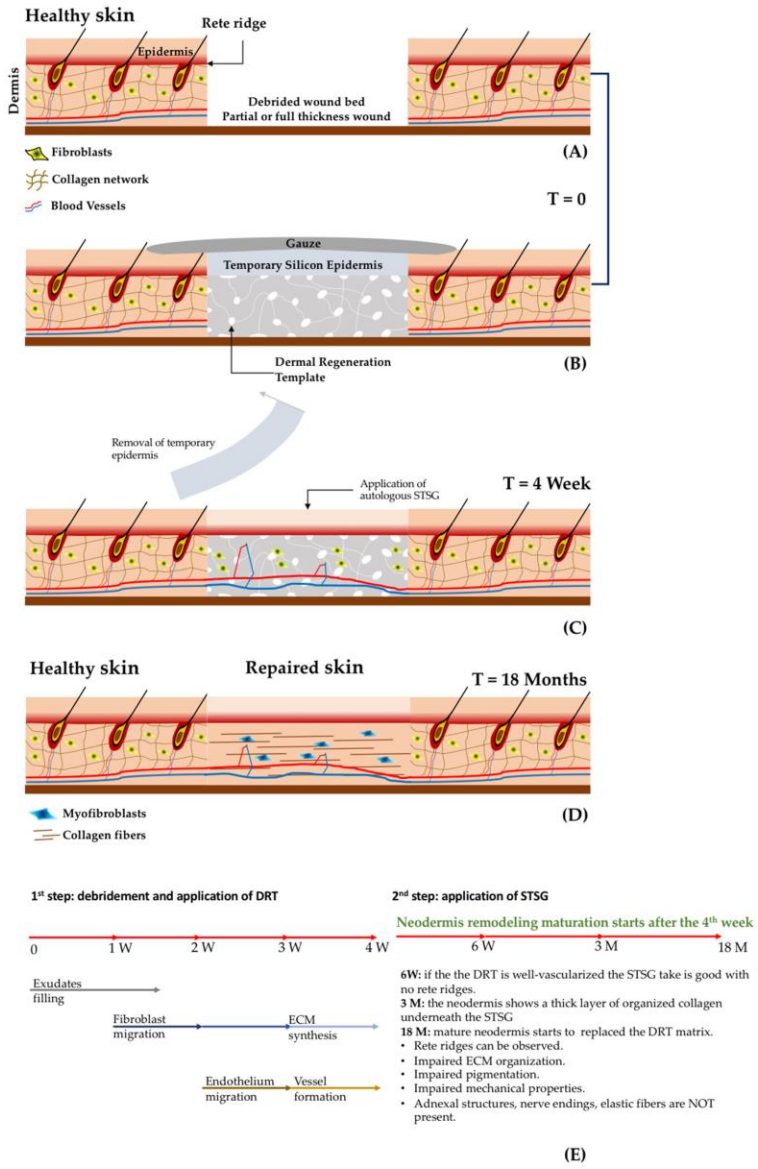
- SKIN GRAFT
  - MOST ARE CELLULAR OR COMPOSITE
- TISSUE ENGINEERED SKIN



PURPOSE

BRIDGE

- TEMPORARY SUBSTITUTES MEANT TO FACILITATE GRAFTING
- PROVIDE PHYSIOLOGIC CLOSURE OF DEEP DERMAL AND FULL THICKNESS WOUNDS
- MOST COMMONLY COMPOSITE OF NATURAL ACELLULAR DERMIS WITH SYNTHETIC SEMI-POROUS EPIDERMIS

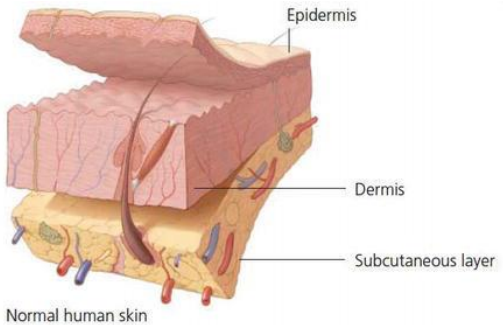


REPLACEMENT

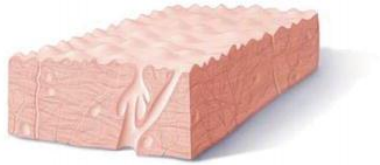
- PERMANENTLY ACHIEVE WOUND CLOSURE
- MEANT TO REPLACE ALL SKIN COMPONENTS
- MAY PROVIDE HIGHER QUALITY SKIN REPLACEMENT THAN SPLIT THICKNESS AUTOGRAFT

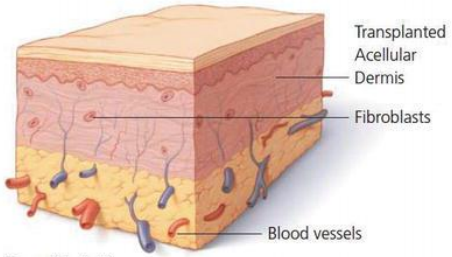
SCAFFOLD

- MOST ARE ACELLULAR SINGLE LAYER DERMIS
- MOST COMMON PRODUCTS AVAILABLE
- MEANT TO FACILITATE EPITHELIALIZATION AND PAIN CONTROL
- COMPOSED MOSTLY OF COLLAGEN

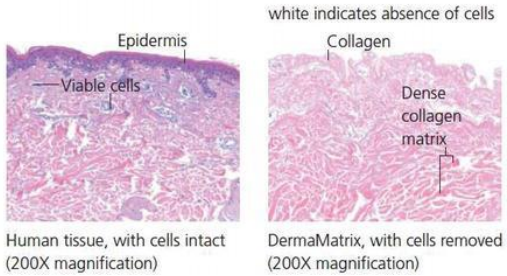


Normal human skin


DermaMatrix 3D Collagen Matrix



Remodeled skin



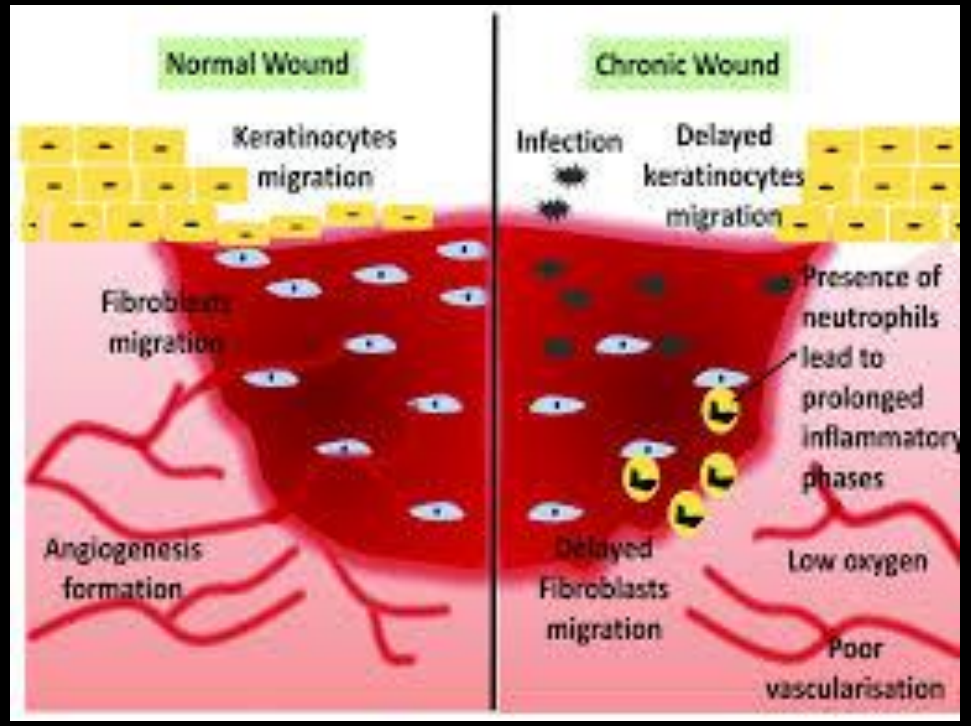
Human tissue, with cells intact (200X magnification)

DermaMatrix, with cells removed (200X magnification)

APPLICATION

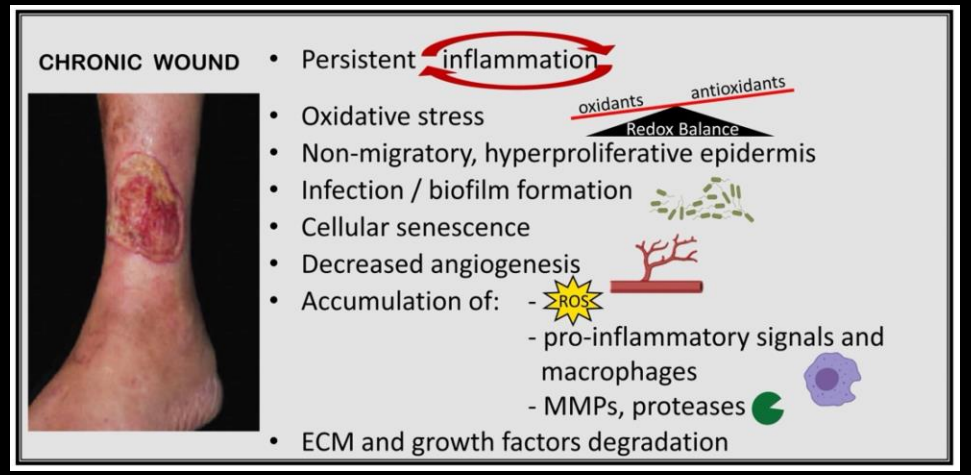
WOUND TYPES

- INITIALLY INTRODUCED TO MANAGE EXTENSIVE BURNS
- MOST COMMONLY EVALUATED CURRENTLY: DIABETIC FOOT ULCERS
- OTHER COMMON WOUNDS INCLUDE VENOUS LEG ULCERS, PRESSURE ULCERS, AND ARTERIAL LEG ULCERS



CHRONIC WOUNDS

- FAIL TO PASS THROUGH NORMAL HEALING PROCESS IN TIMELY FASHION
- REMAIN IN INFLAMMATORY PHASE
- NO PROGRESSION TO PROLIFERATION AFTER 4 WEEKS OF STANDARD THERAPY



WHEN TO TREAT

- STANDARD OF CARE
  - DEBRIDEMENT
  - MAINTAIN MOISTURE BALANCE
  - PREVENT OR TREAT INFECTION
  - CORRECT ISCHEMIA
  - COMPRESSION FOR VENOUS HYPERTENSION
  - OFFLOADING FOR DFUS
- INDICATIONS FOR ADDITIONAL THERAPIES
  - LESS THAN 50% WOUND SIZE REDUCTION AFTER 4 WEEKS
  - 50% OR GREATER REDUCTION A STRONG PREDICTOR OF HEALING BY 12 WEEKS

DATA FOR SOC V SUBSTITUTE

ACELLULAR DERMIS

- TWO FOLD INCREASE CHANCE OF COMPLETE HEALING IN DFU'S
- SHORTER TIME TO HEAL IN BOTH DFU'S AND VSU'S
- STATISTICALLY SIGNIFICANT IMPROVEMENTS NOTED UP TO 16 WEEKS
- ADVERSE EFFECTS:
  - DIABETIC FOOT INFECTIONS
  - CELLULITIS
  - OSTEOMYELITIS
  - RECURRENCE

CELLULAR DERMIS

- STATISTICALLY SIGNIFICANT IMPROVEMENTS NOTED UP TO 12 AND 16 WEEKS
- WOUNDS HEALED AND TIME TO HEAL IN VSU'S IMPROVED WITH 4 LAYER COMPRESSION
- COMPLETE HEALING IN DFU'S SIGNIFICANTLY FAVORED
- LESS CHANCE OF RECURRENCE

ACELL V CELL DERMIS

- SIMILAR BENEFIT REPORTED FOR DFU'S HEALED UP TO 10 WEEKS
- SIMILAR RESULTS ALSO NOTED:
  - TIME TO HEAL
  - CHANGE IN SIZE
  - 6 MONTH RECURRENCE
- SIMILAR ADVERSE EVENTS ALSO NOTED

DATA FOR SUBSTITUTE V SUBSTITUTE

CELL DERMIS V CELL BILAYER

- STATISTICALLY SIGNIFICANT BENEFITS NOTED IN DFU'S AT 12 WEEKS INCLUDING WOUNDS HEALED AND TIME TO HEAL

CELL BILAYER V CELL BILAYER

- NO STATISTICALLY SIGNIFICANT DIFFERENCES NOTED FOR VSU'S
- NO RECURRENCES NOTED

FURTHER STUDY

- LACK OF STUDIES FOR NUMBER OF AVAILABLE PRODUCTS
- LACK OF CLINICALLY RELEVANT DATA
  - AMPUTATION RATES
  - WOUND RECURRENCE
  - RETURN TO FUNCTION
  - PAIN CONTROL
  - EXUDATE
  - ODOR
- VARIABILITY OF SOC
- RISK BIAS

QUESTIONS?

THANK YOU FOR YOUR ATTENTION