



Integra...

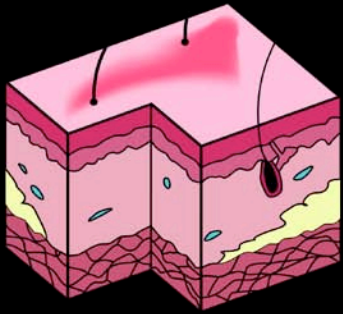
Overpriced, Understudied, Overrated

Phillip D. Smith, MD

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Department of Surgery Grand Rounds
University of Colorado

Burn Thickness



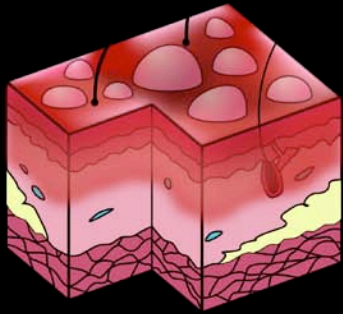
Epidermis

Dermis

Subcutaneous Tissue



Superficial



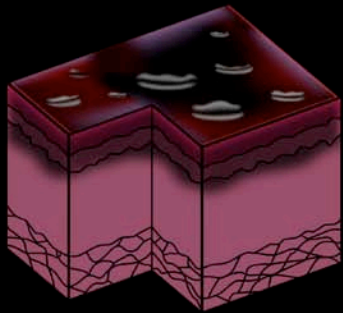
Epidermis

Dermis

Subcutaneous Tissue



Partial Thickness



Epidermis

Dermis

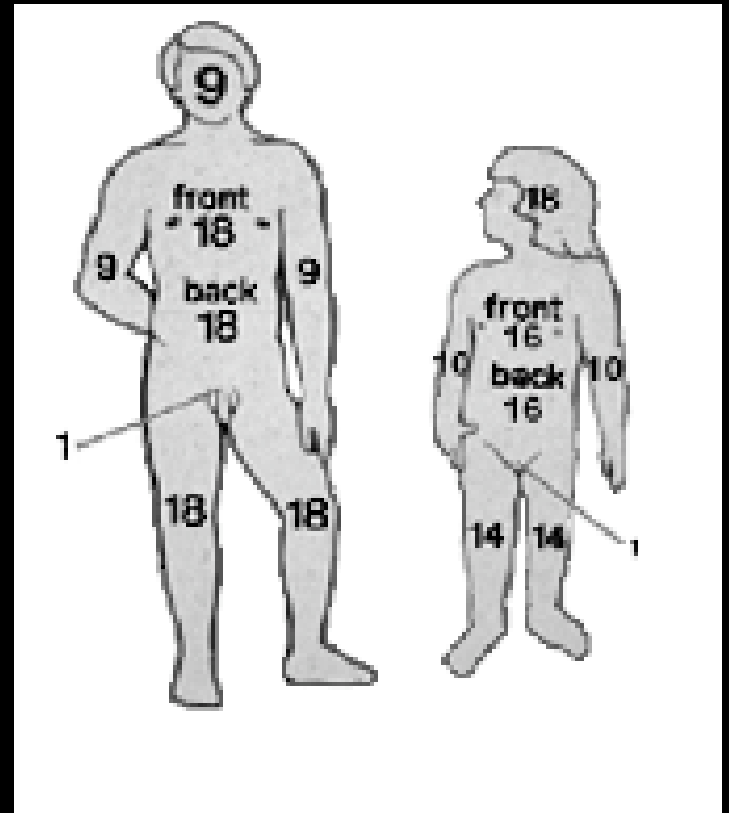
Subcutaneous Tissue



Full Thickness

Burn Center Referral Criteria

- Partial Thickness Burns > 10% TBSA
- Face, hands, feet, genitalia, perineum, major joints
- Any full thickness
- Electrical/lightening injury
- Chemical Burns
- Inhalational Injury
- Significant Comorbidities



Initial Burn Management

- Intubation
 - GCS < 8, stridor/hoarseness, post pharyngeal burns, TBSA > 60%
- Escharotomy
 - Extremity escharotomy for compartment syndrome
 - Torso escharotomy for \uparrow PAP
- Resuscitation
 - Parkland = 4 cc x weight (kg) x % TBSA
 - $\frac{1}{2}$ in first 8 hours, second $\frac{1}{2}$ over next 16
- Early excision and grafting

Options for Covering the Extensive Burn Wound

Autograft

Allograft

Integra

Biobrane

Transcyte

Integra

Pros

Decrease burn sepsis

Cosmesis

Contracture

Cons

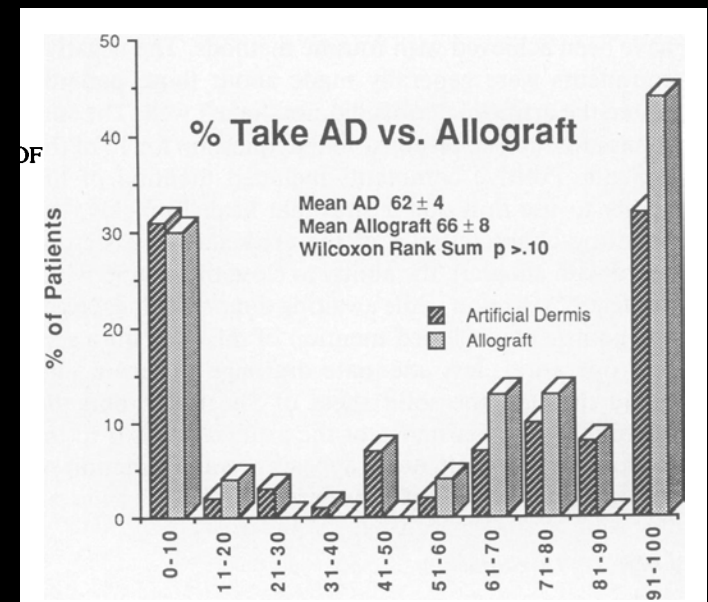
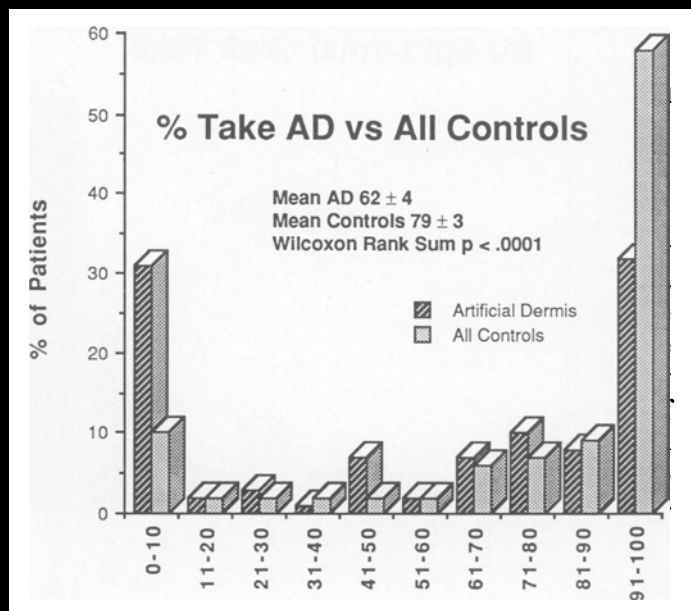
Expense

Graft infection

Efficacy

Artificial Dermis for Major Burns

- Ann Surg. 1988.
 - Prospective, randomized, multicenter trial
 - 139 sites, 106 patients



All controls 95% versus Integra 80%

Important Points

- No mortality data
- No LOS data
- All advantages were based on subjective assessment
 - “Normalcy” of donor site, surgeon’s overall evaluation of graft, etc.

FDA Approval 1996 → Treatment of severe burns

Integra Decreases LOS

- Retrospective review
 - 270 patients with > 20% TBSA burns between 1990 and 2000

Total Patient Population

	Control: No Integra®	Treatment: Integra®	t-test
Number of patients	227	43	NA
Age (mean ± SD)	46 ± 20 years (range 18–94 years)	50 ± 21 years (range 19–83 years)	<i>P</i> = .24
Percent BSA Burned	42 ± 22% (range 20–97%)	50 ± 22% (range 25–90%)	<i>P</i> = .02*
Inhalation injury present	67 patients (30%)	31 patients (72%)	<i>P</i> < .001*
Mortality	69 patients (30%)	13 patients (30%)	<i>P</i> = 1.00

Total Survivors

	Control survivors	Integra® survivors	t-test
Number of patients	158	30	NA
Age	39 ± 15 years	43 ± 15 years	<i>P</i> = .20*
Percent BSA burned	36 ± 17%	51 ± 21%	<i>P</i> < .001*
Inhalation injury present	42%	63%	<i>P</i> = .04*
Escharotomy required	27%	89%	<i>P</i> < .001*
Number of mortality risk factors present	0.7 ± 0.7	1.4 ± 0.7	<i>P</i> < .001*
LOS	47 ± 47 days	64 ± 23 days	<i>P</i> < .001†

Subgroup Analysis

> 60 years old, > 40% TBSA, inhalational injury, escharotomy

	No Integra®	Integra®	P value
Number patients	29	15	
Age (Mean \pm SD)	42 \pm 18 years	42 \pm 20 years	Not significant
Inhalation injury present	100%	100%	Not significant
Percent BSA burned	59 \pm 21% BSA	55 \pm 19% BSA	Not significant
Full-thickness burn (percent BSA excised and grafted)	44 \pm 19% BSA	45 \pm 16% BSA	Not significant
Percent BSA grafted with Integra®	0	19 \pm 13% BSA	Not applicable
Percent of patients who required escharotomies	55%	93%	0.009 †
Time-to-clinically effective wound closure	79 \pm 60 days	49 \pm 14 days	0.11*
LOS	107 \pm 60 days	63 \pm 18 days	0.014*

- Integra group all treated after 1996
 - Historical controls
 - ICU critical pathways established
 - ARDS net developed
 - Decreased OR time
 - Surgeon practice patterns changed

Postapproval Clinical Trial

- J Burn Care Rehab. 2003 (24):1.
- Prospective, observational study of 222 patients
 - No control arm... all patients received Integra
- 13.2% superficial infections
- 3.1% invasive infections
- 76.2% take

Increased infections and decreased take

Integra in Pediatric Populations

- Crit Care Med. 2007 (35):11.
 - Prospective, randomized trial
 - 10 children per arm
 - Integra decreased energy expenditure, increased bone density and biochemical markers
 - No difference in sepsis
 - 20% increase in cosmetic score

Statistically significant, clinically irrelevant

Debunking Allograft Myths

- Only 1 reported case of HIV transmission (none since 1987)
- No reported cases of hepatitis transmission
- Scant evidence for CMV seroconversion
- Tissue Banking increasing

Integra Cost

- \$11/cm²
- 6' 180 lb male = ~2 m²
- For 40% TBSA burn = \$ 88,000

Summary

- Integra
 - No proven efficacy
 - Infection rates increased compared to allograft
 - Expensive
 - Minimal cosmetic benefit
 - Cost prohibitive

Conclusion

Integra has no proven efficacy and is cost prohibitive as a mainstay in the treatment of severe thermal injuries