Lessons Learnt Using Integra® in Lower Leg and High Risk Foot Wounds

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Declaration of Financial Interests or Relationships

Speaker Name: Donna Angel

I have no financial interest or relationship(s) to disclose
Integra® Dermal Regeneration Template

Bilayer membrane system for skin replacement

**Layer one**
- Porous matrix of fibers crossed-linked with bovine tendon collagen
- Glycosaminoglycan (chondroitin-6-sulfate) (shark cartilage)
- Controlled porosity and defined degradation rate

**Layer two**
- Epidermal substitute layer – silicone layer
  - Control moisture loss from the wound
  - Barrier from microbes

**Single layer**
- Dermal replacement layer only
Integra® Dermal Regeneration Template

The shark cartilage and collagen mimic the substructure of the dermis providing a framework for the blood vessels and cells to regrow a new dermal layer.
Aim

Prospective observational study
14 patients with complex wounds
Integra® dermal replacement template
To promote wound healing
August 2017 – May 2018

Ethics approval not required
Integra® available on the tender for use in complex wounds
## Demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>3</td>
<td>23.07</td>
</tr>
<tr>
<td>Male</td>
<td>11</td>
<td>76.92</td>
</tr>
<tr>
<td>Age range</td>
<td>39 - 80</td>
<td></td>
</tr>
<tr>
<td>Mean age</td>
<td>61.76</td>
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</table>
Wound Aetiology

- Arterial: 1
- Neuro-ischaemic: 2
- Mixed: 1
- Neuropathic: 8
- Pyoderma gangrenosum: 2
Anatomical Location

- Amputated toe/s: 3
- TMA: 4
- Plantar: 3
- Malleolus: 2
- Lower leg: 1
- Dorsal: 1
Co-morbidities

- PAD: 5
- T2DM: 12
- ESRF: 0
- HTN: 6
- Peripheral Neuropathy: 13
- Hyperlipidaemia: 6
Single Layer Integra® Application

**Theatre**
- Two patients
- Single layer
- Integra®

**Patient One**
- Split skin graft
- **Mepital®** as interface layer
- Smith and Nephew – Renasys™

**Patient Two**
- Split skin graft
- **Acticoat** as interface layer
- Smith and Nephew – Renasys™
Bilayer Integra® Application

Theatre
• Eight patients bilayer Integra®

Seven patients
• Acticoat interface layer
• KCI ActiV.A.C®
• Sealed for 7 days

One patient
• Acticoat interface layer
• Smith and Nephew – Renasys™
• Sealed for 7 days
Bilayer Integra® Application

**Ward**
- **One** patient Bilayer Integra®
- Acticoat interface layer
- KCI ActiV.A.C®
- Sealed for 7 days

**Outpatients**
- **Three** patients Bilayer Integra®
  - **One** patient: Acticoat only
  - **Two** patients: Acticoat interface layer, KCI ActiV.A.C®
## Bilayer Integra® Silicone Layer Removal

<table>
<thead>
<tr>
<th>Silicone layer removed in 12 patients</th>
<th>Time to removal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum</td>
<td>7 days</td>
</tr>
<tr>
<td>Maximum</td>
<td>27 days</td>
</tr>
<tr>
<td>Average</td>
<td>17.62 days</td>
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<tr>
<td>Not recorded</td>
<td>2 patients</td>
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</table>
Wound Healing

Largest wound size
Circumferential

Smallest
1.6 x 1.1 cm

Bone on view
4 patients

Tendon on view
2 patients
Wound Healing

Wound Healed within 4 months
7 patients
One patient
neuro-ischaemic
revascularised
Single layer Integra®
SSG – failed
Subsequent wound healing

Almost healed!
5 patients

One patient - BKA
One Patient - AKA
Losses

41 year old male

Chronic ulcer 2nd MTPJ
Washout – April 2017
Long term oral A/B's
OM Dx August 2017

T2DM, HT, depression, sleeve gastrectomy

Palpable pedal pulses

5/9/17
5/9/2017
12/9/2017
Losses

7/8/2017
Elective Right 2nd toe & MT head amputation

D/C Day 7 post-op

Oral Moxifloxacin 4/52

Integra® bilayer applied day 22 in OPD (tendon on view)
Losses

Acticoat flex and NPWT (KCI-Acti V.A.C®) for 7 days

Cam walker

Weekly review on MDFU

Silicone layer and staples removed day 28
Losses

All progressing well until...

3 weeks later wound deteriorated, probing to bone

Urgent white cell bone scan – OM

Patient wanted a trial of conservative Mx – A/B’s

TMA 7/12/2017
June 2018 OM 3rd Mt Stump
Oral A/b’s
Serial x-rays
Losses

64 year old female

Chronic leg ulcer
  3 year duration
  Prolidase deficiency
  Pyoderma gangrenosum
    Methotrexate
    Infliximab
    Prednisolone

Hyperbaric oxygen therapy

8/11/2017

8/11/2017
Losses

Although stable recurrent admissions with cellulitis pain ongoing issue

After much deliberation ....

Limb salvage procedure?

Debridement and application of Integra® bilayer in theatre

Discharged with Acticoat, NPWT (Renasys™ GO)
Losses

Followed up weekly in wound clinic

Silicone layer removed
1 month later

Wound care
Prontosan® cleanse
Acticoat

All appears to be going well...
Losses

March 2018
Gradual deterioration
Then rapid
Under regular review by vascular, dermatology, wound Mx
Unbearable pain
Infection

AKA 22/5/2018
Win

37 year old female

Chronic ulcer plantar aspect of foot

4 day Hx increasing pain, swelling, fevers
Initially started as callous – no trauma or FB

T2DM, HTN, ↑ Cholest

Palpable pedal pulses
Win

Presents 22/8/2017 septic foot, pus tracking to mid-foot

Urgent TMA

Further debridement 4 days later

Debridement and integra® bilayer 4 days later

Acticoat and NPWT (KCI-Acti V.A.C®)
Win

Discharged Day 11
  4 days post Integra® application

Oral A/b’s
  MSSA on proximal bone
  Pseudomonas from wound swab
  Augmentin duo forte and Ciprofloxacin 4 weeks

30/8/2017 Day 20
Win

Day 7 post-operatively
   NPWT removed in wound clinic

Day 27
   Silicone layer removed

Day 42
   Split Skin Graft
Win

3 months later
Wound closure

May 2018
Achilles tendon lengthening

Regular podiatry review
Cam boot

28/11/2017
Win

62 year old male

6 day history increase pain and swelling
  Referred by GP
  Likely secondary to ill fitting work boots

T2DM, ↑ Cholest, hyperferrintaemia

Palpable pedal pulses
Win
6/10/2017
Incision and debridement over right 1st and 2nd MT heads (frank pus, necrotic tissue)

Day 3
Debridement and application of Intergra® bilayer
Acticoat and NPWT (KCI-Acti V.A.C®)
Win

Day 7
- Discharged Home
- NPWT ceased
- Acticoat

Day 21
- Silicone layer removed

2 months later
- Wound virtually healed
Win

80 year old male

4/52 hx non healing ulcer left plantar foot over 5th MTH

Initially started as callous
Progressed to tissue loss wife has been dressing the wound

T2DM – newly diagnosed on this admission

Palpable pedal pulses
Win

2 small ulcers on plantar aspect of foot, expressing pus

Cellulitis extending to dorsum of foot, dusky left 5th toe

Elevated inflammatory markers
BSL 21.4

Amputation left 5th toe

Discharged day 5 – IVA/B’s
Win

One month later Integra® bilayer applied in OPD

Acticoat and NPWT (KCI-ActiV.A.C®)

Silicone layer removed day 14

Wound healed 3 months later
Lessons Learnt

- Careful patient selection
- Wound bed preparation
- Don’t get confused with infection
- Fenestrate to prevent accumulation of exudate
Lessons Learnt

- Be patient with the removal of the silicone layer
- Consistency in management
- Keep wound bed stable
- Less is best for dressing changes
Conclusion

Still early days

Careful patient selection

Wound bed preparation vital

There is a role for Integra® Dermal Regeneration Template complex wounds