Platelet Rich Plasma: A way to close tracts and tunnels

FDA cleared for exuding wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and for the management of mechanically or surgically-debrided wounds.
The Components of AutoloGel

Platelets
- Growth Factors
- Cytokines, Chemokines
- Antimicrobials

Plasma
- Coagulation Proteins
- Protease Inhibitors
- Fibrinogen / Albumin

Additives
- Ascorbic Acid, Calcium Chloride, Thrombin

Bioactive AutoloGel
A Patient Specific Wound Treatment
Platelet-Rich Plasma

Obtain Blood; Centrifuge

Draw PRP Component

Add Reagents

Apply to Wound
**PRP: Healing from Within**

- Stimulates the formation of granulation tissue to fill in the wound volume, area, undermining, sinus tracts, and tunneling to speed closure
- May be used in wounds with:
  - Exposed bone, hardware, tendon, ligament, joint, nerves and blood vessels
  - Undermining, sinus tracts and tunneling
  - Slough and necrotic tissue

FDA cleared for exuding wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and for the management of mechanically or surgically-debrided wounds.
80 lb MS patient, 3 PPD smoker
STAGE IV (ACTUALLY HAS DEEP TRACT TO BONE) WHICH CLOSED WITH PRP
Right Ischial Pressure Ulcer – Healed in 44 days

Arrows Indicate Extent of Undermining

L = 4.7 cm
W = 4.2 cm
D = 2.3 cm

3/05/02
rt ischial wound post debridement

2002 - Measurement Date

Sq/Cubic Centimeter

Volume
Area

PRP: Healing with 6 treatments in severe DFU

A retrospective, longitudinal study design was used to compare treatment outcomes of 40 severe, chronic, non-healing lower extremity wounds in 39 patients. Mean number of PRP gel treatments was 6.1 with a range of 1-17.
AutoloGel RCT Shows Improved Healing Rate vs. Standard of Care*

- US multicenter, randomized, blinded controlled trial\(^1\)
- Patients with type 1 or 2 diabetes between 18 – 95 years
- Both applications provided for a maximum of 12 weeks
- Significantly \((p=0.036)\) more AutoloGel treated wounds healed than standard of care*
- Mean time to healing = 42.9 days for AutoloGel vs. 47.4 days for Control

*Wounds less than 7 cm\(^2\)

**Observational case series study of 285 wounds using a multicenter registry database in 39 centers.**

<table>
<thead>
<tr>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic Foot Dehiscence</td>
</tr>
<tr>
<td>Pressure Ulcers</td>
</tr>
<tr>
<td>Sickle Cell</td>
</tr>
<tr>
<td>Venous Ulcers</td>
</tr>
<tr>
<td>Arterial Ulcer</td>
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<tr>
<td>Traumatic Wounds</td>
</tr>
<tr>
<td>Spinal Cord Injury</td>
</tr>
</tbody>
</table>

Mean age of wounds prior to PRP gel treatment was 337 days

*96.5% of all wounds responded to AutoloGel treatment in 15 days or less

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Comparative Healing Rates in DFU

RCT Results: Diabetic Foot Ulcers

<table>
<thead>
<tr>
<th>Product</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>AutoloGel*</td>
<td></td>
</tr>
<tr>
<td>Grafix²</td>
<td></td>
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<tr>
<td>Apligraf³</td>
<td></td>
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<tr>
<td>Regranex⁴</td>
<td></td>
</tr>
<tr>
<td>Dermagraft⁵</td>
<td></td>
</tr>
</tbody>
</table>

*Wounds Less Than 7cm²

Separate studies include:

Dougherty, Edward. An Evidence Based Model Comparing the Cost-Effectiveness of Platelet Rich Plasma Gel to Alternative Therapies for Patients With Non-Healing Diabetic Foot Ulcers. Advances in Skin and Wound Care, 2008;21:568-75

**Bar Chart:**

- **Cost Over 5 Years (2006 USD)**
- **Average Cost of Other Therapies**

- **AutoloGel**: $25,000
- **Standard Care**: $30,000
- **Ultra-sound**: $35,000
- **Graft A**: $40,000
- **Graft B**: $25,000
- **Graft C**: $35,000
- **Single GF**: $50,000
- **NPWT**: $45,000

- Average costs of other therapies is nearly 2.5 times lower than the average cost of AutoloGel.
AutoloGel Patient Experience

- 58 year old woman with a primary diagnosis of C1 tetraplegia from a traumatic injury in 1968
- Current wound: 8 year history - patient started on Medicare March 2007
- Between March 2007 and February 2010
  - Medicare Wound Care Expenditures: $408,371.17
  - Patient Out of Pocket: $45,333.39
  - Total pre-AutoloGel Treatments: $453,704.56
- AutoloGel treatments: 3 @ $540 = $1620
- Results 93.9% volume reduction in 23 days after 3 treatments

Photograph included with permission of patient
Effective July 1, 2013, AutoloGel is covered for data collected under the CED program

- Product and associated procedures covered
- Patients must be enrolled in protocol
- Data on treatment and results must be collected
- Publication of results will be used as basis for future coverage decision

- Four protocols designed by Cytomedix and approved by CMS
4 Approved CED Protocols

Coverage with Evidence Development

- Protocols compare AutoloGel Therapy to Usual and Customary Care:
  - A Multi-Center, Prospective, Clinical Trial in Wagner 1 and 2 Diabetic Foot Ulcers  
    http://clinicaltrials.gov/ct2/show/NCT01816672  
    CMS Approval Date: 02/21/2013
  - A Multi-Center, Prospective, Cohort Trial in All Wagner Grades of Diabetic Foot Ulcers  
    http://clinicaltrials.gov/ct2/show/NCT01816633  
    CMS Approval Date: 02/21/2013
  - A Multi-Center, Prospective, Cohort Trial in Venous Leg Ulcers  
    http://clinicaltrials.gov/ct2/show/NCT01817543  
    CMS Approval Date: 02/21/2013
  - A Multi-Center, Prospective, Cohort Trial in Stage II-IV Pressure Ulcers  
    http://clinicaltrials.gov/ct2/show/NCT01819142  
    CMS Approval Date: 02/21/2013