

# Appendix B

## Evidence Table: Acute Wounds

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results		Methodological Comments																		
				Intervention group	Control group																			
Trowbridge , 2005	<p>Prospective, nonrandomized, unblinded, single center</p> <p>Inclusion= all patients &gt;19 years old undergoing cardiac surgery from Oct 2002 to June 2005</p> <p>Exclusion= none stated</p> <p>Wound types: sternal, vein and artery harvest sites</p> <p>3 groups were studied:</p> <ul style="list-style-type: none"> <li>PRP applied</li> <li>Concurrent control-- No PRP</li> <li>Historical control (surgical patients from the 18 months prior to start of study)</li> </ul>	<p>N= 2259 divided into 3 groups:</p> <ul style="list-style-type: none"> <li>PRP: n= 382</li> <li>No PRP: n= 948</li> <li>Historical control: n=929</li> </ul> <p>Mean (SD) age=</p> <ul style="list-style-type: none"> <li>PRP: 64 (14)</li> <li>No PRP: 64 (13)</li> <li>Historical control: 65 (13)</li> </ul> <p>Gender=</p> <ul style="list-style-type: none"> <li>PRP: 66% M</li> <li>No PRP: 65% M</li> <li>Historical control: 64% M</li> </ul>	<p>~70% of patients received PRP produced using the CATS (Terumo Cardiovascular Systems Corp) system</p> <p>~15% of patients received PRP produced using the SmartPRP (Harvest Technologies, Inc) system</p> <p>~15% of patients received PRP produced using a COBE Cardiovascular Inc system</p> <p>PRP was applied first to the subcutaneous area and then to the cutaneous incision.</p> <p>Outcome= rate of superficial and deep sternal wound infections</p> <p>Subgroup data analysis to determine risk factors for infection</p>	<p>Rate of infection:</p> <p>Superficial—0.3</p> <p>Deep sternal—0.0</p> <p>Low rate of infection precluded a subgroup analysis.</p>	<p>Rate of infection:</p> <p><u>No PRP</u></p> <p>Superficial—1.8#</p> <p>Deep sternal—1.5*</p> <p><u>Historical control</u></p> <p>Superficial—1.5#</p> <p>Deep sternal—1.7*</p> <p>* p&lt; 0.01</p> <p># p&lt; 0.05</p>	<p>Retrospective analysis design without benefit of randomization or blinding provides for less robust evidence to support net health outcome decisions.</p>																		
Hom, 2007	<p>Prospective, controlled, pilot study with blinded photographic assessment</p> <p>Inclusion= healthy volunteers &gt; 21 years</p> <p>Exclusion= history of diabetes, keloid/scar formation, collagen vascular disease, or bleeding disorder; anticoagulant or steroid use during past month</p> <p>Wound type: iatrogenic punch wound (4-6 mm diameter)</p>	<p>N= 8 (80 wounds)--- 5 full-thickness wounds on each thigh in each volunteer)</p> <p>Age range= 21-58</p> <p>Gender ratio= 4 M/4 F</p>	<p>Magellan (Medtronic Inc) system used to produce PRP</p> <p>Each of the 5 sets of bilateral thigh wounds were assigned to one of 5 groups:</p> <p><u>Phase 1</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th>PRP</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Applied on Day 0 + petrolatum ointment</td> <td>Topical antibiotic</td> </tr> <tr> <td>2</td> <td>Applied on Day 0</td> <td>None</td> </tr> </tbody> </table> <p>* all wounds covered with a semi-occlusive dressing</p> <p><u>Phase 2</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th>PRP</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>3</td> <td>Applied on Days 0 &amp; 7 + petrolatum ointment</td> <td>Topical antibiotic</td> </tr> <tr> <td>4</td> <td>Applied on Days 0 &amp; 7</td> <td>None</td> </tr> </tbody> </table> <p>* all wounds covered with a semi-occlusive dressing</p> <p>Group 5 allowed to heal by secondary intention alone.</p> <p>Outcomes= time to complete wound closure</p>	Group	PRP	Control	1	Applied on Day 0 + petrolatum ointment	Topical antibiotic	2	Applied on Day 0	None	Group	PRP	Control	3	Applied on Days 0 & 7 + petrolatum ointment	Topical antibiotic	4	Applied on Days 0 & 7	None	<p>No drop outs</p> <p>RESULTS APPEAR TO BE POOLED ACROSS GROUPS</p> <p>Day 21: 63% PRP-treated wounds had full closure</p> <p>Day 24: 81% PRP-treated wounds had full closure</p> <p>Day 28: 88% PRP-treated wounds had full closure</p> <p>The average time to achieve complete closure was 29.75 days for PRP-treated wounds. Presence or absence of statistical significance not reported.</p> <p>No serious adverse events; no infections</p>	<p>RESULTS APPEAR TO BE POOLED ACROSS GROUPS</p> <p>Day 21: 31% of control wounds had full closure</p> <p>Day 24: 44% of control wounds had full closure</p> <p>Day 28: 56% of control wounds had full closure</p> <p>The average time to achieve complete closure was 35.38 days for control.</p> <p>None of the above results achieved statistical significance.</p>	<p>Small sample size.</p> <p>Very difficult to determine which wounds received which intervention.</p> <p>Poor reporting of results. Results appeared to be pooled across groups despite the fact that each group received different treatment.</p> <p>Age range not representative of Medicare population.</p> <p>Healthy status not representative of Medicare population.</p>
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Evidence Table: Chronic Wounds

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results		Methodological Comments
				Intervention group	Control group	
Anitua, 2007	<p>Randomized, open-label, controlled, prospective</p> <p>7-day washout period then a baseline assessment then 8-week treatment period.</p> <p>Inclusion= <math>\geq 1</math> ulcer <math>&lt; 12</math> cm diameter nonhealing after 4 weeks standard care.</p> <p>Exclusion= arterial origin of ulceration, history of insulin-dependent diabetes mellitus, systemic and/or local ulcer infection, inadequate nutritional status, active</p>	<p>N= 15 (8 PRP; 7 control)</p> <p>Mean age: 45 yrs PRP; 61 yrs control</p> <p>Gender: 4 men PRP; 4 men control</p> <p>Mean ulcer area: 5.5 cm<sup>2</sup> PRP; 8.9 cm<sup>2</sup> control</p>	<p>Initially: wound cleansing with normal saline/ moist saline gauze dressings; debridement for ulcer bed infection</p> <p>PRP group: received some PRP via injection into ulcer margins &amp; remainder as direct topical application to ulcer bed; PRP administered 1x/wk for 8 weeks.</p> <p>Autologous PRP was produced using the PGRF System (BTI Biotechnology Institute, Vitoria-Gasteiz, Spain).</p> <p>Control group: debridement &amp; saline cleansing 1x/wk for 8 weeks.</p> <p>Sterile moist saline gauze dressings</p>	<p>3 drop-outs</p> <p>Mean percentage of surface healed at eight weeks= 72.94% (p&lt;0.05).</p> <p>1 ulcer bed infections</p> <p>1 case of anemia but unclear from which group</p>	<p>3 drop-outs</p> <p>Mean percentage of surface healed at eight weeks= 21.48%</p> <p>2 ulcer bed infections</p>	<p>Very small sample size (as acknowledged by the authors).</p> <p>The statistically significant result at 8 weeks appears to be based on a sample size of only 9 (the originally planned intent-to-treat analysis would be based on a sample size of 15).</p>

	<p>vasculitis, anemia.</p> <p>The primary outcome was percentage of ulcer surface area that healed. Intent-to-treat was the primary analysis. There was no mention of a power calculation.</p> <p>Wound types: 64% venous; 29% pressure; 7% other.</p>		<p>were applied in both groups.</p> <p>Primary outcome= percentage of ulcer surface area that healed. Intent-to-treat was the primary analysis. There was no mention of a power calculation.</p>			
Barrett, 2003	<p>Uncontrolled, unblinded prospective</p> <p>Inclusion= failed <math>\geq</math> 4 weeks standard wound care</p> <p>Exclusion= infected wound</p> <p>Wound types: diabetic, decubitis, venous stasis, complicated surgical wound dehiscence</p>	<p>N= 16 (17 wounds)</p> <p>#patients or wounds per wound type= not provided</p> <p>Age range= not provided</p> <p>Gender ratio= not provided</p>	<p>PRP produced using SmartPReP (Harvest Technologies Corp) system</p> <p>Initial= Debridement + PRP + petrolatum impregnated gauze + gauze dressing</p> <p>Maintenance= daily topical hydrocolloid &amp; gauze dressing; PRP after 2 weeks as needed until complete closure</p> <p>Outcome= 100% re-epithelialization</p>	<p>16/17 (94%) wounds had complete wound closure</p> <p>1 recurrence due to non-compliance</p> <p>#PRP applications per patient= 1-5</p> <p>No adverse reactions reported.</p>	None	<p>Small sample size. Due to lack of randomization, blinding, and control, case reports do not provide robust evidence to support net health outcome decisions.</p>

<p>Crovetti, 2004</p>	<p>Uncontrolled, unblinded prospective</p> <p>Inclusion= none stated</p> <p>Exclusion= presence of infection, cellulites, osteomyelitis, or vascular insufficiency in wound area</p> <p>Wound types: diabetic, trauma</p>	<p>N= 3/24 qualified for autologous PRP but only 2/3 were reported on in the article:</p> <p>Patient #2: 73 year old man with a traumatic wound</p> <p>Patient #11: 46 year old woman with a diabetic wound</p>	<p>(complete wound closure)</p> <p>PRP produced using MCS+ (Haemonetics Inc) system</p> <p>Saline washings, PRP 1x/wk, occlusive dressing</p> <p>Antibiotics as needed</p> <p>Outcome= wound area reduction, granulation tissue formation, wound bed detersion, regression/absence of infective processes</p>	<table border="1" data-bbox="982 350 1356 548"> <thead> <tr> <th>Patient #</th> <th>Result</th> <th>#PRP applications</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>&gt;50% recovery</td> <td>44</td> </tr> <tr> <td>11</td> <td>Stopped treatment*</td> <td>7</td> </tr> </tbody> </table> <p>*due to onset of osteomyelitis</p> <p>No adverse reactions reported.</p>	Patient #	Result	#PRP applications	2	>50% recovery	44	11	Stopped treatment*	7	<p>None</p>	<p>Small sample size. Due to lack of randomization, blinding, and control, study design does not provide robust evidence to support net health outcome decisions.</p>																								
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<p>Mazzucco, 2004</p>	<p>Nonrandomized, unblinded, prospective treatment group with a retrospective control group</p> <p>Inclusion= none stated</p> <p>Exclusion= none stated</p> <p>Wound types: dehiscent sternal wounds, necrotic skin ulcers</p>	<p>N= 53</p> <p><u>Dehiscent Sternal Wounds</u></p> <table border="1" data-bbox="411 984 743 1182"> <thead> <tr> <th></th> <th>PRP</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>10</td> <td>12</td> </tr> <tr> <td>Mean age (SD)</td> <td>64 (8)</td> <td>66 (5)</td> </tr> <tr> <td>Gender ratio- M/F</td> <td>6/4</td> <td>8/4</td> </tr> </tbody> </table> <p><u>Necrotic Skin Ulcers</u></p> <table border="1" data-bbox="411 1263 743 1380"> <thead> <tr> <th></th> <th>PRP</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>17</td> <td>14</td> </tr> <tr> <td>Mean age (SD)</td> <td>61 (18)</td> <td>63 (16)</td> </tr> </tbody> </table>		PRP	Control	N	10	12	Mean age (SD)	64 (8)	66 (5)	Gender ratio- M/F	6/4	8/4		PRP	Control	N	17	14	Mean age (SD)	61 (18)	63 (16)	<p>A specific system was not stated</p> <p><u>Dehiscent Sternal Wounds</u></p> <p>Treatment= PRP 2x/wk Control= daily washing and cleaning of wound; 1 patient received hyperbaric therapy</p> <p><u>Necrotic Skin Ulcers</u></p> <p>Treatment= saline washings, PRP</p>	<p><u>Dehiscent Sternal Wounds</u></p> <table border="1" data-bbox="1016 984 1323 1240"> <thead> <tr> <th></th> <th>PRP</th> </tr> </thead> <tbody> <tr> <td>Time to complete healing (median, weeks)</td> <td>3.5*</td> </tr> <tr> <td>total hospital length of stay (median, days)</td> <td>31.5#</td> </tr> </tbody> </table> <p>* p= 0.0002 # p&lt; 0.0001</p> <p><u>Necrotic Skin Ulcers</u></p>		PRP	Time to complete healing (median, weeks)	3.5*	total hospital length of stay (median, days)	31.5#	<p><u>Dehiscent Sternal Wounds</u></p> <table border="1" data-bbox="1432 984 1713 1263"> <thead> <tr> <th></th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Time to complete healing (median, weeks)</td> <td>6</td> </tr> <tr> <td>total hospital length of stay (median, days)</td> <td>52.5</td> </tr> </tbody> </table> <p><u>Necrotic Skin Ulcers</u></p>		Control	Time to complete healing (median, weeks)	6	total hospital length of stay (median, days)	52.5	<p>Lack of randomization and blinding weakens the study design.</p> <p>Relatively small sample sizes. The absolute number and frequency of complete healing not reported.</p> <p>Strongly statistically significant results for both wound types.</p>
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		Gender ratio- M/F	8/9	5/9	1x/wk Control= daily washing/cleaning with ialuronic acid; 1 patient received autologous cultured fibroblasts  Antibiotics given as needed  <u>Dehiscent Sternal Wounds</u>  Outcome= time to complete healing; total hospital length of stay  <u>Necrotic Skin Ulcers</u>  Outcome= time to need for surgery	<table border="1"> <tr> <td></td> <td>PRP</td> </tr> <tr> <td>time to need for surgery (median, weeks)</td> <td>15*</td> </tr> </table> <p>*p&lt; 0.0001</p> <p>Data from patients who received hyperbaric therapy or autologous cultured fibroblasts were censored during statistical analysis</p> <p>No adverse reactions reported.</p>		PRP	time to need for surgery (median, weeks)	15*	<table border="1"> <tr> <td></td> <td>Control</td> </tr> <tr> <td>time to need for surgery (median, weeks)</td> <td>35.5</td> </tr> </table> <p>No adverse reactions reported.</p>		Control	time to need for surgery (median, weeks)	35.5	
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McAleer, 2006	Case report  Wound type: diabetic	N= 1  Age= 57  Gender= male			A Biomet system was used to produce PRP  Debridement + PRP + compressive dressing 1x/week	Complete closure by week 4 of treatment  No adverse reactions reported.	None	Small sample size. Due to lack of randomization, blinding, and control, case reports do not provide robust evidence to support net health outcome decisions.								
Klayman, 2006	Case report  Wound type: chronic incision wound post total knee	N= 1  Age= 51  Gender= male			PRP produced using SmartPReP (Harvest Technologies Corp) system	Wound size decreased from 15x15 cm to 8x6 cm with sufficient granulation tissue to proceed to skin grafting.  No adverse reactions reported.	None	Due to lack of randomization, blinding, and control, case reports do not provide robust								

	arthroplasty in a patient with diabetes		PRP applied about once per week for 4 weeks; a continuous vacuum-assisted wound closure device was applied after each PRP treatment			evidence to support net health outcome decisions
McAlear, 2006	<p>Uncontrolled, unblinded prospective</p> <p>Inclusion= presence of chronic nonhealing lower extremity wound treated unsuccessfully for <math>\geq 6</math> mos with traditional methods</p> <p>Exclusion= ankle-arm indices <math>&lt;0.60</math>, signs of systemic or lower extremity soft tissue infection; radiographic evidence of osteomyelitis; gangrenous changes</p> <p>Wound types:</p>	<p>N= 24 (33 wounds)</p> <p>#patients or wounds per wound type=</p> <ul style="list-style-type: none"> <li>• venous stasis: 3</li> <li>• decubitus ulcer: 2</li> <li>• arterial insufficiency: 5</li> <li>• traumatic ulcers in patients with diabetes: 8</li> <li>• ulcers due to diabetes-induced neuropathic pathology: 6</li> </ul> <p>Age range= 25-91 (median: 62)</p> <p>Gender ratio= 13 F/11 M</p>	<p>A Biomet system was used to produce PRP</p> <p>Initial= Debridement + PRP + sterile gauze + compressive dressing</p> <p>Maintenance= debridement + PRP every 2 weeks until complete closure; limited weight-bearing</p> <p>Outcome= complete wound closure</p>	<p>20/33 (61%) wounds had complete wound closure</p> <p>Mean time to complete closure: 11 weeks</p> <p>5/33 wounds had no improvement</p> <p>Drop-outs:</p> <ul style="list-style-type: none"> <li>• 2 patients lost to follow-up</li> <li>• 2 patients discontinued due to lower extremity infection-related below-the-knee amputation</li> <li>• 1 patient had skin grafting</li> <li>• 1 patient had wound closure during surgical correction of an anatomic deformity</li> </ul> <p>No adverse reactions reported.</p>	None	<p>Small sample size. Due to lack of randomization, blinding, and control, study design does not provide robust evidence to support net health outcome decisions.</p>

	venous stasis, decubitus ulcer, arterial insufficiency, traumatic ulcers in patients with diabetes, ulcers due to diabetes-induced neuropathic pathology													
Driver, 2006	<p>Prospective, randomized, double-blinded, controlled, multi-center with a 7-day screening period (which included baseline wound assessment and debridement and application of control saline gel), a 12-week treatment period, and a 12-week follow-up period.</p> <p>Inclusion= age 18-95, wound area between 0.5 and 20 cm<sup>2</sup> inclusive, full-thickness without exposure of tendon, muscle, ligaments or bone; wound <math>\geq</math> 4</p>	<p>For the intention-to-treat analysis group: N= 72 (40 PRP; 32 control)</p> <p>Mean (SD) age= 56 (10) PRP; 57 (9) control</p> <p>Gender ratio= 80% M PRP; 84%M control</p> <p>Mean (SD) wound area (cm<sup>2</sup>)= 4 (5) PRP; 3 (3) control</p> <p>Mean (SD) wound volume (cm<sup>3</sup>)= 1.7 (4) PRP; 0.9 (1.2) control</p>	<p>PRP produced using Autologel (Cytomedix Inc) system</p> <p>PRP group: Debridement + PRP + contact layer dressing + foam dressing</p> <p>Control group: debridement + normal saline gel + contact layer dressing + foam dressing</p> <p>Treatment was applied 2x per week til the wound completely healed, the 12-week treatment phase ended, or the patient withdrew or was withdrawn from the study.</p> <p>All patients used</p>	<p><b><u>INTENT-TO-TREAT EFFICACY ANALYSIS</u></b></p> <p>Wide variability in baseline wound area and volume seen in the PRP group and in the control group (with volume variability significantly greater in PRP group compared to control; p&lt;0.0001)</p> <p>There were no other statistically significant differences between groups.</p> <table border="1"> <tr> <td></td> <td>PRP</td> </tr> <tr> <td># patients with complete wound closure (%)</td> <td>13/40 (32.5)</td> </tr> </table> <p>p= 0.79</p> <p>Results from analysis of secondary outcomes not reported.</p> <p>A subsequent independent audit of the study showed a 44% rate of protocol violations (32/72) that prompted a revised sample size and analysis.</p> <p><b><u>PER PROTOCOL EFFICACY</u></b></p>		PRP	# patients with complete wound closure (%)	13/40 (32.5)	<table border="1"> <tr> <td></td> <td>Control</td> </tr> <tr> <td># patients with complete wound closure (%)</td> <td>9/32 (28)</td> </tr> </table>		Control	# patients with complete wound closure (%)	9/32 (28)	<p>Randomized controlled trial design was compromised by the large number of protocol violations.</p> <p>The lack of statistical significance in the primary efficacy analysis was most likely due to the variability inserted by the large number of protocol violations and by the wide variability in wound size.</p> <p>The results of this trial can serve to generate hypotheses for future randomized controlled trials but not to</p>
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	<p>cm from other wounds; adequate arterial perfusion</p> <p>Exclusion= wound infected, A1C ≥ 12; &gt;50% reduction in wound size during 7-day screening period</p> <p>Wound type: diabetic foot ulcer</p>		<p>fixed ankle-foot orthoses and crutches or a walker</p> <p>During the 12-week treatment phase, re-initiation of treatment was prompted by re-opening of a complete closed wound.</p> <p>Primary outcome= complete wound closure</p> <p>Secondary outcomes= %change in wound area from baseline; %change in wound volume from baseline; area closure rate /day; volume closure rate /day</p> <p>Inter-site enrollment variability led to grouping of sites during statistical analysis; 5 groups formed: teaching facilities, army facility, physicians in private practice (2 distinct sites), ambulatory care</p>	<p style="text-align: center;"><b><u>ANALYSIS</u></b></p> <p>No statistically significant differences between groups except %Caucasians in PRP was greater (P=0.02).</p> <table border="1" data-bbox="1018 402 1320 662"> <thead> <tr> <th></th> <th>PRP</th> </tr> </thead> <tbody> <tr> <td># patients with complete wound closure (%)</td> <td>13/19* (68)</td> </tr> <tr> <td>Kaplan-Meier median time to complete closure (days)</td> <td>45#</td> </tr> </tbody> </table> <p>*p= 0.125      #p= 0.126</p> <p>Size frequency distributions showed 35/40 (88%) of wounds had an area of ≤ 7.0 cm<sup>2</sup> and a volume of ≤ 2.0 cm<sup>3</sup>. An efficacy analysis of the non-outlier group (called the majority wounds group) was performed.</p> <p style="text-align: center;"><b><u>SUBSET EFFICACY ANALYSIS</u></b></p> <table border="1" data-bbox="1018 966 1320 1109"> <thead> <tr> <th></th> <th>PRP</th> </tr> </thead> <tbody> <tr> <td># patients with complete wound closure (%)</td> <td>13/16 (81)</td> </tr> </tbody> </table> <p style="text-align: center;">P= 0.036</p> <p>Wide variation in healing outcomes between the 4 remaining investigational site groups (1 of the original 5 groups was eliminated during the audit) was found: 50-100% variability in PRP group and 25-67% variability in control group.</p>		PRP	# patients with complete wound closure (%)	13/19* (68)	Kaplan-Meier median time to complete closure (days)	45#		PRP	# patients with complete wound closure (%)	13/16 (81)	<p style="text-align: right;">demonstrate the efficacy of PRP in wound care.</p> <table border="1" data-bbox="1421 347 1724 607"> <thead> <tr> <th></th> <th>Control</th> </tr> </thead> <tbody> <tr> <td># patients with complete wound closure (%)</td> <td>9/21 (43)</td> </tr> <tr> <td>Kaplan-Meier median time to complete closure (days)</td> <td>85</td> </tr> </tbody> </table>  <table border="1" data-bbox="1421 883 1724 1026"> <thead> <tr> <th></th> <th>Control</th> </tr> </thead> <tbody> <tr> <td># patients with complete wound closure (%)</td> <td>8/19 (42)</td> </tr> </tbody> </table>		Control	# patients with complete wound closure (%)	9/21 (43)	Kaplan-Meier median time to complete closure (days)	85		Control	# patients with complete wound closure (%)	8/19 (42)
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			clinics.	No statistically significant differences in the rate of adverse events were seen between PRP and control groups.		
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