

The VAC and New-Fangled Strategies for Wound Management: Overrated

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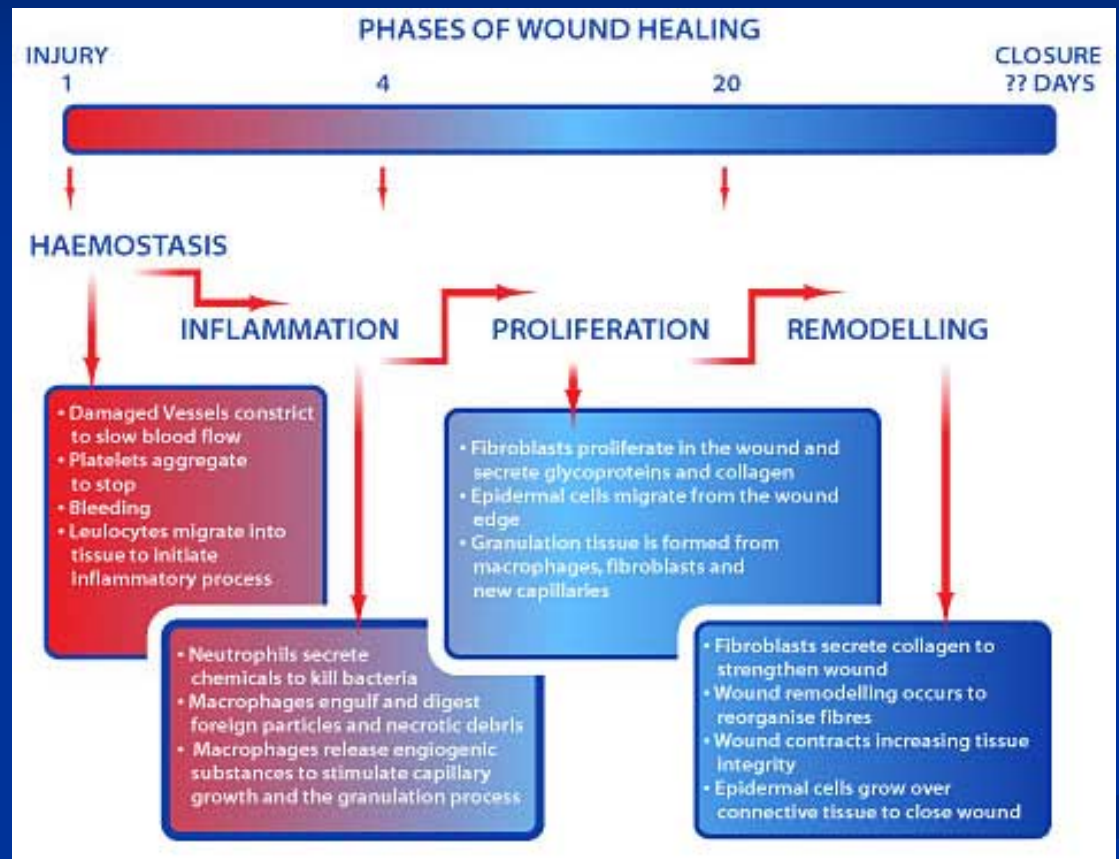
General Surgery Grand Rounds

Overview

- Wound healing
- Barriers to wound healing
- Idea behind negative pressure wound therapy
- Why it is not better
- “New-Fangled Strategies”

Wound Healing

- Hemostasis
- Inflammation
- Proliferation
- Remodeling



Barriers to Wound Healing

- Infection
 - Remains in the inflammatory phase
- Edema
 - Extra fluid in extracellular matrix impedes blood flow and increases diffusion distances for oxygen and nutrients
- Dryness
 - Scab forms to keep moisture in wound: reduces cell proliferation, leukocyte activity, wound contraction, revascularization and epithelialization
- Poor blood flow
 - Needs oxygen and nutrients

Idea Behind Wound Vac

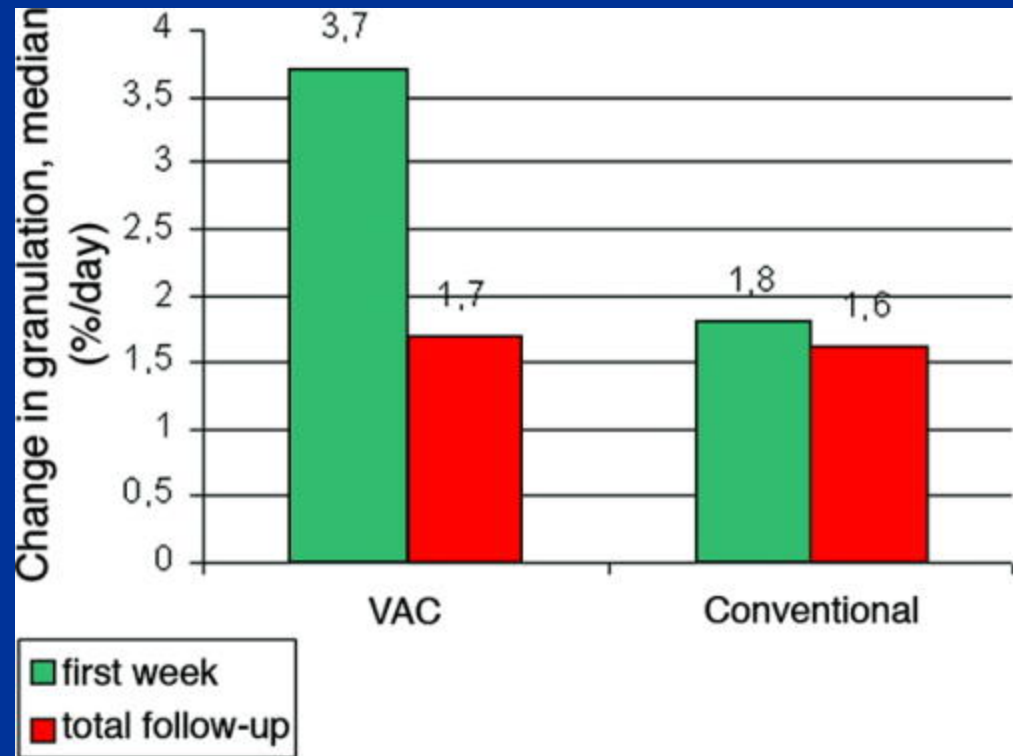
- Contraction of wound
- Stabilization of wound
- Removal of extracellular fluid
- **Increase blood flow**
- **Increase granulation tissue**
- Increased compliance (fewer dressing changes)

Blood Flow

- Proponents of NPWT cite the supposed increase in blood flow and angiogenesis
 - Laser doppler measures red cell velocity (not flow)
 - A decrease in vessel diameter can increase fluid velocity even though the overall flow is decreased
 - Wackenfors (2004) measured “flow” (laser doppler) around porcine wounds treated with VAC: **hypoperfusion** within about 1.5 cm from the edge. While tissue peak flow increased when the vacuum was turned off, it actually decreased during the “on” periods.
 - Kairinos (2009) measured tissue perfusion in healthy subjects with a **radiotracer** technique and showed a **decrease in perfusion** correlating to increased suction
 - Negative-pressure wound therapy should be used with caution on tissues with compromised vascularity,

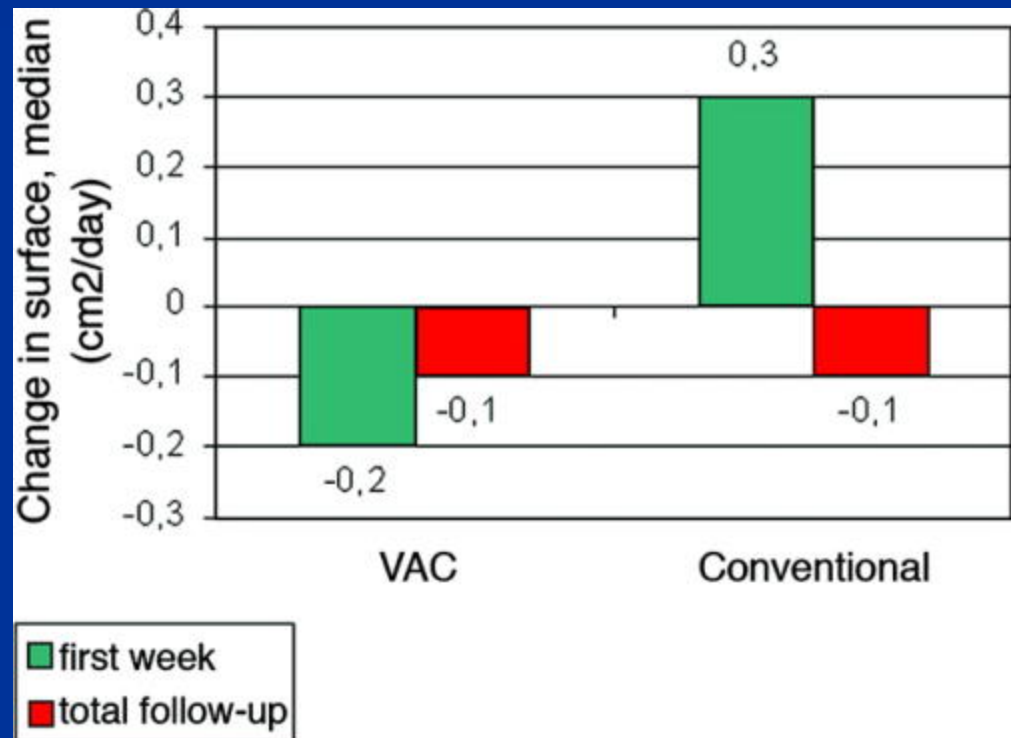
Granulation

- Braakenburg (2006) showed no significant difference in overall granulation



Wound Surface Area

- Braakenburg showed no difference in overall change in surface area



Potential Complications

- Since 2007 the FDA has received reports of **12 deaths and 174 injuries** associated with negative-pressure wound therapy (www.FDA.gov)
- Bleeding
 - 4 of 69 (5.8%) with deep sternal infections treated with NPWT (Petzina 2010)
- Infection (mixed results)
 - Braackenburg: bacterial growth in 84% of the wounds treated with vacuum-assisted closure and in 58% treated conventionally
 - Moues: 54 pts (1/2 assigned to VAC, 1/2 assigned to dressing changes with NaCl)
Pts with nonfermentative, gram-negative bacilli had decreased bacterial loads over time, whereas patients with *staph aureus* had increased bacterial levels over time
- Retained foam dressing pieces
- Adherent foam

Cannot use on...

- Exposed vasculature
- Nerves
- Anastamotic sites
- Organs
 - The polyvinyl alcohol foam is a white, nonadherent foam that is used by some clinicians over and to reduce pain with dressing changes; there are no Level I or II studies using this type of foam.

Cost

- Moues et al:
 - Significantly higher material cost in NPWT vs. conventional therapy (\$601 vs \$21, $p < 0.0001$)
 - No significant difference in total cost (\$3249 vs. \$3728)
 - Study funded by KCI
- Vuerstaek et al:
 - Conventional dressing total cost significantly more expensive than NPWT (\$5452 vs. \$3881, $p = 0.001$)
 - Study funded by KCI
- Braakenburg et al:
 - Total greater for NPWT (E353) vs. conventional (E273)

Problems with the research

- Mostly retrospective clinical studies and case series
- Subjective endpoints
- Heterogeneity of the wounds
- Difficulty blinding
- Device company supported trials

Ubbink 2008

Table 1 Quality assessment of included studies

Reference	Randomization	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
13	Sealed envelopes	Yes	P	Yes	No	Yes	No	No	No	No	No	Yes	Yes	?	Yes	KCI	Yes
14	Block randomization with envelopes	Yes	P	Yes	Yes	Yes	No	No	No	No	No	?	No	Yes	Yes	KCI	Yes
15	Random number generator	Yes	P	No	Yes	No	No	No	No	Yes	No	Yes	Yes	Yes	Yes	No	No
16	Odd/even patient numbers	No	P	Yes	Yes	?	No	No	No	No	Yes	No	No	Yes	Yes	No	
17	Random letters	?	P	No	Yes	No	No	No	No	Some	Yes	Yes	No	Yes	Yes	KCI (among others)	No
18	?	?	P	No	No	No	No	No	No	No	Yes	No	No	Yes	No	?	No
19	Labelled files	No	W	Yes	No	No	?	No	No	Yes	?	Yes	No	Yes	Yes	Partially by KCI	No
20	Computer generated	Yes	P	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
21	Flip of coin	No	P	?	No	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Partially by KCI	No
22	?	?	W	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No
23–25	Patients picked envelope	Yes	P	No	Yes	Yes	No	No	No	Some	Yes	Yes	Yes	Yes	Yes	KCI and Esser foundation	No
26	Computer randomization in three strata	Yes	P	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	Yes	KCI	Yes
27	?	No	P	Yes	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No
Total (%)		46		62	69	46	0	0	0	31	69	77	62	92	85	53	38

Variables: 1, allocation concealment; 2, unit of allocation (P, patient; W, wound); 3, group comparable at baseline; 4, withdrawals described; 5, intention to treat; 6, evidence differential loss to follow-up; 7, patient blinded; 8, healthcare workers blinded; 9, outcome assessors blinded; 10, proportion of patients that completed follow-up over 80 per cent; 11, similar treatment apart from intervention; 12, reliability of outcome measures; 13, informed consent; 14, approved by medical ethics committee; 15, financial support and, if so, by whom; 16, sample size calculation performed.

Older Conclusions

Table. Health technology assessment summary

<i>Health technology assessment</i>	<i>Conclusions</i>	<i>Comments</i>
Ontario Health Technology Advisory Committee, 2004 ¹⁴	VAC therapy may be useful for healing various types of wounds but <u>effectiveness could not be empirically quantified</u>	<ul style="list-style-type: none"> – Small sample size and patient populations – Poor study design – Outcome measures could not be compared
AHRQ/BlueCross/BlueShield, 2004 ¹⁵	Body of <u>evidence insufficient</u> to support conclusions about effectiveness	<ul style="list-style-type: none"> – Small number of studies – Inadequate randomization in most studies – Study groups not comparable
Cochrane Review, UK, 2003 ¹⁶ Centre for Clinical Excellence, Australia, 2003 ¹⁷	<u>Weak evidence</u> of effectiveness VAC may have advantages over other forms of wound dressings studied but too few reports to say	<ul style="list-style-type: none"> – 3 articles met inclusion criteria – No Level I or II were identified
NHS Quality Improvement Scotland, 2003 ¹⁸	<u>Limited evidence</u> for effectiveness and adverse events	<ul style="list-style-type: none"> – Saline gauze is not standard treatment of wounds in Scotland – Need for more RCTs
Cochrane Review, UK, 2001 ¹⁹	<u>Weak evidence</u> that TNP is superior to gauze dressings	<ul style="list-style-type: none"> – Small sample sizes – Methodological limitations

VAC, Vacuum-assisted closure; AHRQ, Agency for Healthcare Research and Quality; RCT, randomized clinical trial; TNP, topical negative pressure.

Conclusions

- Gregor 2008: “Although there is some indication that NPWT may improve wound healing, the body of **evidence available is insufficient** to clearly prove an additional clinical benefit of NPWT. The large number of prematurely terminated and unpublished trials is reason for concern.”
- Ubbink 2008: “There is **little evidence** to support the use of TNP in the treatment of wounds.”

Decision Time

- No strong evidence to support NPWT use
- Proven risks

New Fangled

- Topically applied growth factors
- Alginates, absorbent, promote the breakdown of necrotic tissues while decreasing pain
- Silver coated foam
- Instillation VAC

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