ABL Medical™

Presentation on:

SilvrSTAT®

Antibacterial Wound Dressing Gel

2020

Our **story.**

ABL Medical™

- Our father, Bill Moeller, was devoted to making the world a better place with a core value of living healthy.
- He was aware of the health benefits of silver, but was not satisfied with the available products and their safety.
- He worked with a chemist and an electrical engineer to improve on existing silver technology, but instead, they discovered a completely new technology. From this SilverSol®, was developed.
- He founded the American Biotech Labs in 1998 with his five sons. Within years, his grandchildren also joined this growing company as the third generation.
- The medical division of American Biotech Labs is called ABL Medical.
- Thousands of lives have been saved to date, while tens of thousands more have been helped.
- American Biotech Labs (ABL) maintains its dedication to research with over 400 independent studies.
- In 2013, SilverSol® was studied in the first human clinical trials done on a nano-silver particle, showing that SilverSol® is completely safe.

Our **beliefs.**

We believe that strengthening one's physical well being will further the ability to live a more balanced life, including mentally and spiritually, and essentially empower an active lifestyle with confidence.

By combining the awesomeness of nature and the power of science, American Biotech Labs continues to research and develop innovative products that help consumers live a stronger and healthier lifestyle by safeguarding their health.

ABL Medical™

Our **Mission.**

To help our customers and consumers live an active and balanced lifestyle through the empowerment of a strong, healthy physical self.

ABL Medical **SILVER Technology.**

- Global Leader In Nano-Silver Technology
- Patented 56 Patents Globally – Patents Pending
- Pharmacy Grade For Prescription & OTC
- Does Not Affect The Taste Or Smell Of The Products It Is Used In
- Used as a Preservative In Hundreds of Products
- Stable - Can Be Frozen Or Boiled Without Change
- More Than 22,000,000 Units Sold Worldwide
- No Reported Side Effects Or Negative Interactions

- Calorie Free
- Stable and Versatile
- Contains:
  - ✓ No Parabens
  - ✓ No Alcohol
  - ✓ No Sorbates
  - ✓ No Benzoates
  - ✓ No Quaternary Ammonium Compounds

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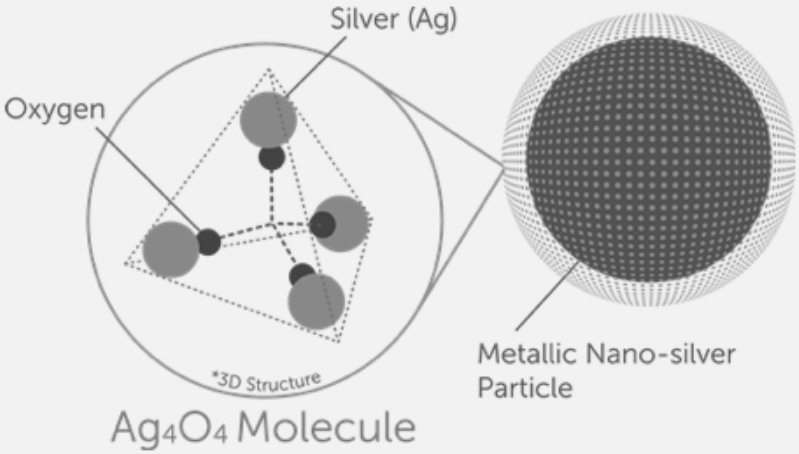
The Science **Behind The Line.**



More than 420 major reports and studies, completed by more than 60 different independent institutions, labs, government agencies, and universities.

Millions of dollars invested in safety and efficacy tests, with continued expansion of approved uses and patents.

SilverSol Technology® shown safe with more than 30 safety studies and the only double-blind, IRB-Board Certified, FDA-Cleared, human-ingestion safety clinical.

We have FDA-cleared Rx and OTC products that use SilverSol Technology, and many more products pending.

ABL Medical™

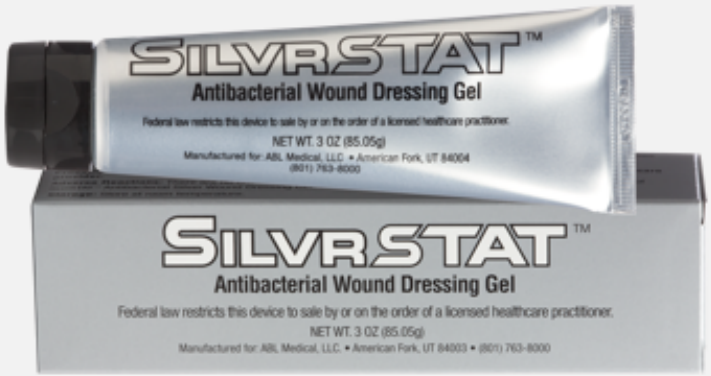
WOUND CARE **silver gel.**

- Our antibacterial silver wound dressing gel is indicated for the OTC local management of:

  - ✓ 1st and 2nd Degree Burns
  - ✓ Lacerations
  - ✓ Abrasions
  - ✓ Minor Cuts
  - ✓ Skin Irritations

- And by the order of a licensed healthcare practitioner for the management of:

  - ✓ Wounds Such as Stasis Ulcers, Pressure Ulcers, and Diabetic Ulcers
  - ✓ Device Insertion Site Wounds
  - ✓ Surgical Incision Sites
  - ✓ Graft Sites
  - ✓ Donor Sites
  - ✓ Skin Tears



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

American Biotech Labs, LLC
% Biologics Consulting Group, Inc.
Ms. Miriam Provost
Senior Consultant
1317 King Street
Alexandria, Virginia 22314

NOV 12 2009

Re: K092826
Trade/Device Name: ASAP® Antibacterial Silver Wound Dressing Gel
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 10, 2009
Received: September 14, 2009

Dear Ms. Provost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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Silver Wound Gel **purpose/ingredients.**

- Our antibacterial silver wound dressing gel contains silver that in laboratory tests has been shown to inhibit the growth of microorganisms such as:

  - ✓Staphylococcus Aureus
  - ✓Pseudomonas Aeruginosa
  - ✓Escherichia Coli
  - ✓Antibiotic Resistant Strains
  - ✓MRSA
  - ✓VRE
  - ✓Fungi Such As Candida Albicans

- Made with Patented Silver Technology

  - ✓No Stinging
  - ✓No Staining
  - ✓No Sticking
  - ✓No Chloride
  - ✓No Scent

- Probiotic friendly

- **Contents:** 32 ppm Proprietary Silver (purified water, nano-silver at .01 micron), Propylene Glycol, Triethanolamine, Carbomer.

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Silver Wound Gel
Purpose/ingredients.

- Our antibacterial silver wound dressing gel contains:
  - ✓ No Sulfa Components
  - ✓ No Alcohol
  - ✓ Non-Toxic
  - ✓ Chloride Free
  - ✓ Non-Flammable

- SilvrSTAT hydrates and acts as prevention-based product; contains no alcohol or petroleum, so it won't dry out the skin or leave a greasy feeling. It pulls into the top layer of the skin (or covers the wound) and forms a smooth protective barrier after application

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INDEPENDENT IN VITRO REPORT

Comparing SilvrSTAT® With Other Products In Same Regulatory Category

PRODUCT	EXPOSURE INTERVAL	MRSA 3.8X10⁵ CFU/ml	VRE 7.2x10⁵ CFU/ml	P. aeruginosa 5.2x10⁵ CFU/ml	E. Coli 8.1x10⁵CFU/ml	C. albicans 6.8x10⁵CFU/ml	S. agalactiae 4.3x10⁵ CFU/ml
SilvrSTAT®	10 min	220000	500000	<10	8000	<10	250000
	1 hr	1200	10000	<10	<10	<10	15000
	4 hr	200	250	<10	<10	<10	<10
	24 hr	<10	<10	<10	<10	<10	<10
Medical Grade Honey	10 min	18000	450000	300	500000	700	8500
	1 hr	10000	180000	100	350000	<10	8000
	4 hr	20000	150000	<10	200000	<10	800
	24 hr	<100	600	<10	1300	<10	100
Mupirocin Ointment	10 min	<10	400000	65000	500000	150000	<10
	1 hr	<10	150000	700	80000	40000	<10
	4 hr	<10	150000	<10	16000	14000	<10
	24 hr	<10	180000	100	<10	12000	<10
Ionic Silver Gel	10 min	150000	350000	180000	450000	250000	280000
	1 hr	80000	35000	<10	75000	40000	3500
	4 hr	200	15000	<10	<10	35000	200
	24 hr	200	18000	<10	<10	800	<10
Silver Sulfadiazine Cream	10 min	120000	350000	1300	65000	7000	4000
	1 hr	2000	7000	100	300	100	100
	4 hr	300	<10	100	100	<10	<10
	24 hr	100	100	<10	<10	100	<10
Botanical Extract Gel	10 min	150000	420000	500	5500	14000	8000
	1 hr	75000	200000	100	200	300	3000
	4 hr	15000	200000	<10	<10	<10	100
	24 hr	<10	40000	<10	<10	100	200

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ABL Medical Date on File - Analytical Resource Laboratory; Orem, UT 03/14

Independent *In Vitro* Report on Antimicrobial Effects of the Active Ingredient in SilvrSTAT®

Kill Time Study with 32PPM Gel				
Organism	**Exposure Interval**	**Avg. Control Titer (CFU/ml)**	**Percent Reduction**	**Log Reduction**
MRSA	1 HR	1.9×10^6	>99.99	>4.98
	24 HR	1.9×10^6	>99.99	>4.98
P. Aeruginosa	1 HR	2.1×10^6	>99.99905	>5.02
	24 HR	2.1×10^6	>99.99905	>5.02
VRE	1 HR	1.9×10^6	>99.56	2.35
	24 HR	1.9×10^6	>99.99	>5.38

Bacteria	Not less than 1.0 log reduction from the initial calculated count at 7 days, not less than 3.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days

FDA Required Time Study: Nelson Laboratories (#474527, #474527A, #474527B, #474527C, #474527D, #474527E Data on File

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Independent *In Vitro* Report on the Antibacterial Effects of the Active Ingredient in SilvrSTAT®

Disinfectant Efficacy Results @ 5 and 10 Minutes of 60 Different Tests Per Bacteria

ORGANISM	TIME POINT (MIN.)	CARRIER TITER (CFU/CARRIER)	NUMBER OF CARRIERS TESTED	NUMBER SHOWING GROWTH	NUMBER SHOWING NO GROWTH
P. aeruginosa	5	5.5×10^4	60	0	60
	10	5.5×10^4	60	1	59
S. aureus	5	5.5×10^6	60	6	54
	10	5.5×10^6	60	1	59
S. choleraesuis	5	5.5×10^6	60	1	59
	10	5.5×10^6	60	0	60

Data on File

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Benefits of

ABL Silver Technology.

- Provides a clear protection barrier, that lasts up to three (3 days, and has a cytotoxicity rating of 1, just as ‘safe as water’
- In comparing our wound care silver gel with other products in same regulatory category (including triple antibiotic ointment) using comparison date measuring kill rate and duration of kill, our wound care silver gel virtually eliminated pathogens within 24 hours via Independent In Vitro studies
- 420+ reports and studies
- 5 human ingestion studies – When ingested, no negative action with other drugs, on blood platelets, organs, and body systems
- Probiotic studies showing that our patented nano-silver, does no damage to probiotic systems
- No Silver buildup; no accumulation. Particles exit the body within 24 hours, unlike other forms of silver
- No known or expected adverse events due to the low 24ppm silver concentration

ABL Medical™

ABL Medical's **SILVER IS SAFE.**

- **Over 400 Independent Studies & Test Reports – Performed By More Than 60 Leading Independent Laboratories, Universities, Government, & Military Labs**
- **3 Published & FDA Cleared Human Ingestion Studies**
- **Peer-Reviewed & Published Scientific & Medical Journal Articles**

- **Available upon request:**
  - ✓ **Safety Studies**
  - ✓ **USP 51 Challenge Tests**
  - ✓ **Key Publications**
  - ✓ **Clinical Trials**
  - ✓ **Product Demonstration Videos**

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Independent *In Vitro* Report on SilvrSTAT®

Organism at control titer of 1,000,000 to 10,000,000 CFU/ml	0 hour Log_{10} reduction results	7 day Log_{10} reduction results	14 day Log_{10} reduction results	28 day Log_{10} reduction results
Staphylococcus aureus	0.91	>4.72	>4.72	>4.72
Pseudomonas aeruginosa	>3.31	>4.31	>4.31	>4.31
Escherichia coli	>3.12	>4.56	>4.56	>4.56
Candida albicans	>3.73	>4.73	>4.73	>4.73

Organism	Exposure interval	Average control titer (CFU/ml)	Percent reduction (%)	Log_{10} reduction
Methicillin-resistant *Staphylococcus aureus* (MRSA), ATCC#4330	1 hour	1,900,000	99.9989	>4.98
Methicillin-resistant *Staphylococcus aureus* (MRSA), ATCC#4330	24 hours	1,900,000	99.9989	>4.98
Vancomycin-resistant *Enterococcus faecalis* (VRE), ATCC#51575	1 hour	4,800,000	99.56	2.35
Vancomycin-resistant *Enterococcus faecalis* (VRE), ATCC#51575	24 hour	4,800,000	>99.99958	>5.38

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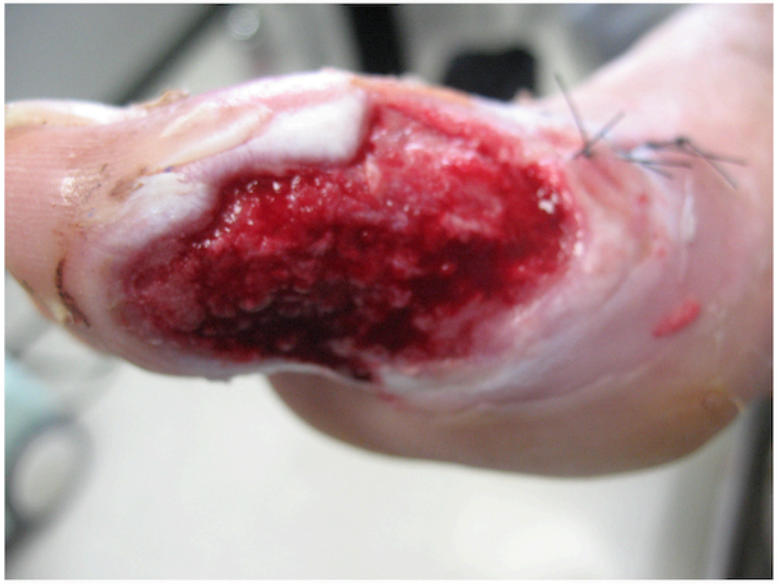
SILVRSTAT®
Antibacterial Wound Dressing Gel

THE NEXT GENERATION IN WOUND DRESSINGS



Day 1
4.2 x 3.4 x 0.2 cm

Patient Summary

33-year-old patient was seen in the hospital for an infected right great toe ulceration. Patient has had previous history of diabetic foot infections and this was his 3rd occurrence on this foot. Patient had extreme pain to his right foot on clinical presentation. 2.0 diameter ulcer to medial aspect of right great toe. 4 cm tunnel from proximal plantar 1st MPJ to distal plantar right great toe. No probing to bone identified.

PMH: IDDM (x 26 years); depression; asthma; left great toe amputation (2012)

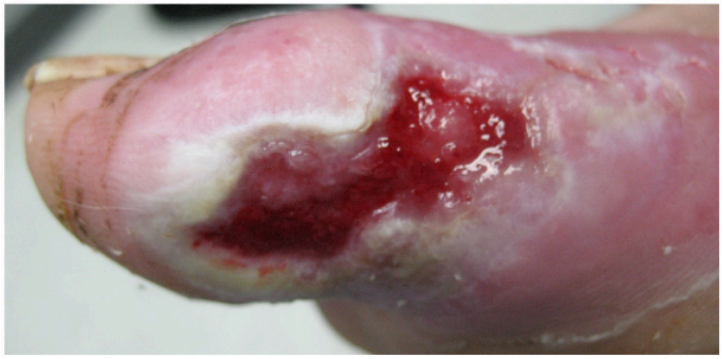
Allergies: Erythromycin and iodine

Clinical Course

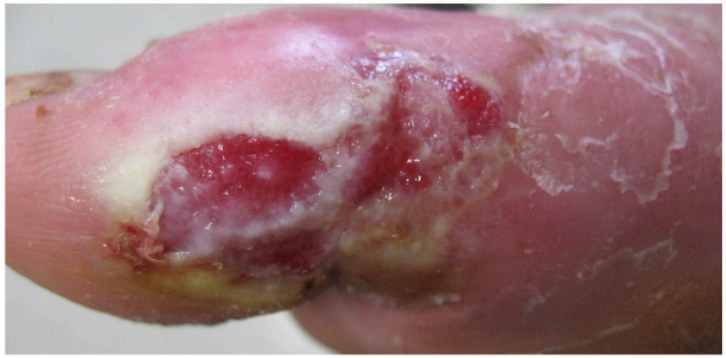
Operative treatment included debridement and incision/drainage of abcess. Application of SilvrSTAT® changed every 3 days.

SILVRSTAT®
Antibacterial Wound Dressing Gel

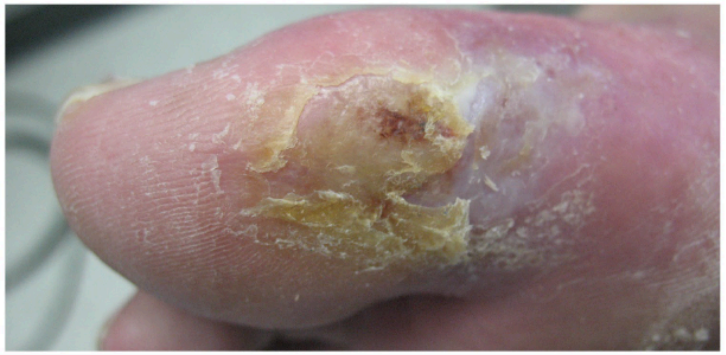
THE NEXT GENERATION IN WOUND DRESSINGS



Day 8
3.5 x 2.5 x 0.15 cm



Day 18
1.5 x 2.0 x 0.15 cm



Day 25

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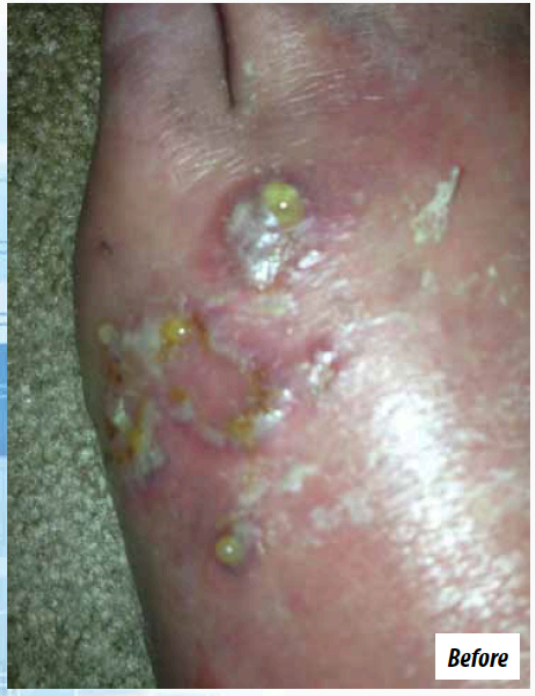
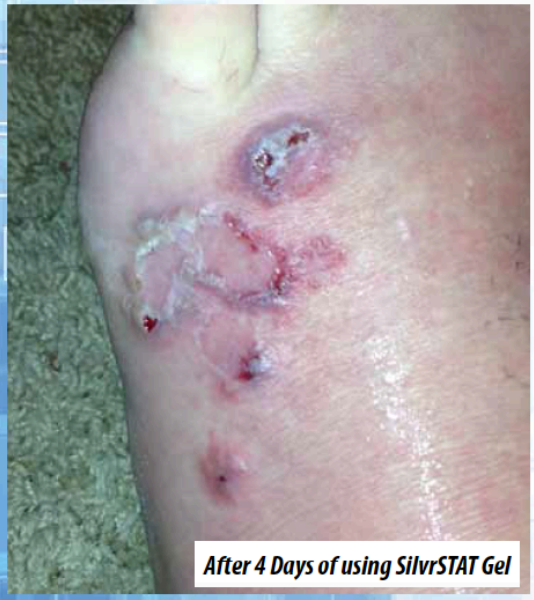
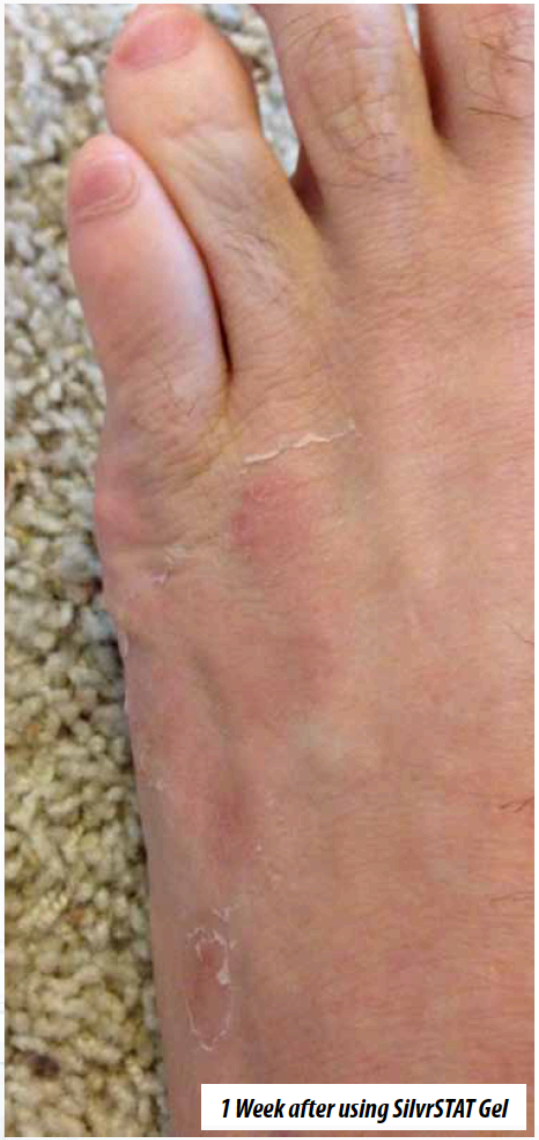
MRSA Wound : Foot
54 year old Male
Case Study







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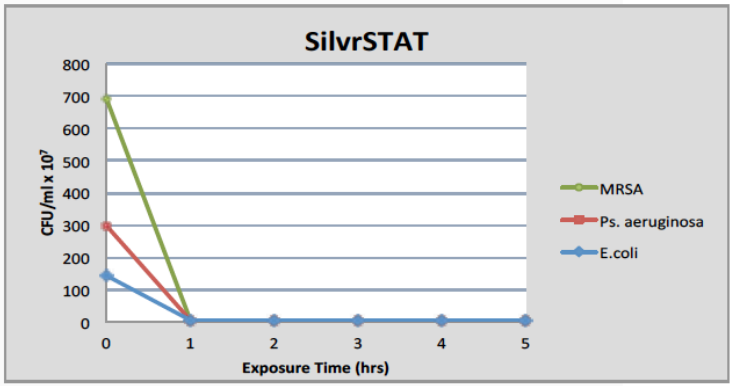
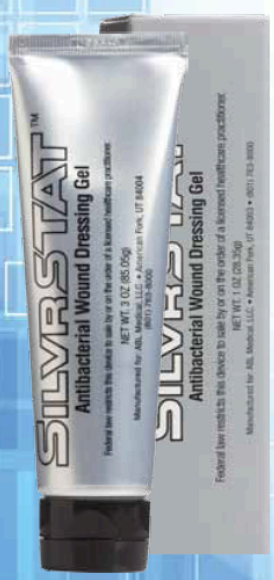
SILVRSTAT®

Antibacterial Wound Dressing Gel





- SilvrSTAT Antibacterial Wound Dressing Gel is indicated for the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites and donor sites.[2]
- It is ***not*** an ionic silver.[1]
- SilvrSTAT should be applied directly to the affected area and covered with an appropriate dressing.[2]
- For burns, SilvrSTAT should be applied to the affected area and allowed to dry.
- There are no known adverse events associated with the use of SilvrSTAT for external wound management.[2]

SilvrSTAT offers:

- Superior wound management
- Inhibition of broad spectrum bacteria including MRSA and VRE
- Visualization of the wound through a transparent gel
- No Sulfa or Alginate components
- No Alcohol
- Non-flammable

References

1. R. Roy et al, Materials Research Innovations 2007 Vol 11 No 1
2. SilvrSTAT Antibacterial Wound Dressing Gel United States Package Insert
ABL Medical Data On File

ABLMedical™
801.763.8000 American Fork, UT 84003
www.silvrstat.com
www.ablmedical.com

J Wound Care. 2017 Apr 1;26(sup4):S16-S24. doi: 10.12968/jowc.2017.26.Sup4.S16.

The ability of a colloidal silver gel wound dressing to kill bacteria in vitro and in vivo.

Tran PL[1], Huynh E[1], Hamood AN[2], de Souza A[3], Mehta D[3], Moeller KW[4], Moeller CD[4], Morgan M[5], Reid TW[6].

Author information

Abstract

OBJECTIVE: Inhibiting bacterial biofilms is of major significance for proper wound healing. The choice of the dressing material plays a key role, as bacteria can live in dressings and keep reinfecting the wound. This study examines the effectiveness of a colloidal silver gel (Ag-gel) wound dressing in inhibiting the growth of bacteria in a mouse wound model.

METHOD: Staphylococcus aureus, Pseudomonas aeruginosa, Acinetobacter baumannii and two different meticillin-resistant Staphylococcus aureus (MRSA) strains were examined. Bacteria were measured in vitro on the dressing, and in vivo studies were carried out to analyses both the dressing and the infected tissue. The silver gel product used was SilvrSTAT from ABL Medical, LLC.

RESULTS: Using colony-forming unit (CFU) assays, over 7 logs of inhibition (100%) were found for Staphylococcus aureus, Pseudomonas aeruginosa and Acinetobacter baumannii for the Ag-gel dressing when compared with the control dressing. In vivo, complete inhibition was observed for the three most common bacteria on the Ag-gel dressing and the tissue under that dressing. These results were confirmed by an in vivo live imaging system. However, with MRSA strains, only 2-3 logs of inhibition were recorded.

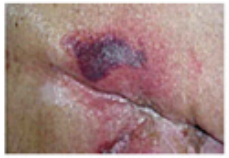
CONCLUSION: The Ag-gel was effective in preventing biofilm infections caused by both Gram-negative and Gram-positive bacteria.

KEYWORDS: biofilm; in vitro model; in vivo model; infection; silver; wound; wound dressing

PMID: 28379105 DOI: 10.12968/jowc.2017.26.Sup4.S16

Skin and Wound Care Quick Reference/Guideline
Protocols Provided By MEDEON

SILVRSTAT



Suspected Deep Tissue Injury (sDTI)

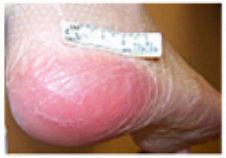
Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear.

Further description: The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with treatment.

Prevention Guidelines
- Pressure redistribution support surface as appropriate
- Turn and reposition q 2h in bed and q 1h in chair
- Offloading device to keep heels elevated off bed
- Monitor skin at least q 8hrs

Cleanse
- Cleansing Shampoo, Foam, or Body Wash

Apply
- Skin Repair Cream to moisturize skin
- Skin prep for at risk skin
- Zinc prep for compromised skin
- SilvrSTAT for yeast/fungus



Stage I Pressure Ulcer

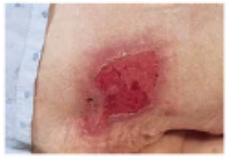
Intact skin with non-blanchable erythema of a localized area usually over a bony prominence. Discoloration of the skin, warmth, edema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching.

Further description: The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons.

Intact Skin

Cleanse
- Cleansing shampoo or foam

Apply
- Protective Barrier or Hydrocolloid



Stage II Pressure Ulcer Partial Thickness Skin Loss or Blister

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum filled or serosanginous filled blister.

Further description: Presents as a shiny or dry shallow ulcer without slough or bruising. This category/stage should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration or excoriation.

Dry to Scant Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type and condition of the wound

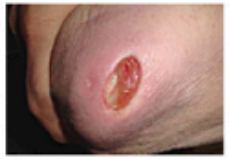
Moderate to Heavy Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT hydrogel to base
- Alginate filler

Cover
- Silicone adhesive foam gentle/Super absorbent dressing

Change
- Daily or as indicated by type and condition of the wound



Stage III Pressure Ulcer or Stage IV Pressure Ulcer or Full Thickness Wound

Stage III: Full Thickness tissue loss (fat visible) Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Some slough may be present. May include undermining and tunneling.

Further description: The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

Dry to Scant Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type and condition of the wound

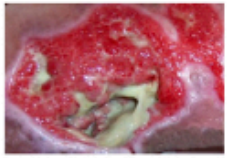
Moderate to Heavy Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT hydrogel to base
- Alginate filler

Cover
- Silicone adhesive foam gentle/Super absorbent dressing

Change
- Daily or as indicated by type and condition of the wound



Stage IV: Full Thickness tissue loss (muscle/bone visible). Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often include undermining and tunneling.

Further description: The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g. fascia, tendon or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/muscle is visible or directly palpable.

Dry to Scant Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type and condition of the wound

Moderate to Heavy Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT hydrogel to base
- Alginate filler

Cover
- Silicone adhesive foam gentle/Super absorbent dressing

Change
- Daily or as indicated by type and condition of the wound

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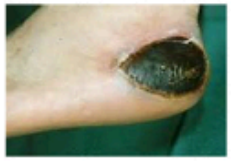
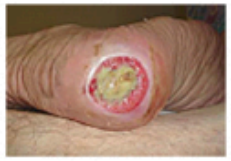
Rev 10/14

Skin and Wound Care Quick Reference/Guideline
Protocols Provided By MEDEON

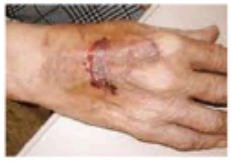
SILVRSTAT



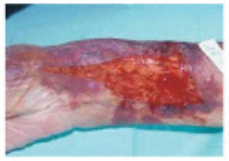
Unstageable Pressure Ulcers



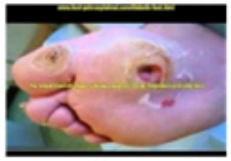
Necrotic Wounds



Skin Tear Category I or II



Skin Tear Category III



Colonized or Infected Wounds

Unstageable: Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

Further description: Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either a Category/Stage III or IV. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as "the body's natural (biological) cover" and should not be removed.

Category I: Skin tear without tissue loss. Characteristics are based on whether the damage is a linear tear or a skin-flap type tear. Both tears can be fully approximated.

Category II: Skin tear with partial tissue loss. Tears will have a partial thickness epidermal tissue loss. The tears are further classified as scant versus moderate to large tissue loss.

Category III: Skin tear with complete tissue loss where the epidermal flap is absent. These are wounds with complete tissue loss.

Colonized: Bacterial load is high enough that the host is losing control over wound environment may not show critical signs of infection.

Infected: Represents the invasion of bacteria into healthy tissue where they continue to proliferate and elicit a reaction from the host will typically show signs of clinical infection.

Solid Dry Eschar on Heels

Cover
- No Dressing
- Keep Dry

Float heels to relieve pressure

Other Necrotic Wounds with Eschar, Yellow or Black Slough

Cleanse
- Wound Cleanser

Apply
- Skin prep to periwound skin
- Sharp debridement if possible, if not then use an enzymatic debrider for 4 -5 days.
- Following debridement use SilvrSTAT Hydrogel

Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel to wound

Cover
- Gauze/Rolled Gauze

Change
- Daily or as indicated by type and condition of the wound

Approximate edges when possible with moistened swab

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel to wound bed

Cover
- Silicone adhesive foam gentle/Super absorbent dressing

Change
- Daily or as indicated by type and condition of the wound

Dry to Scant Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel

Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type and condition of the wound

Moderate to Heavy Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel

Cover
- Calcium Alginate cover dressing

Change
- Daily or as indicated by type and condition of the wound

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Rev. 10/14

Independent *In Vitro* Report on the Cytotoxicity of SilvrSTAT®

The MEM Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the sample was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

CONDITIONS OF ALL CULTURES	REACTIVITY	GRADE
No cell lysis, intracytoplasmic granules.	NONE	0
Not more than 20% rounding, occasional lysed cells.	SLIGHT	1
Not more than 50% rounding, no extensive cell lysis.	MILD	2
Not more than 70% rounding and lysed cells.	MODERATE	3
Nearly complete cell destruction.	SEVERE	4

IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
Negative Control	0	0	0	0
Media Control	0	0	0	0
Positive Control	4	4	4	4
429606 Lot #060908	1	1	1	1

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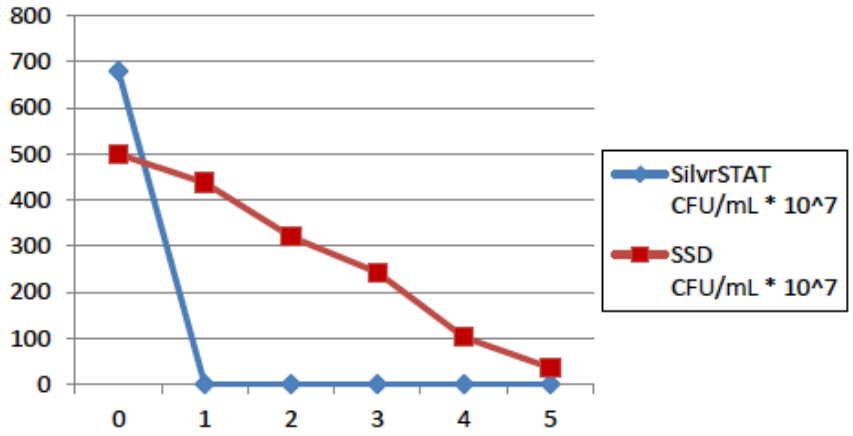
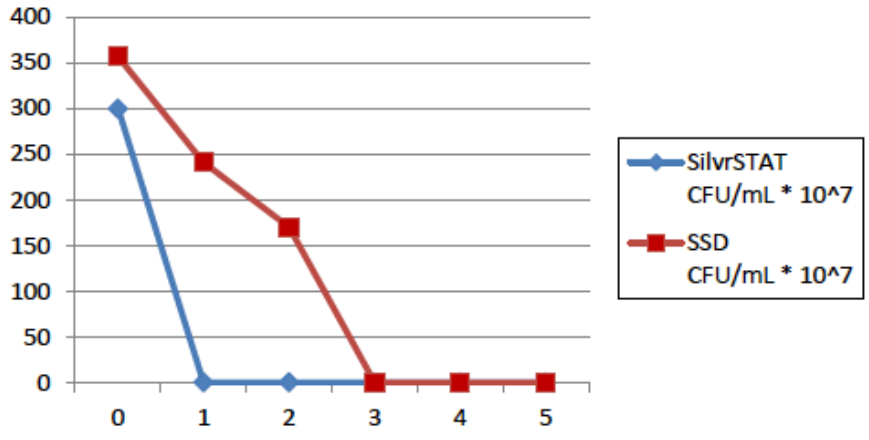
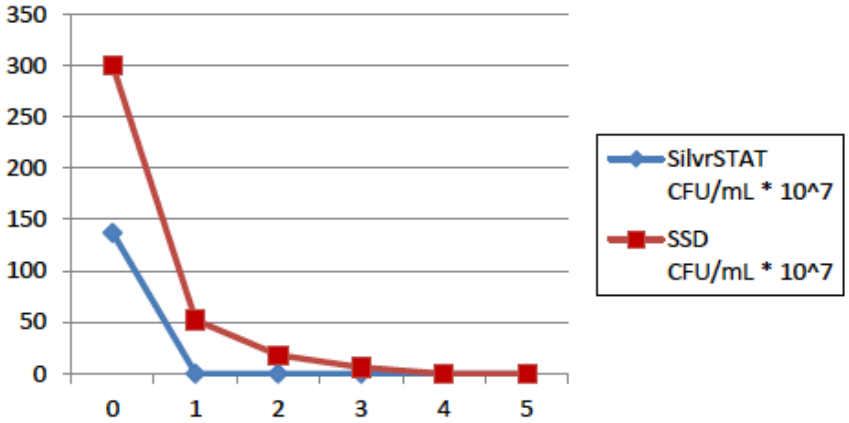
Independent *In Vitro* Report of SilvrSTAT® vs Silver Sulfadiazine



P. Aeruginosa



MRSA



E. coli

- SilvrSTAT® 32ppm vs. Silver Sulfadiazine (SSD) 10,000ppm to determine the killing curve of both products *in vitro.*
- Despite the lower concentration of silver, SilvrSTAT® provides quicker bactericidal activity versus the commonly used silver sulfadiazine.
- Wounds free of pathogens may heal more quickly than those which have high bacterial loads.

ABL Medical, American Fork, UT - Data on File

ABL Medical™

Healing a Complicated Wound Using a Multivalent Silver Nanoparticle Gel

Adam Falivene, BA; Anthony R. Iorio, DPM, MPH, FACWCA
New York College of Podiatric Medicine

INTRODUCTION

Silver has been used for centuries in medicine and in hygiene, largely due to bactericidal and broad-spectrum antimicrobial activity. By the seventeen hundreds silver nitrate was being used for treatment of ulcers . Silver is regularly used now in wound care and medical devices for dental work and catheters. Silver Sulfadiazine, a topical treatment, has regularly been used to treat burn wounds. At this stage, nanotechnology is being used create silver nanoparticles which are more efficient than silver ions alone.

Nanoparticles are particles smaller than 100 nm and the effectiveness of silver nanoparticles has been widely tested and shown to have broad spectrum antibacterial properties for Gram-positive and Gram-negative bacteria. Silver Nanoparticles are known to have strong bacteriocidal effects on many different types of bacteria, including Methicillin-resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa*, ampicillin resistant E. Coli and S. Pyogenes. Their biological activity stems from its associated silver ion and its soluble complexes that generate reactive oxygen species. Specifically, the silver ion binds to thiol groups in key enzymes causing a disruption of the bacterial respiratory chain. The reactive oxygen species created in this process cause oxidative stress and cell damage to the bacteria. Interestingly, the small form of nanosilver particles, offers a large surface area to volume ration in its application, increasing the potential for silver ions to be released in the affected area.

SilvrSTAT® is a multivalent silver nanoparticle gel that was released as a antibacterial wound dressing gel in 2012. It's active ingredient is a nanoparticle that has a core of metallic silver with a coat of tetra silver tetroxide (Ag4O4) that has areas of positive charge and negative charge. This molecule is partly ionic and partly covalent, with two silver atoms in the +1 oxidation state and two silver atoms in the +3 oxidation state, making it multivalent and a very powerful oxidizing agent. When one of the areas of positive charge comes within close contact to a bacterial cell wall, it dislodges electrons and causes immediate collapse of the cell wall. The advantage of this multivalent silver nanoparticle is that it is able to kill bacteria rapidly and stay effective at relatively low levels of silver concentration; 32ppm. Our hypothesis is that by using this multivalent silver nanoparticle gel on a diabetic ulcer, we will see faster and improved ulcer closure than with another hydrogel.

CASE STUDY

A 66-year-old female with a history of uncontrolled Type II Diabetes Mellitus and diabetic peripheral neuropathy presents with two ulcers – one on the plantar aspect of each foot .The patient was diagnosed with Multiple Sclerosis five years ago. She has NKDA and denies a history of smoking, but drinks 1 to 2 drinks daily. Pre-treatment the wound on the left measured 1 cm x 1 cm x 0.1 cm, with granular, erythematous base and hyperkerotic border. The patient followed up with us for weekly standard of care treatment by mechanical debridement, infection control, and appropriate offloading and dressing of both the ulcers. At each visit the patient also received application of the multivalent silver nanoparticle gel (SilvrSTAT®) to the left ulcer. The weekly visits were followed by instructions to apply the multivalent silver nanoparticle gel to the wound on her left foot and another hydrogel to the wound on her right foot. Using this technique and monitoring the wounds every week, we saw saw reduction in the size of the wounds, with faster closure of the wound on the left foot.

RESULTS

The time for closure of the wound on the left foot, receiving application of the the multivalent silver nanoparticle gel was 6 weeks.

The time for close for the wound on right foot, not receiving application of of the multivalent silver nanoparticle gel was 8 weeks.

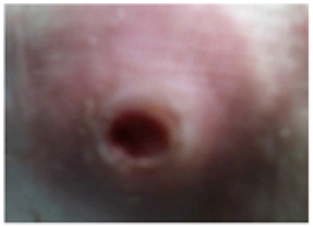


Figure 1: Week 1 Wound on Left: Measured 1 cm x 1 cm x 0.1 cm

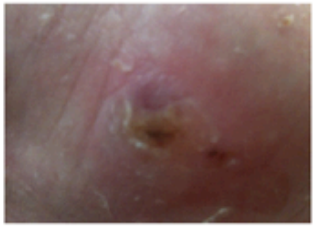


Figure 2: Week 6 Wound on Left: Closed

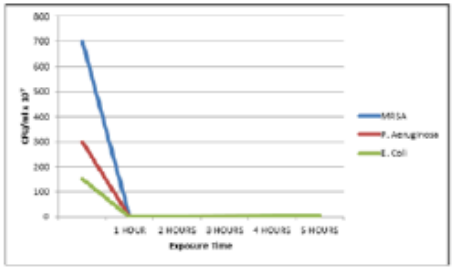


Figure 3: Graph of the kill rate of SilvrSTAT® and showing effectiveness with infection control against common organisms infecting wounds.

KILL TIME STUDY WITH 32 PPM GEL				
ORGANISM	EXPOSURE INTERVAL	AVG. CONTROL TITER (CFU/ml)	% REDUCTION	LOG REDUCTION
MRSA	1 HR	1.9×10^8	> 99.99	> 4.98
	24 HR	1.9×10^8	> 99.99	> 4.98
P. Aeruginosa	1 HR	2.1×10^8	> 99.999 05	> 5.02
	24 HR	2.1×10^8	> 99.999 05	> 5.02
VRE	1 HR	1.9×10^8	> 99.56	> 2.35
	24 HR	1.9×10^8	> 99.99	> 5.38

Figure 4: Kill Time of SilvrSTAT® against common org

METHODS

1. Standard of care treatment with mechanical debridement was performed initially at every encounter to both wounds.
2. Sterile Saline was then applied to clean the wounds with infection control and appropriate off-loading of the wounds conducted.
3. Application of the multivalent silver nanoparticle gel to the wound on the left, application of another hydrogel to the wound on the right.
4. The patient was instructed to continue daily application of the gels as noted in Step 3.

CONCLUSION

Silver properties may have enhanced the healing properties of the wound, causing it to heal faster. The wound treated with the multivalent silver nanoparticle gel closed sooner by two weeks perhaps by the antimicrobial properties associated with silver, however more studies need to be conducted before we can prove this hypothesis. With daily applications of the multivalent silver nanoparticle gel to the wound on the patient's left foot, we saw improvement of healing and time to close as compared to the wound on the patient's right foot. Our results show that multivalent silver nanoengineered technology is an effective and economical hydrogel in wound healing.

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Poster Presented at Spring SAW-C 2014

A Novel New Nanoparticle Silver Hydrogel* on Surgical Sites - A Case Series

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West Boca Center for Wound Healing

The investigator retained full independence in the conduct of this research.

ABSTRACT

Over the years there have been many opportunities to address surgical site contamination and post-operative infections in the outpatient setting. Most notably, since the advent of Methicillin-resistant infections and an increasing diabetic patient population (this also includes pre-diabetic patients), the risks for surgery have increased in the ability of a patient to properly heal, even with primary intention closure.

For centuries, human beings have utilized silver-based dressings and silver itself as a method of battling contaminant bacteria and viruses. In today's modern age of medicine, the use of nanometric silver products has become mainstream.

A newer, more agile molecular silver hydrogel has shown effective use in the treatment of nosocomial infections and bacteria. This novel new silver hydrogel is a 32 ppm nanoparticle which has multivalent and catalytic antimicrobial properties. The molecular silver hydrogel is multivalent, resulting in multiple electrons being physically pulled from the bacteria cell wall, allowing for rapid antimicrobial effect. Additionally, this multivalent silver hydrogel is catalytic, causing a reaction where the molecular silver remains unbound allowing for use at low concentration and reducing potential side effects.

This new nanoparticle silver hydrogel is clinically indicated for pressure ulcers, diabetic foot ulcers, surgical incision sites, autograft and allograft sites, first and second degree burns, venous stasis ulcers, lacerations and abrasions, device insertion site wounds and donor sites.

This case study series will demonstrate this new nanoparticle molecular silver hydrogel and its use in preventing surgical site infections and contamination on high-risk diabetic and peripheral arterial disease patients. The use of this nanoparticle molecular silver hydrogel not only showed high effectiveness in preventing infection or contamination, but as a result, also prevented dehiscence of the surgical sites.

METHODS

The purpose of this case study series is to show the use of a new nanoparticle silver hydrogel effect on surgical wound sites both post-operative and during the follow-up phases of surgery, which shows that the use of the hydrogel effectively continues to maintain an antimicrobial layer between the sutures and the incision site.

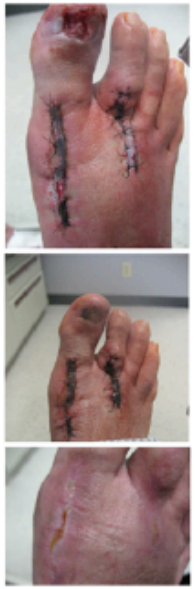
The use of the nanoparticle silver hydrogel is to maintain a moist healing environment, but also maintain an antimicrobial environment, capable of destroying and killing bacteria that cause nosocomial post-operative infections.

Applications of nanoparticle silver hydrogel immediately post-operative and at each post-surgical visit until suture removal. All patients were cleared post-surgically of any residual contamination or infection by day 14. There was no evidence of any dehiscence or breakdown of the incision after 14 days.

In short, the use of Nanoparticle silver hydrogel can be beneficial in areas of surgical management of high to low-risk surgical patients in the inpatient and outpatient settings where the need for more antibiosis is required in patients post-operatively.

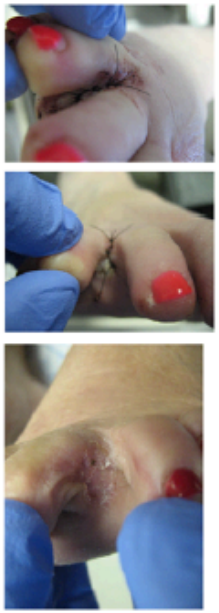
Case 1

52 y/o diabetic male patient underwent elective corrective repair for hallux valgus and prediabetic 2nd MPJ right foot. Patient was given nanoparticle silver hydrogel immediately post-operative and throughout the duration of post-operative suture care every 3rd day. Patient sutures removed at day 18 without any signs of infection, dehiscence or pull-out from the nanoparticle silver hydrogel.



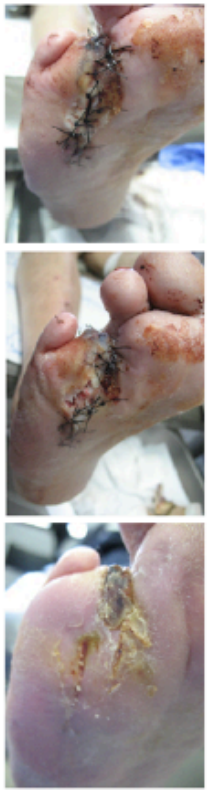
Case 2

56 y/o female patient underwent elective plantar digital neuroplasty to her 3rd interspace right foot. Nanoparticle silver hydrogel was used post-operatively and changed every 3rd day. Sutures removed at day 15 without pull-out, dehiscence or infection.



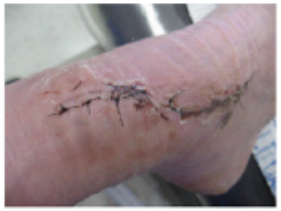
Case 3

72 y/o male diabetic patient underwent non-elective surgical resection of his 4th metatarsal head secondary to acute osteomyelitis. Wound was closed on day 3 post-operatively with use of nanoparticle silver hydrogel. Wound coapted and healed with every 3rd day dressing changes at day 21.



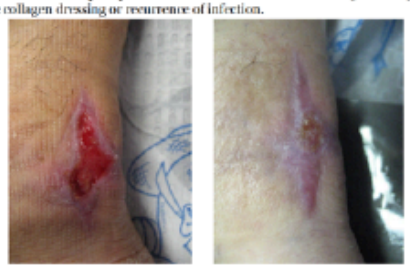
Case 4

34 y/o female underwent emergency I&D of abscess to her right foot secondary to IV Dilaudid injection abuse. Wound closed post I&D at day 4, with application of nanoparticle silver hydrogel. Dressing changed weekly x 2-5 weeks until coaption of tissues. Sutures removed at day 21 without signs of infection, dehiscence or pullout.



Case 5

38 y/o female was seen for emergency as result of brown-recluse spider bite to right medial lower leg. Wound was treated and irrigated, with nanoparticle silver hydrogel applied post-procedure. Nanoparticle silver hydrogel was used in conjunction with ovine forestomach dermal template to obtain wound closure at week 6 post-procedure. There was no evidence of cytotoxicity with the collagen dressing or recurrence of infection.



CONCLUSIONS/LIMITATIONS

The above case series demonstrates that the use of a nanoparticle silver hydrogel with a multivalent structure can be used both post-surgically as a primary dressing and post-surgically with an open wound with concomitant use of collagen wound dressings without loss of tissue due to cytotoxicity. The ability of the silver hydrogel to not only catalytically destroy bacteria, but maintain a moist wound healing environment is novel in the marketplace and further controlled studies and/or post-market RCT should be developed to further introduce this product's wound healing principles. Although this is a small sample case series, the author believes that there is enough clinical evidence to show the functional ability of this product in not only elective post-surgical, but in high-risk, highly infected individuals where the need for a more versatile silver hydrogel product can be used.

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**SilvrSTAT® Antibacterial Wound Dressing Gel*
ABL Medical, LLC, American Fork, UT

ABL Medical™

KEY PUBLICATIONS **TO DATE.**

Journal of Wound Care; North American Supplement, Vol. 26; No. 4; April 2017. The Ability of a Colloidal Silver Gel Wound Dressing to Kill Bacteria In-Vitro and In-Vivo (including 2 Different MRSA Strains).

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Evolution **of Silver.**

Brief Evolution of Silver Particles Before SilverSol Technology®

ANCIENT REMEDY
Silver has been used for thousands of years for its anti-microbial properties.

Mid 19th CENTURY
Silver Ions were isolated using electrodes, direct current and water.

1891 Mild
Silver Protein was developed in an attempt to stabilize ionic silver particles.

1996 American Biotech Labs
develops a safe, highly stable, multi-valiant nano-silver particle SilverSol Technology®.

ABL Medical™

Awards **won.**

Award Winning Technology

American Biotech Labs, LLC, is an eight time recipient of the Best of State award for Medical Innovation by the premier recognition and rewards program for the State of Utah.

The Best of State Awards are awarded annually to companies deemed to have achieved exceptional excellence in an area of endeavor. Of hundreds of biotech and medical products companies who have facilities in the state, the 2007, 2009, 2011, 2015-2018 winner was American Biotech Labs.

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Questions & Answers

For medical responses or data on file, contact
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