

A Clinical Review of the Treatment of Diabetic Ulcers, Pressure Ulcers and Venous Stasis Ulcers in Human Subjects Using Silver Sol Gel While Residing in a Geriatric Health Care Facility

By

Gordon Pedersen Ph.D.

Abstract

Diabetic ulcers, pressure ulcers and venous stasis ulcers were treated with Silver Sol Gel in conjunction with Advanced Healing Systems Formulary process that includes new technologies that are in combination with the best practices available in wound care resulting in remarkable recoveries. The weekly photographic and empirical quantification of the healing processes are recorded in this study. The weekly improvements seen in very difficult cases illustrate the broad-spectrum abilities of Silver Sol Gel. Diabetics suffer from hormone changes, reduced blood flow to extremities and wounds that heal very slowly if at all. These diabetic wounds remain open for long periods of time and are susceptible to bacterial, viral and fungal infection. Diabetic wounds have been shown to be polymicrobial and difficult to treat.

Silver Sol Gel was used to treat the diabetic ulcer, pressure ulcers and venous stasis ulcers of patients being treated in outpatient and long term care facilities where data was collected by Advanced Health Systems (AHS). The resident doctors and nurses applied Silver Sol Gel to these types of wound and recorded the size of wound depth of wound, area of wound and time to closure. In addition photos were taken and recorded on a weekly basis.

In this study Silver Sol Gel in combination with best practices reduced the size of the wound, the depth of the wound and area of wounds found in diabetic ulcers, pressure ulcers and venous stasis ulcers, and accomplished complete wound closure and healing in 5 to 12 weeks. The improvements seen in the weekly photographs visually depict three remarkable recoveries using Silver Sol. The remarkable recoveries can be explained by the fact that silver sol completely destroys bacteria, viruses and fungi. By reducing the polymicrobial infections sustained in diabetic wounds, the associative swelling was reduced, thus allowing better circulation immune access and improved wound healing.

Literature Review

Type 1 Diabetes is a chronic disease that occurs when the beta cells of the pancreas are not able to produce enough insulin to properly control blood sugar levels (3). In the absence of insulin, glycogenesis and glycolysis are adversely affected (4). It is currently thought that insulin acts primarily at the cell membrane facilitating transport of glucose into the cell (4). Symptoms of diabetes appear or are aggravated through the following causes: Genetics, infections, pancreas dysfunction and lack of exercise and poor diet (4).

Diabetic Ulcers are also called Diabetic Bullae, Skin Ulcers & Diabetes, and Bullosis Diabeticorum. An ulcer can apply to any open wound or sore., but a diabetic ulcer usually involves a serious condition usually found in the extremities or back and is always associated with a person who has diabetes.

People with diabetes are at increased risk of developing pressure sores (bed sores) which present with a breakdown in the skin and underlying tissues due to prolonged pressure such as laying in bed for extended periods of time.

Diabetes may produce numerous complications that can lead to problems throughout all systems of the body. Especially serious and debilitating problems include open sores that don't heal. These open sores or ulcers are caused by the decrease in circulation, infections and changes in blood vessels due to symptoms of diabetes. Many patients have diabetic ulcers that become infected before they are discovered due to neuropathy caused by diabetes.

Typically diabetic ulcers consist of more than one type of bacterium (called Polymicrobial ulcers). It is common for 4 to 6 different bacteria to be present in the diabetic wound. The most common infective agents include staph and streptococcus although pseudomonas and candida (a yeast) may also co-contaminate these diabetic ulcers (1). Since Diabetics have vaso-constricted arteries the amount of blood flow is compromised which results in a decrease in immune competency, blood flow, oxygen and nutrients necessary for the healing process to proceed at a normal rate. These patients may develop minor wounds that don't close or heal for years, due to the fact that they are open and become infected with numerous types of bacteria and yeast. Once infected the diabetic patient has a much more difficult time in closing and healing the wound compared to normal heal rates. Over time, infected ulcers may cause enough tissue damage to require surgical intervention or amputation. For this reason diabetes is the number one cause of foot amputations in America (2).

This study focuses on human diabetic subjects that have developed diabetic ulcers and were treated with the anti-microbial, antifungal and antiviral agent Silver Sol. Silver Sol gel was applied topically to diabetic wounds and found to destroy the cause of infection and help improve wound healing in diabetic patients residing in a geriatric health care facility.

Silver Sol gel has been demonstrated to completely destroy bacteria and yeast (5). It improves healing outcomes from MRSA (7), and has been shown to promote faster and less painful healing times (7). For these and many more reasons Silver Sol was selected to treat infected wounds in the diabetic patients.

Materials and Methods

Three case studies were selected for diabetes and open wounds based on the quality of their photographic recordings of Silver Sol and best practices treatment. Health care professionals treated each patient with Silver Sol Gel, best practices and photographed their progress.

These photographs illustrate routine but significant improvements in wound closure and healing that regularly take place at this facility. All patients were under the care of properly licensed physicians and nurses. Silver Sol Gel was applied once or twice daily depending on the doctor's recommendations.

Wounds were measured for length depth and area and records recorded weekly. Photographs were taken before silver sol treatment was initiated and then every week afterwards.

Size of wound, area of wound, time to closure and photographs of before, during and after treatment with silver sol were recorded with the intent that doctors from other facilities could observe these results and compare similar treatments and outcomes.

The Silver Sol Gel (24 ppm), contains purified water, pure silver and the gelling agents carbomer/TEA, and was obtained from American Biotech Labs, Alpine Utah.

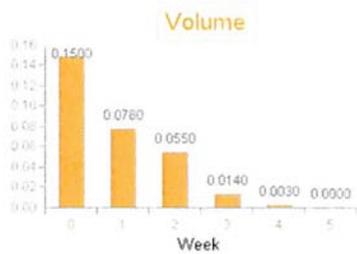
Results

Three cases were selected to illustrate diabetic ulcers, pressure ulcers and venous stasis ulcers. To date AHS has treated hundreds of these types of patients and have a remarkable record of healing using the silver sol product.

Subject #1 Diabetic Ulcer.

The diabetic patient presented with a foot ulcer, was treated with silver sol gel twice a day and achieved total recovery in 5 weeks.

Patient		Wound											
ID #	Name	Age	Sex	Health	Name	Type	Location	Stage	Onset Date	Formulary Date	Resolved Date	Onset Age	Formulary Age
549	Stuart, Margaret	71	Female	Fair	Foot Ulcer 1	Diabetic	Foot - Right, Anterior	3	1/5/2008	4/27/2008	6/4/2008	5.03	1.27
Week	Date	Length	Width	Depth	Volume	% Closure	Formulary	Note					
0	04/27/2008	1.5	1	0.1	0.1500	0	PEMF AHS Silver Sol						
1	05/05/2008	1.3	0.6	0.1	0.0780	48.00	PEMF AHS Silver Sol						
2	05/12/2008	1.1	0.5	0.1	0.0550	63.33	PEMF AHS Silver Sol						
3	05/19/2008	0.7	0.2	0.1	0.0140	90.67	PEMF AHS Silver Sol						
4	05/28/2008	0.3	0.1	0.1	0.0030	98.00	PEMF AHS Silver Sol						
5	06/04/2008	0	0	0	0	100.00	PEMF AHS Silver Sol						



Date

Wound Image

04/27/2008



Date

Wound Image

05/05/2008



05/12/2008



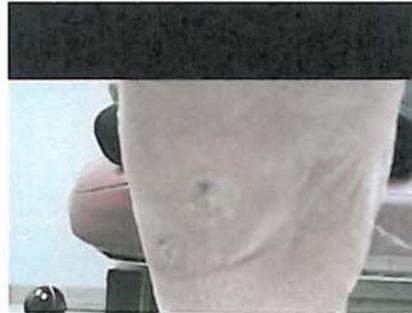
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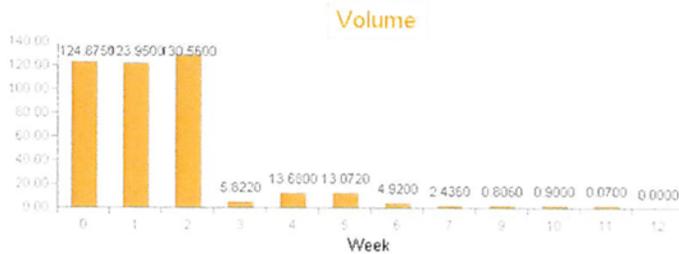
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Subject #2 Pressure Ulcer

The patient presented with a pressure ulcer was treated with silver sol gel twice daily and achieved wound closure and complete healing in 12 weeks.

Patient													
ID #	Name	Age	Sex	Health	Wound								
850	Thomas, Dorothy	0	Female	Fair	Name	Type	Location	Stage	Onset Date	Formulary Date	Resolved Date	Onset Age	Formulary Age
					R lower extremity#4	Injury	Lower Leg - Right, Lateral	Unstageable	10/30/2008	11/6/2008	3/12/2009	4.43	4.20
Week	Date	Length	Width	Depth	Volume	% Closure	Formulary	Note					
0	11/13/2008	13.5	3.7	2.5	124.8750	0	PEMF AHS Silver Sol						
1	11/20/2008	13.4	3.7	2.5	123.9500	0.74	PEMF AHS Silver Sol	undermining 8.7cm at 11 o'clock to 2 o'clock Previous blood clot passed making undermining deeper Wound bed looks clean.ABambenekWCC					
2	11/25/2008	13.6	4.8	2	130.5600	-4.55	PEMF AHS Silver Sol	Undermining @11 o'clock 6.9cm, 12 o'clock 8.8cm, 1 o'clock 6.5cm No photo taken. Measurements provided by floor nurse.					
3	12/04/2008	14.2	4.1	0.1	5.8220	95.34	PEMF AHS Silver Sol	Undermining @ 11 o'clock 7.4 cm, 12 o'clock 4.1cm, 1 o'clock 4.0 cm.Patient combative no photo taken.					
4	12/11/2008	15.2	4.5	0.2	13.6800	89.05	PEMF AHS Silver Sol	Undermining 11 o'clock measures 6.5 cm 12 o'clock measures 1.8 cm Wound is healing.					
5	12/18/2008	15.2	4.3	0.2	13.0720	89.53	PEMF AHS Silver Sol	undermining @10:00 o'clock measures 7.7 cm, undermining @11:00 o'clock measures 4.8 cm, 12:00 measures 2.3 cm Wound is clean and pink in color with areas of granulation wound edges are attached and defined. Scant amount of drainage serosanguineous drainage. no odor.					
6	01/08/2009	12	4.1	0.1	4.9200	96.06	PEMF AHS Silver Sol	Undermining is resolved. small amount of sanguineous drainage present. No odor. Tissue is firmly adherent. 100% beefy red granulation tissue.Epithelialization present at wound edges. Surrounding skin intact. No indications of infection. No c/o pain. Current tx PEMF silver and vaselinegauze secured with ABD pad.ABambenekWCC					
7	01/15/2009	8.4	2.9	0.1	2.4360	98.05	PEMF AHS Silver Sol	Scant amount of serosanguineous drainage No odor. Wound tissue firmly adherent 100% beefy red granulation tissue wound bed filling in nicely Epithelialization tissue present. Surrounding tissue present.No indications of infection No c/o pain with dressing change No change to tx. ABambenekWCC					
9	01/30/2009	6.2	1.3	0.1	0.8060	99.35	PEMF AHS Silver Sol	wound bed is granulating and filling in toward closure.					
10	02/05/2009	6	1.5	0.1	0.9000	99.28	PEMF AHS Silver Sol						
11	02/24/2009	1	0.7	0.1	0.0700	99.94	PEMF AHS Silver Sol	Wound bed 100% red beefy granulation tissue.Wound edges are intact.					
12	03/12/2009	0	0	0	0	100.00	PEMF AHS Silver Sol	Wound resolved.ABambenekWCC					





Subject #3 Venous Stasis Ulcer

Patient presented with venous stasis ulcer was treated with silver sol and achieved total wound closure and healing in 8 weeks.

ID #		Name		Patient		Age	Sex	Health		
1200		HEROLD, VIRGIL				96	Male	Fair		
Name	Type	Location	Stage			Onset Date	Formulary Date	Resolved Date	Onset Age	Formulary Age
left lower limb	Venous	Lower Leg - Left, Medial	SDTI Suspected Deep Tissue Injury			3/10/2009		4/29/2009	1.67	0.00
Week	Date	Length	Width	Depth	Volume	% Closure	Formulary	Note		
0	03/11/2009	3.1	2.8	0.1	0.8680	0		ulcer on left lower limb 100% slough tx as ordered cleanse with NS pat dry iodasord to wound bed, cover with alginate no telfa, GD with kirlex, NO S/S OF INFECTION, no odor noted, surrounding skin is red/dark brown remnants of venous stasis insufficiency		
1	03/17/2009	3.1	1.5	0.1	0.4650	46.43		venous stasis wound, dressing in place, mild amount of drainage, wound bed is 100% slough, surrounding skin is WNL, cool to touch, no odor noted, mild pain while cleansing with NS, and applying new dressing,		
2	03/25/2009	1.8	1.9	0.1	0.3420	60.60		minimal amount of drainage noted on dressing, no s/s of infection, skin is cool to touch, is tender for resident was cleansing is being done, surrounding skin is WNL, wound bed is light pink with scant bleeding when being cleansed, wound edges are adherent and there is slough around the edges, new dressing was applied		
3	03/31/2009	1.8	1.2	0.1	0.2160	75.12		wound bed is 80% granulated tissue, each time dressing is changed staff nurse does need to gently rub to remove ointment this does cause a small amount of bleeding, is painful for resident when this is done, surrounding skin is WNL no tunneling/undermining noted, no odor, s/s of infection, cont with tx as ordered, NP are following wound care for St. Mary's		
4	04/09/2009	1.9	1.4	0.1	0.2660	69.35		wound is healing nicely, surrounding skin is slightly pink and is warm, some staining from isosorbide cream that is being applied, wound bed is 100% granulated tissue no s/s of infection, no tunneling or undermining noted scant amount of drainage		
5	04/14/2009	1.2	1.3	0.1	0.1560	82.03		wound bed is 90% granulated tissue, remaining 10% is yellowish slough, resident does not complain of pain when dressing is being changed and wound is being cleansed, surrounding skin does have some yellowish/brown staining from the iodasord cream, there is no tunneling/undermining noted, dressing is @40% covered with yellowish drainage, cont tx as ordered, resident is being followed by NP.		
6	04/22/2009	1	0.4	0.1	0.0400	95.39		wound is healing, there is scant drainage, no s/s of infection, odor, tunneling or undermining, dressing was changed, dated and initialed		
7	04/29/2009	0	0	0	0	100.00		resident passed away.		
7	04/28/2009	1	0.6	0.1	0.0600	93.09		Wound rounds today. Measurement @ 1.0- x .6 x 1. Minimal amount of serosanguinous drainage on dressing No obvious odor noted. No signs of infection. Resident's overall condition deteriorating		





Date



03/12/2009



03/19/2009



03/24/2009



04/02/2009

Date



04/08/2009



04/15/2009



04/23/2009



04/29/2009

Conclusions

Silver Sol has been shown to completely destroy the bacteria viruses and yeast in vitro and in vivo (8). This is extremely important to the diabetic patient because their wounds typically consist of multiple bacteria and yeast. Silver Sol reduces the inflammation and tissue damage caused by bacteria, viruses and yeast thus reducing the infections that impede normal circulation, blood flow, immune function and healing.

Silver Sol Gel significantly reduced the infection in diabetic wounds, as measured by size of wound, time to closure and reduction of infection.

Table 4
Summary of Wound Healing

<u>Diagnosis</u>	<u>Size of wound</u>	<u>Percent wound closure (weeks)</u>			
		<u>wk 3</u>	<u>wk 6</u>	<u>wk 8</u>	<u>wk 12</u>
Diabetic Ulcer	1.5in X 3.6 in	84	100		
Venous Stasis Ulcer	5.3 in X 5.1 in	83	93	100	
Pressure Ulcer	13.6 in X 5.7 in	75	96	99	100

Table 4 illustrates the size of the wounds and the time to close these wounds. In all cases the wounds closed 75-84 percent within the first three weeks. The time it took for total wound closure was between 5-12 weeks with the larger wounds taking longer to close. It is remarkable that Silver Sol Gel helps promote complete infection free healing while assisting the immune system in closing wounds.

Ulcers in the diabetic patient can be polymicrobial and thus present a difficult problem is selecting a drug that is effective against numerous pathogens. Since there is no drug that has activity against bacteria, viruses and fungi, multiple drugs must be considered and many side effects controlled. Silver Sol has demonstrated the ability to destroy bacteria, viruses and fungi (broad spectrum of activity), making it a very desirable choice against the pathogens causing diabetic ulcers or any open wound. Silver Sol gel has been demonstrated to be an antimicrobial wound disinfectant, provide a moist protective barrier from pathogens, is water soluble, has been shown to reduce inflammation and stimulate stem cell activity. It contains no alcohol so it doesn't cause any discomfort or burning sensation when applied to the wound. It contains no grease which would cause maceration of the wound. It allows the wound to breathe and heal at the same time it kills bacteria and yeast.

Wounds that would not previously heal were healed. No patients complained. There were no painful side effects.

This study demonstrates remarkable anti-microbial activity against polymicrobial diabetic wounds. By removing the infecting pathogens and helping support immune function,

silver sol promotes improved wound healing, which is of utmost significance in the diabetic patient. The diabetic patient who uses Silver Sol as recommended in this study should expect to see benefits in the first three days with continuous improvement until all the pathogens are killed and the wound completely heals (in 5-12 weeks). This healing appears to be three times faster than similar treatments that do not contain silver sol. This can be supported by numerous wound healing studies which found the use of Silver Sol gel (applied twice daily) to result in three times faster wound healing as determined by time to wound closure (1, 5, 7).

Daily use of silver sol is recommended for preventive treatment against bacteria, viruses and fungi, and has been reported to improve naturally occurring stem cell activity (6) thus assisting the diabetic patient in multiple ways yielding remarkable broad spectrum recoveries not previously produced in diabetic subjects.

In this study Silver Sol Gel reduced the size of the wound, the depth of the wound and area of wounds found in diabetic ulcers, pressure ulcers and venous stasis ulcers, and accomplished this complete wound closure and healing in 5 to 12 weeks. The improvements seen in the weekly photographs visually depict three remarkable recoveries using Silver Sol Gel. The remarkable recoveries can be explained by the fact that Silver Sol completely destroys bacteria, viruses and fungi. By reducing the polymicrobial infections sustained in diabetic wounds, the associative swelling was reduced, thus promoting better circulation, immune access and improved wound healing.

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