Nanogen Aktiv

Naz Wahab MD, FAAFP, FAPWCA
Genadyne Biotechnologies, Inc.

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TABLE 1: CLINICAL RATIONALE FOR NANOGEN AKTIV

CLINICAL PRESENTATION	ISSUES	RATIONALE FOR NANOGEN AKTIV
Non-healing wounds that have failed to progress to closure despite aggressive wound therapy for 4 weeks or greater.	Wounds, which have failed to achieve closure have usually halted in the inflammatory stage of wound healing.	Nanogen Aktiv is a new generation of topical dressings in which plant stem cells can be utilized to decrease inflammation, edema and stimulate wound bed proliferation.
Wounds that have a thick, adherent yellow/white fibrous necrotic layer in the wound bed and autolytic debridement is needed.	Nonviable tissue in the wound bed will inhibit granulation tissue and epithelialization of the wound.	Nanogen Aktiv should be considered in patient populations in which sharp debridement may not be feasible either due to patient's comorbidities, clinician's scope of practice or other social issues. Nanogen Aktiv should not be utilized in wounds with black necrotic tissue >40% of the wound bed.
Chronic wounds in which deep seeded bioburden is suspected.	Patients, who have inevitably suffered from wounds for months to years, will have wound bed bioburden. The surrounding wound edges and periwound tissue will also be afflicted with this bioburden. Removing the bioburden decreasing inflammation and MMP activity, and physically removing the microorganisms that inhibit healing is needed to achieve wound healing.	Nanogen Aktiv carries a positive charge at physiologic pH. Most bacteria and other blood byproducts carry a negative charge. Application of Nanogen Activ creates an electrostatic force that helps physically remove nonviable tissue from the wound bed to initiate granulation tissue formation. This application is also useful in patients where systemic or topical antimicrobials have failed. Once Nanogen Aktiv has stimulated these senescent cells, it works best by treating the infection with bacteriocidal medications while continuing to use the Nanogen Aktiv.
Patients suffering from autoimmune disorders and wounds.	Autoimmune patients are chronically in an inflammatory state. Healing for these individuals can be very challenging if their wounds fail to close promptly.	Nanogen Activ, being 100% plant based has less chance of creating an autogenetic inflammatory response than other bovine or ovine species products. These plant-based stem cells will help in regeneration and aid in the immunocompromised state.

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Wounds that you are concerned with scarring or for fibrosis management.	Genetically some individuals are predisposed to scarring or fibrosis that leads to a poor aesthetic effect and decrease range of motion. Also, fibrosis or scarring is a form of increasing tensile strength in the wound.	Nanogen Aktiv can lead to decrease periwound edema, decrease fibrosis leading to a better aesthetic effect. Using on areas or patients that are concerned about scar tissue to minimize loss of range of motion or pain associated with thick fibrotic tissue.
Surgical scar revisions	Surgical procedures are performed simply for scar management to help increase range of motion, decrease the thick fibrotic bands, and have a better aesthetic effect	Utilizing Nanogen Activ for surgical scar revisions at the time of surgical closure or in conjunction with postoperative scar management
Post Operative Surgical Sites	Surgical sites are at high risk for infection. The number one reason for postoperative wound dehiscence is infection.	The ability to use an entirely natural product on surgical closure sites as part of postoperative wound management. Nanogen Activ is a non-silver based antimicrobial that will aid in wound healing, help fights infection and is completely biodegradable. (Although recommended to remove)
Pediatric Wounds	The pediatric wound population can be challenging due to altered patient immunity, toxicity to medications (even topicals), and avoidance of heavy metals on neurologically developing children.	Using an all natural plant based product can help avoid immunogenetic factors that would lead to patient rejection of the material and decrease the inflammatory response. Non-silver based antimicrobial activity to avoid heavy metals. Regeneration through stem cells will aid in the immunocompromised state.

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Radiation-induced wounds	Radiation wounds have a lack of blood supply that lead to thick fibrotic hypoxic wounds.	Using Nanogen Activ will move wounds into a proliferative stage of wound healing which will help increase cell signaling with biochemical pathways and angiogenesis.
Wounds with significant depth or tunneling	Wounds with deep cavities are difficult to treat when halted in the inflammatory state. These wounds often get deeper with sharps debridement and utilizing regenerative techniques is needed to fill the potential space.	Nanogen Activ has active stem cells within an extracellular matrix that helps build granulation tissue and inhibits MMP's.
Wounds, in which NPWT was a failure or the wound has halted in its progress with NPWT	The mechanical stretch and pull of tissues with NPWT helps recruit acute phase reactants to the wound site to aid in healing. However, chronic mechanical irritation can also halt wound healing if the body or wound is malnourished, or deficient in nutrients	Nanogen Activ has active stem cells within an extracellular matrix to regenerate tissue. There are many vitamins and antioxidants infused in the Nanogen Activ system that are used to nourish the wound, helps maintain a moist wound healing environment without mechanical stress. This system builds granulation and decreases nonviable tissue.
Palliative Wounds	Wounds that are for palliative treatment only because the patient is too sick to heal. Invasive malignant wounds that need bioburden control and tumor or necrotic tissue debulking.	Nanogen Activ is a Nano-biotechnology membrane created from plant extracts and plant stem cells that have potential antitumor properties to help in debulking. Nanogen Activ also has the positive charge which can aid in pulling out necrotic tissue and bioburden from the wound bed.

Case #1 NON-HEALING LAMINECTOMY

Patient is a 75-year old female with a history of type 2 diabetes, hypertension, hypercholesterolemia, renal insufficiency, and chronic back pain, who had undergone an L3-L4 laminectomy in 2005. Postoperatively the wound failed to heal. She has been with a non-healing wound since 2005. She has had multiple surgical revisions, a failed surgical flap, surgical debridements, hyperbaric oxygen treatments (last in 2010), split thickness skin grafts, Living skin substitutes, negative pressure therapy, and a variety of topical wound care products to stimulate healing without success.

- Nanogen Aktiv was used with visible success within one application.

Week 1	Week 3	Week 6
0.8 x 0.3 x 0.4cm	0.5 x 0.3 x 0.4cm	0.3 x 0.3 x 0.2cm
Volume: 0.096cm3	Volume: 0.06cm3	Volume: 0.018cm3



CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv reduced the size of the wound by 50% within the 6-week period. The wound bed increased in granulation, decreased in nonviable tissue, and contracted in size. Sharp debridements were performed as clinically deemed necessary. The patient was placed on antibiotics during week one for 10 days due to Corynebacterium species. Only Mepitel, steri-strips and dry sterile gauze were used for secondary dressings.

Case #2 NON-HEALING SURGICAL STERNOTOMY

Patient is a 67-year old female with a history of Coronary Artery Disease, Hypertension, Hypercholesterolemia, Congestive Heart Failure, and Renal insufficiency who had undergone a Coronary Artery Bypass surgery in September 2014. Postoperatively she had an area along the midline chest incision that failed to heal. Within 4 weeks, she was taken back to the OR for a partial sternectomy and sternal wire removal secondary to hardware infection. Postoperatively she was placed on negative pressure therapy for 3 consecutive weeks without significant change in wound volume.

- Nanogen Aktiv was started, and the negative pressure therapy was discontinued.

Week 1
16.0 x 5.0 x 2.8cm
Volume: 224cm3

Week 3
14.8 x 2.8 x 2.5cm
Volume: 103.6cm3

Week 7
9.0 x 1.9 x 1.9cm
Volume: 32.49cm3

CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was initially applied twice weekly for 4 weeks while patient was in a rehabilitation unit. From weeks, 5 – 7 only one application of Nanogen was used per week. Within 2 weeks of Nanogen Aktiv therapy, the wound volume has decreased, and granulation tissue quality had improved. She received IV antibiotics for the first 4 weeks of treatment due to a pseudomonas infection. Sharp debridements were performed as clinically necessary. Only Mepitel, steri-strips, and abdominal pads were used for secondary dressings to cover the wound.

Case #3 NON-HEALING SURGICAL STERNOTOMY

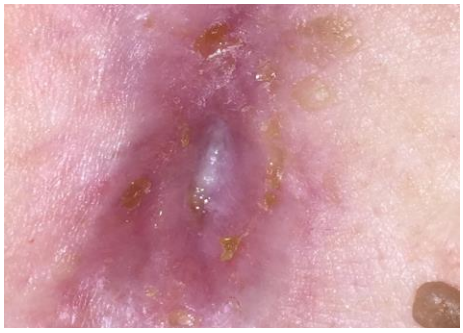
Patient is a 59-year old female with a history of Coronary Artery Disease, Hypertension, Congestive Heart Failure, Renal insufficiency who had undergone a Coronary Artery Bypass in January 2014. Postoperatively she developed a "scab" on the distal end of the midline chest incision. This same area began draining within 2 months. She was topically treated with antimicrobials and finally brought to the wound center for further wound care. The wound was thoroughly debrided, and tracts were exposed.

- Nanogen Aktiv was initiated after approximately 11 months of non-healing. Within 3 applications of Nanogen Aktiv, the patient's wound was visibly smaller and healing.

Week 1
2.1 x 1.1 x 1.0cm
Volume: 2.31cm3

Week 3
1.0 x 0.5 x 0.5cm
Volume: 0.25cm3

Week 7
0.0 x 0.0 x 0.0cm
Volume: 0.0cm3



CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was applied once a week for 6 weeks. Within 3 applications of Nanogen Aktiv, the depth of the wound had been reduced by over 50%. Sharp debridements were performed as clinically determined. No antibiotics were needed during the course of treatment. By week 6, the wound had completely healed. Only Mepitel, steri-strips and an abdominal pad were used for secondary dressings to cover the wound.

Case #4 NON-HEALING DIABETIC FOOT WITH MULTIPLE COMORBIDITIES

This patient is a 49-year old male with a history of Type 2 Diabetes, Congestive Heart Failure, Chronic Renal Insufficiency, and Lower extremity edema developed a wound after a hospitalization for congestive heart failure. Patient was discharged to follow up at the wound center. Patient was found to have a severe cellulitis and osteomyelitis of the left calcaneus. He underwent a surgical calcanectomy, but still failed to heal and dehisced his entire surgical site. Patient underwent weekly debridements, IV antibiotics, topical wound care dressing changes, and hyperbaric oxygen treatments. His wound progress halted for a period of 3 months once he discontinued hyperbaric treatments.

- Nanogen Aktiv was started and within 2 applications, the patient had visible decrease in wound size and volume. Prior to the start of Nanogen, the patient's wound was open for 12 months.

Original Wound

Week 1

Week 3

Week 7

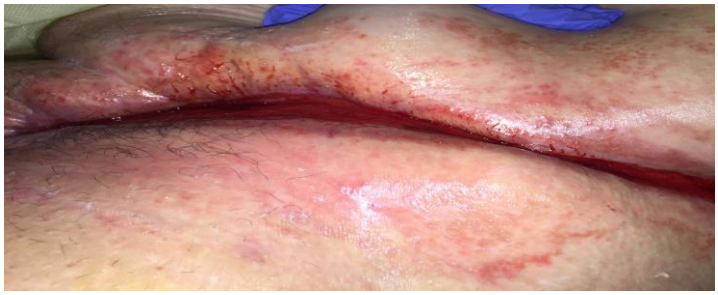
CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was applied once a week for 7 weeks. Excisional debridements were performed as clinically deemed necessary. A continuous increase in healthy pink granulation tissue and a decrease in yellow slough was noted along with a reduction in serous exudate week by week. Sharp debridements were performed as clinically determined. No antibiotics were needed during the course of treatment. By week 8, the wound had completely healed with an epithelial scale. Only Mepitel, steri-strips and foam were used for secondary dressings to cover the wound.

Case #5 NECROTIZING FASCITIS ABDOMINAL WOUND

This patient is a 44-year old female who initially presented to the hospital in August 2014 with a rapidly spreading infection of the left groin. She was found to be a new onset type 2 diabetic with necrotizing fasciitis. She underwent urgent surgical debridement, was placed on IV antibiotics and negative pressure therapy. She was hospitalized in a long-term care facility for 6 weeks. She was discharged and brought to the wound center after wound improvement halted.

Week 1
26.0 x 3.5 x 0.1cm
Tunnel of 4cm
Volume: 9.1cm3



Week 4
26.0 x 2.5 x 0.1cm
Tunnel closed
Volume: 6.5cm3

Week 9
0.0 x 0.0 x 0.0cm
Volume: 0.0cm3

CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was applied once a week for 8 weeks. Within 2 applications of Nanogen Aktiv, the wound volume decreased. Sharp debridements were performed as clinically determined. The patient had a 4 cm tunnel at the lateral edge of the wound and within 2 weeks, the tunnel was closed. A continuous increase in healthy pink granulation tissue and a decrease in yellow slough was noted. Significant reduction in green exudate week by week was also documented. The patient's wound culture was positive for Streptococcus species, MRSA and Pseudomonas. Therefore, oral antibiotics were given for 2 weeks. By week 8, the wound had completely healed. Only Mepitel, steri-strips, and dry sterile dressings were used for primary and secondary covering of the wound.

Case #6 IMMUNOSUPPRESSED SECONDARY TO AUTOIMMUNE DISORDER WITH AN ELBOW WOUND

This is a 74-year old woman with a diagnosis of rapidly progressive scleroderma in 2013 who had developed a right medial elbow wound. She suffered for 9 months with the wound prior to presenting to the wound center. Patient was initially treated with a combination of topical steroids and antimicrobials. With continued worsening of the wound, she presented to the wound center with complete 90-degree contracture of her right elbow and extreme pain at the wound site. After investigation, she was diagnosed with osteomyelitis, treated with IV antibiotics and aggressive topical wound care with Santyl, bovine collagens, and alginates. After the wound size had failed to improve for 6 consecutive weeks the patient, was placed on Nanogen Aktiv.

Week 1
1.0 x 1.0 x 0.2cm
Volume: 0.20cm3

Week 3
0.4 x 0.5 x 0.1cm
Volume: 0.02cm3

Week 7
0.0x0.0x0.0cm
Volume: 0.0cm3

CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was applied once a week for 6 weeks. Upon the initiation of Nanogen Aktiv and within 2 applications, a marked improvement was noted. Sharp debridements were performed as clinically deemed necessary. Per the patient, the wound pain significantly decreased by week 2. At week 7, the wound had completely healed. Mepitel, steri-strips, and foam were used as secondary dressings.

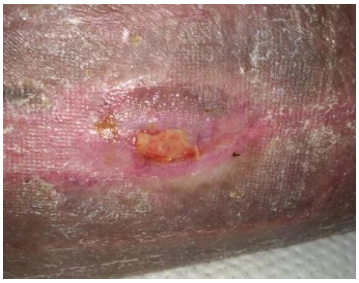
Case #7 THROMBOEMBOLIC DISORDER COMPLICATED WITH HEPARIN ALLERGY

This patient is a 47-year old male with a history of Protein C and Protein S deficiency with multiple incidences of lower extremity deep vein and arterial thrombosis and a severe allergy to heparin. Patient had sustained a Motor Vehicle Accident in 2012 in which he developed compartment syndrome in the right leg. He underwent multiple thrombectomies, and arterial re-vascularizations. Patient subsequently underwent a fasciotomy the second fasciotomy the patient sustained to the same leg secondary due to the previous history of compartment syndrome he had several years prior.

- Patient has undergone arterial endovascular procedures, venous ablation, wears compression stockings, completed several courses of hyperbaric oxygen treatments, and had 2 split thickness skin grafts, all of which failed to achieve complete healing.

Original Wound

Week 3



Week 6

Week 1

Week 3

Week 6

CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was applied once a week for 6 weeks. Upon the initiation of Nanogen Aktiv within 2 applications, there was visible improvement in the wound bed quality, wound size, and a decrease in exudate. Moderate growth of Enterobacter was noted upon culture and patient was started on oral antibiotics. Sharp debridements were performed as clinically deemed necessary. At week 6 the wounds had almost entirely healed. Mepitel, steri-strips, and abdominal pads were used as secondary dressings to cover the wound.

Case #8 INVASIVE SQUAMOUS CELL CARCINOMA OF THE NECK

This is a 75-year-old male with a history of invasive squamous cell carcinoma of the neck, diagnosed in February 2014. Patient underwent a radical neck dissection in July 2014. Due to the extensive surgery, the patient subsequently had two more surgical revisions with rotation skin flaps and autologous skin grafts. Despite aggressive surgical debridements, negative pressure, and topical wound care products, the patient urgently needed to proceed with radiation and chemotherapy, which led to non-healing of the neck wounds.

Week 1

Week 3

CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was applied once a week for 3 weeks. Within the first application of Nanogen Aktiv, there was visible improvement in the wound bed quality and wound size. A wound culture revealed MSSA. The patient was only topically treated with Nanogen Aktiv. Also, sharp debridements were performed as clinically deemed necessary. Mepitel, steri-strips and an abdominal pad were used as secondary dressings to cover the wound. After only 3 applications, there was visible improvement in wound size, character, and quality. The inferior neck wound healed and the periwound edema was visibly decreased.

Case #9 SQUAMOUS CELL CANCER WITH RADIATION INDUCED WOUND

This is a 61-year-old male history of squamous cell carcinoma of the left neck diagnosed in December 2013. Patient underwent radiation and chemotherapy and then sent for a radical neck dissection in August 2014. Postoperatively the surgical wound did not completely heal and worsened with greater necrotic tissue, exudate, pain and odor despite oral and topical antibiotics. Patient was finally sent to the wound care physician for further treatment.

Week 1
4.5 x 1.6 x 0.2cm
Volume: 1.44 cm3

Week 5
3.0 x 1.0 x 0.2cm
Volume: 0.6 cm3

Week 8
2.1 x 0.9 x 0.2cm
Volume: 0.378 cm3

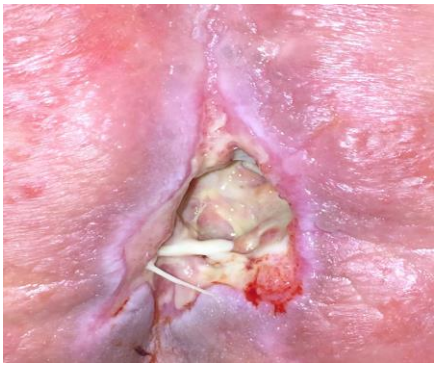
CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was applied once a week for 8 weeks. Within the third application, there was visible improvement in the wound size and a significant decrease in exudate. Sharp debridements were performed as clinically deemed necessary. In the first week, a culture was performed, and it resulted in substantial growth anaerobic bacteria. The patient was placed on oral antibiotics. Mepitel, steri-strips and an abdominal pad were used as secondary dressings to cover the wound.

Case #10 SACRAL PRESSURE WOUND

This is an 86-year old female who had a mechanical fall at home with a non-ST elevation myocardial infarction, rhabdomyolysis and spinal compression fracture in October 2014. She developed a sacral pressure wound during her hospital visit. Numerous topical treatments were tried, and all failed. She has a significant medical history of malnutrition, coronary artery disease, recurrent falls, osteoporosis, and hypertension.

Week 1
2.7 x 1.0 x 1.2cm
Volume: 3.24 cm3



Week 2
2.0 x 1.0 x 1.0cm
Volume: 2.0 cm3

Week 4
1.2 x 0.9 x 0.3cm
Volume: 0.324 cm3

CLINICAL ASSESSMENT AND TREATMENT:

Nanogen Aktiv was applied once a week for 4 weeks. Within the first application, there was visible improvement in the wound size, increased granulation and a significant decrease in exudate and slough. No mechanical debridements were done. Mepitel, steri-strips and an abdominal pad were used as secondary dressings to cover the wound.

APPLICATION PAGE:

1: Cleanse wound with normal saline
2: Apply skin prep to periwound
3: Apply Nanogen Aktiv gel or distilled water to the wound bed
4: Next place Nanogen Aktiv membrane directly onto wound and gently apply pressure to ensure that no air's trapped under the Nanogen Aktiv film
5: Place steri-strips on the outer circumference to secure Nanogen Aktiv to the wound bed
6: Cover with silicone or other non-adherent mesh
7: Lastly secure with a dry sterile dressing and tape

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