Surgaflex™

Provider Education

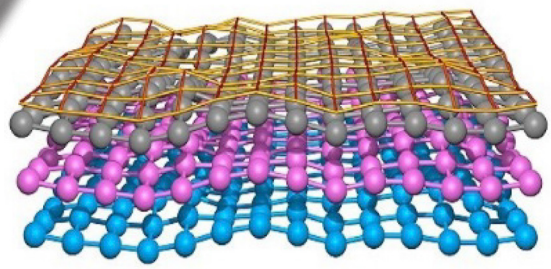
Surgical Wounds

Published Manuscripts
White Papers
Case Reports

Imbed BIOSCIENCES

Created For Surgeons By Surgeons.

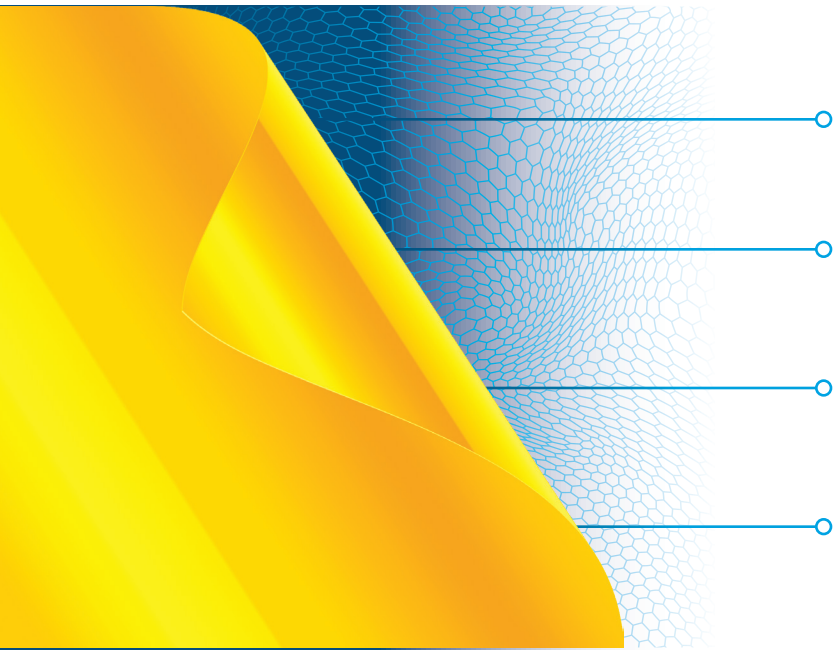
Surgaflex™



Fully-Synthetic Three Dimensional Resorbable Surgical Matrix

Surgaflex™ is a **fully-synthetic,** ultrathin surgical matrix composed primarily of bioresorbable polyvinyl alcohol, with a polymeric surface coating containing **ionic and metallic silver particles**.

Surgaflex™ absorbs wound fluid and **intimately contours** to the surgical site delivering a **powerful** and broad-spectrum **antimicrobial** benefit **without cytotoxicity.**



Bioresorbable Matrix

Bioresorbable polymer matrix eliminates the need to remove residual matrix from wound[2]

Ultra Thin Contouring to Surgical Wound

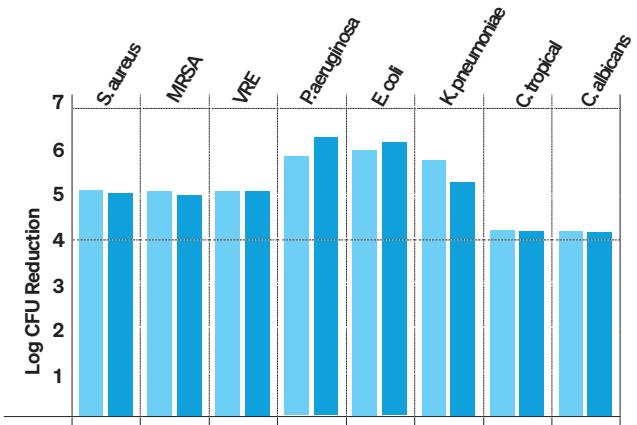
Serves as a **functional template** for cell migration, **vascularization**, and **granular tissue formation**.

Fully Synthetic Three Dimensional Matrix

Allows for **clear view of surgical wound**, isn't of human or animal origin, and has a **long shelf life** at room temp.[4]

Exceptionally Effective

99.99% effective against a broad spectrum of wound related microbes.

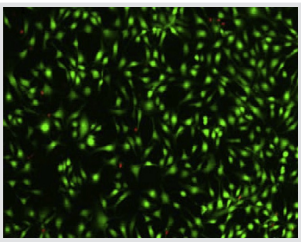


	S.aureus	MRSA	VRE	P.aeruginosa	E.coli	K.pneumoniae	C.tropical	C.albicans
24H	5.13	5.10	5.09	5.88	6.06	5.83	4.20	4.19
72H	5.04	5.00	5.09	6.30	6.19	5.29	4.18	4.16

510(k) cleared for 3-day sustained antimicrobial benefit.

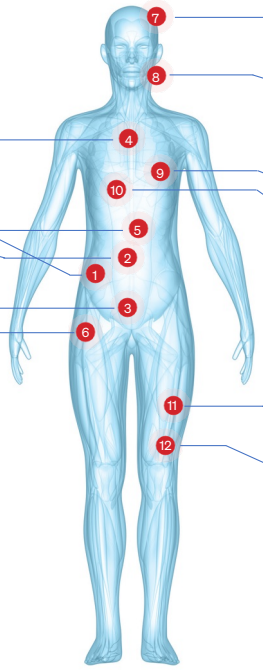
Antimicrobial & Cytophilic

Surgaflex™



Laboratory and preclinical studies indicate that the components of Surgaflex™ allow for **healthy cell** and new **blood vessel growth in wounds.**

Surgical Complications Can Happen Anywhere



1. Hernia Repair
→ 10.1% (Open Procedure)

2. Colon Surgery
→ 5.0%

3. C-Section
→ 3 – 15%

4. Cardiovascular
→ Up to 8.5% Overall

5. Pancreatic Surgery
→ 10%

6. Orthopedics
→ 2.4% Hip Prosthesis
→ 10.4% Hip Fractures (without prophylaxis)
→ 5.4% Hip Fractures (with prophylaxis)

7. Craniotomy (clean)
→ 9.7% (without prophylaxis)
→ 5.8% (with prophylaxis)

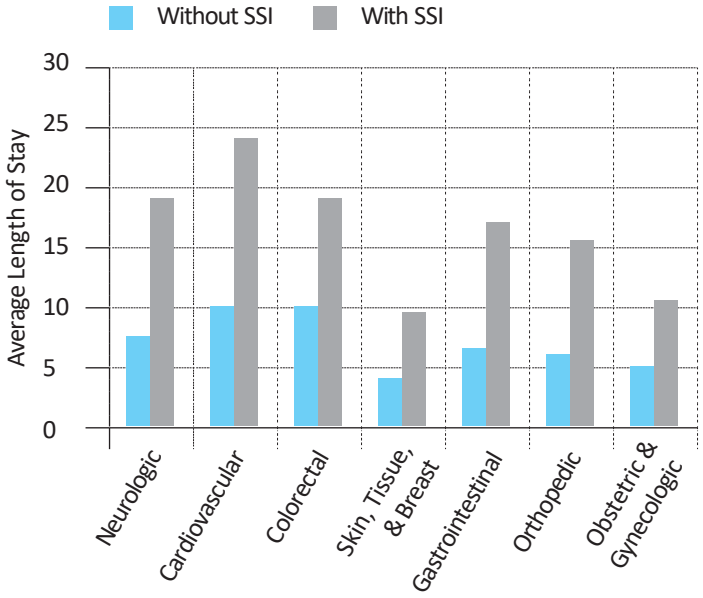
8. Submandibular Gland Excision
→ 24-78% (without prophylaxis)
→ 5-38% (with prophylaxis)

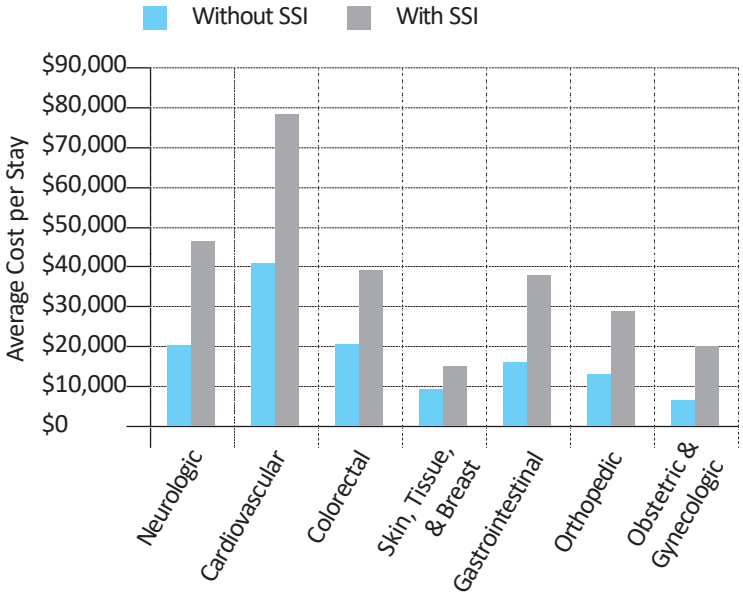
9. Plastics
→ 5.2 – 10.3% (post-mastectomy)
→ 1.9 – 2.5% (breast augmentation)

10. Thoracic Surgery
→ 0.7 – 2.0%

11. Peripheral Vascular Surgery
→ 10.4%

12. Burns
→ 6% TBSA burns > 15%





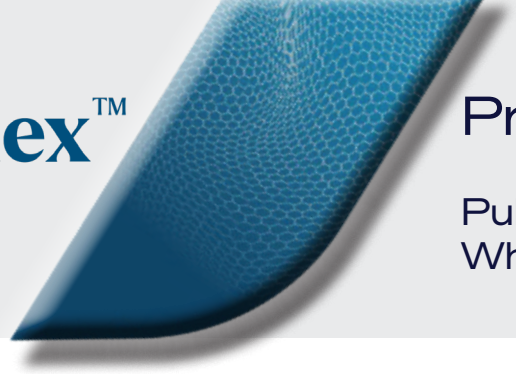
Annual No. of Surgeries	Average SSI Rate	Number of SSIs	Average Cost per SSI
6,000	**2.6%**	**156**	**$30,000**[13,14]
30m procedures 5,000 hospitals[12]	780,000 SSIs 30m procedures[13]	6,000 at 2.6%	**...and CMS does not reimburse!!!**

Surgical site infections can have a tremendous impact on healthcare economics. On average, the length of stay and cost per stay more than doubles where SSI's develop. Importantly, CMS no-longer reimburses.

Solving SSIs means $4,680,000 in savings for your hospital

(Model above assumes 2.6% SSI Rate, 6,000 surgical procedures equating to 156 SSI's at $30k average

Surgaflex™



Provider Education

Published Manuscripts
White Papers & Case Reports

TABLE OF CONTENTS

Imbed BIOSCIENCES

Surgaflex™

The Efficacy of a Novel Bioresorbable Microfilm Matrix in At-Risk Surgical Wounds: A Clinical Case Series

Ryan Chatelain, DPM | Johnson City Medical Center, Johnson City, TN

OBJECTIVE:

Surgery performed on the diabetic individual is fraught with complication, with postoperative infection being of primary concern. A post-op infection rate of up to 13% is noted in diabetics undergoing elective surgical procedures versus less than 3% in nondiabetic populations. The objective of this study was to provide preliminary evaluation of the efficacy of a novel bioresorbable microfilm matrix (20 mm thick) with very low amounts of silver (0.16 mg/in2) in preventing surgical site infections when placed at the level of subcutaneous tissue and dermis prior to primary closure in the diabetic patient undergoing elective surgery.

METHOD:

Diabetic patients undergoing non-emergent or elective foot or ankle surgery and that met the following six criteria were included in the study: neuropathy, infection (treated), open wound, history of recurrent infection, nonhealing wound, or peripheral vascular disease (treated). After informed consent, patients underwent a foot or ankle surgical procedure (amputations (75% of procedures), removal of exostosis (5%), midfoot bone removal (5%), Achilles' tendon repair (5%), bunionectomy (5%), or an elevating osteotomy (5%) specific to their pathology with primary closure of the wound. After hemostasis was obtained and subcutaneous closure, if applicable, the bioresorbable microfilm matrix was applied just deep to the incision at the level of subcutaneous tissue and dermis, and the incision primarily closed. A nonadherent cover dressing was applied over the suture line and patient was scheduled for 3-5-day routine follow-up.

RESULTS:

Signs of infection at the first follow-up 3-5 days postoperative were absent in all 22 patients and all compliant patients went on to heal completely during the 3-month follow-up period. Eighteen of the 22 patients healed at typical rate specific for the respective procedure. Two patients that took longer to heal did so secondary to weight-bearing dehiscence. Two patients were not included in the results secondary to multiple infractions of noncompliance with expected postoperative care.

CONCLUSION:

The application of microfilm matrix in surgical incisions at the level of subcutaneous tissue and dermis prior to primary closure is safe for and has the potential to prevent postoperative surgical site infections in the at-risk diabetic patient population.

Imbed BIOSCIENCES

Surgaflex™

The Efficacy of a Novel Bioresorbable Microfilm Matrix in At-Risk Surgical Wounds: A Clinical Case Series

Ryan Chatelain, DPM | Johnson City Medical Center, Johnson City, TN

Number of Study Participants	**22**
(2 Lost to Non-Compliance)	
Average Age	**58**
Male 55%	
Female 45%	
Inclusion Criteria	**Diabetes**
Infection treated prior to surgery	**70%**
History of MRSA	**80%**
Historic SSI Rate	**13%**

All Patients Tracked for 90 Days

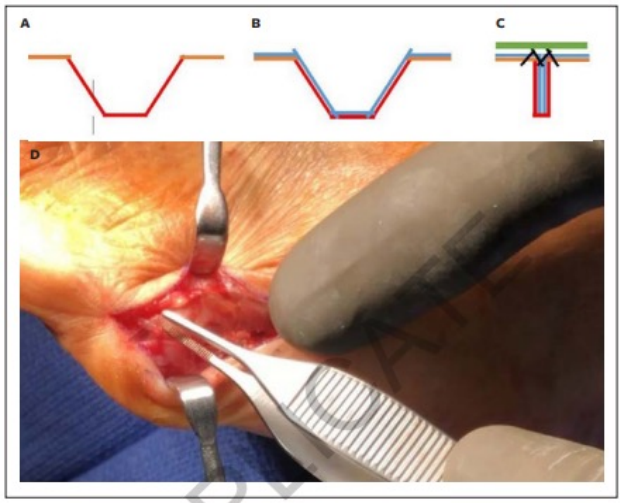
Objective

Reduce SSI Rate from 13%

Actual Results

20 of 20 Healed Without Any Complications

ZERO SSI's on Initial Follow-up
ZERO SSI's on 90 day Follow-up



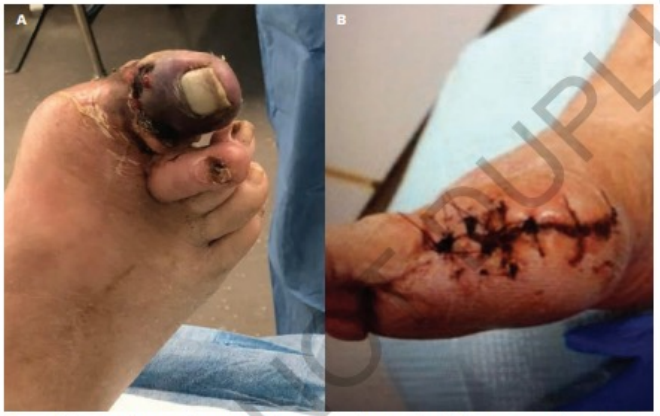


Figure 6. Case 3: a 62-year-old male with history of poorly controlled diabetes, neuropathy, and smoking presented with (A) gangrene of the right great toe. (B) Seven days after amputation of the right great toe.

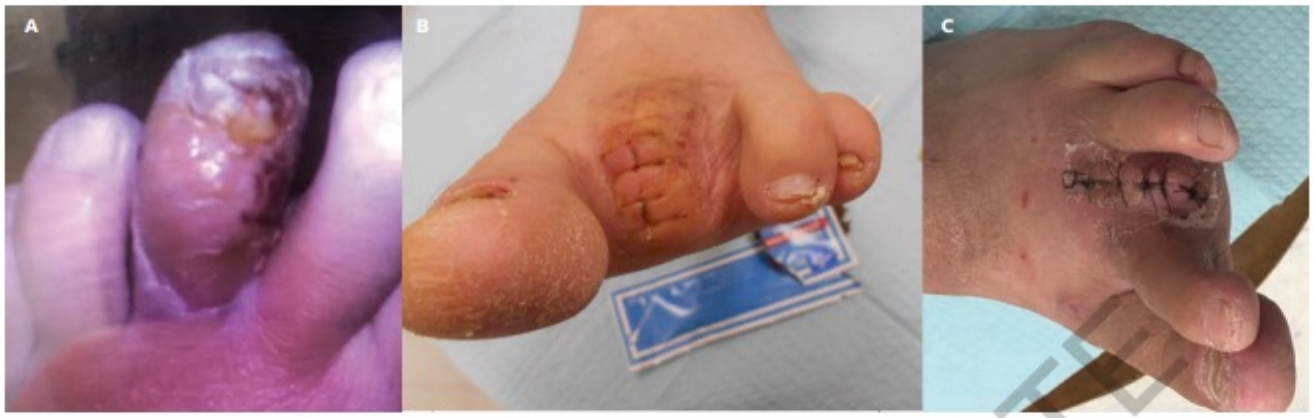


Figure 5. Case 2: a 63-year-old male with poorly controlled diabetes and current smoking status presented with (A) cellulitis with underlying osteomyelitis of the third digit. (B) Five days and (C) 3 weeks after amputation of the third digit.

Imbed BIOSCIENCES

Surgaflex™

Toe Amputation Site

Furqan Alex Khan, APRN ACNS-BC
ProHealthcare, LLC, Dallas

Patient Presentation

A 73-year-old female underwent amputation of the right 5th toe associated with a diabetic foot ulcer and osteomyelitis.

Adjunct Therapy

- Collagen dressing
- ABD Pad
- Gauze roll
- Cloth tape

Procedure & Treatment

- Moistened collagen foam dressing was utilized initially for optimal proteases management.
- Surgaflex™ was applied to the wound (2) times weekly.
- The amputation site was then covered with a single layer of ABD pad and foot was secured with gauze roll and tape.

Clinical Outcome

- After protease activity was controlled with a moistened collagen foam dressing, the bioresorbable polymeric matrix assisted with bioburden management, and increased re-epithelialization rate due to minimal dressing changes.
- Wound closure was achieved in 8 weeks.

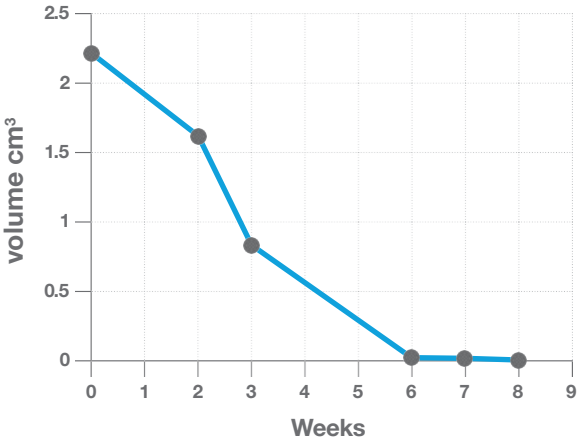


Figure 1.
Bright blue lines indicate period of Surgaflex™ treatment.

Conclusions

Surgaflex™ has consistently proven to be an effective wound management dressing during the proliferation phase of wound healing from granulation to 100% re-epithelialization.

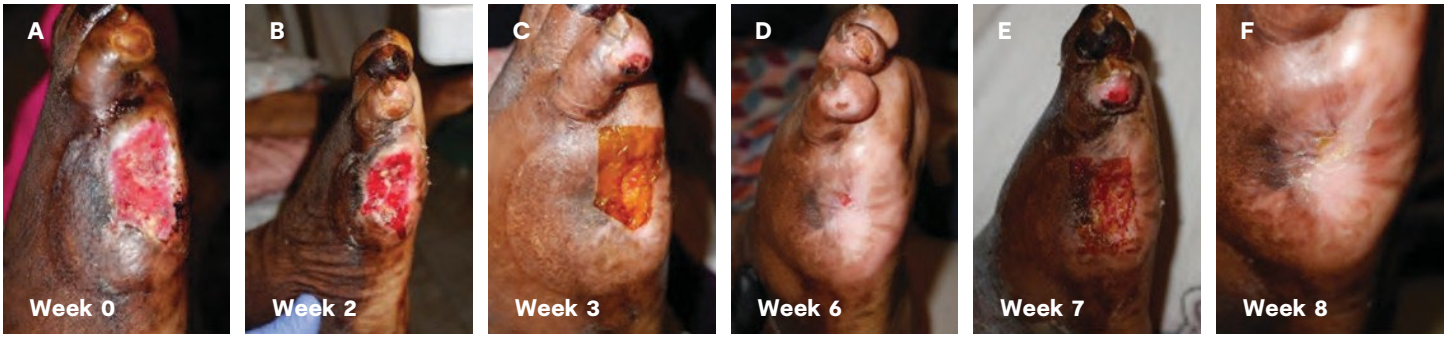


Figure 2: Wound healing progression of amputation site associated with a diabetic foot ulcer. Surgaflex™ was used from week 0 to week 8.

Surgaflex™

Prophylactic Treatment of a Surgical Site Infection in an At-Risk Patient

Michael Schurr, MD, Sarah Waterman-Manning, MD
Mountain Area Health Education Center; Asheville, NC

Patient Presentation

- A 33-year old diabetic woman presented with a left arm MRSA-positive abscess in December 2017.
- Patient also had medical history of ongoing tobacco abuse and recurrent necrotizing soft-tissue infections.
- The abscess was drained and required multiple debridement procedures.
- As a result, patient was left with chronic wound with exposed bicep tendon.
- Attempted split-thickness skin-graft placement in January 2018 failed.

Failed Therapy

- Negative pressure wound therapy
- Intravenous antibiotics
- Surgery

Procedure & Treatment

- Exposed biceps tendon was covered with transparent Surgaflex™.
- Surgaflex™ was used to manage the surgical wound, which was closed via Z-plasty.
- No oral or topical antibiotics were administered.
- Oral or topical antibiotics were not administered

Clinical Outcome

- By post-operative day 4, there was no sign of infection.
- By day 14, the wound was well-healed, and sutures were taken out.
- The wound remained healed and patient regained range of motion in her left elbow.

Conclusion

- Faster and more complete closure of a chronically infected wound was achieved by surgical wound management using Surgaflex™ compared to other failed therapies. This
- patient had multiple risk factors for postoperative surgical site infection including poor glycemic control, poly-microbial infection, and ongoing tobacco abuse.
- At the time of surgery Surgaflex™ was well tolerated and associated with a positive outcome.
- Surgaflex™ shows promise in the management of surgical wounds in at-risk patient populations.

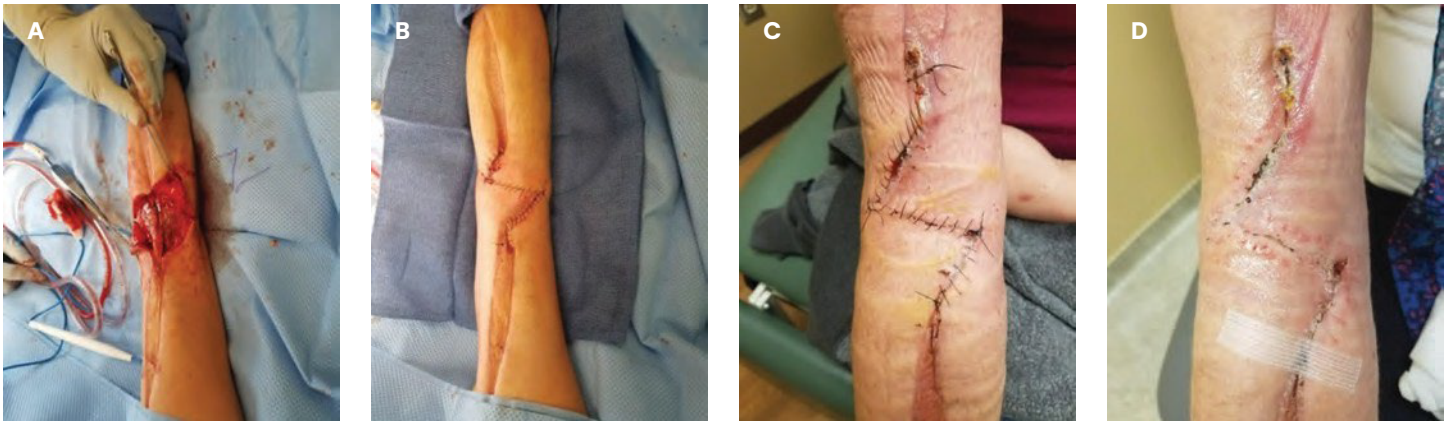


Figure 1: A. Surgaflex™ is applied to surgical wound. B. Surgical wound is closed via Z-plasty. C. Surgical wound is healing and free of infection. D. Healing has progressed over 14 days and sutures have been removed.

Imbed BIOSCIENCES

Surgaflex™

S/P CABG Chest Wound

Furqan Alex Khan, APRN ACNS-BC
ProHealthcare, LLC, Dallas, Texas

Patient Presentation

A 67-year-old diabetic male presented 10 weeks status post coronary artery bypass graft (CABG) surgery.

Adjunct Therapy

- NPWT
- ABD pad
- Medipore tape

Treatment

- Patient was treated with NPWT for 10 weeks after CABG procedure.
- Once wound edges were approximated, Surgaflex™ was applied as the contact layer, followed by an ABD pad which was then secured with Medipore tape.
- Surgaflex™ was changed twice per week for 6 weeks.
- At initial application of Surgaflex™, hypergranulation with moderate bleeding was noted.

Clinical Outcome

There was no incidence of infection due to optimal bioburden management, and re-epithelialization was achieved in 6 weeks.

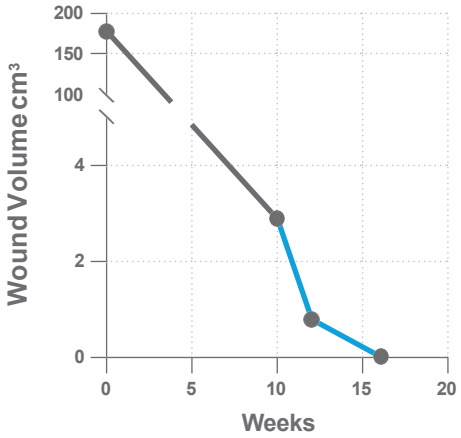


Figure 1. Bright blue lines indicate period of Surgaflex™ treatment .

Conclusions

- During the proliferation phase of wound healing; granulation and re-epithelialization process is often delayed or stalled due to bacterial contamination.
- Surgaflex™ successfully managed wound bio - burden, and moisture control through optimal vapor transfer rate, and resulted in faster re-epithelialization and wound closure.

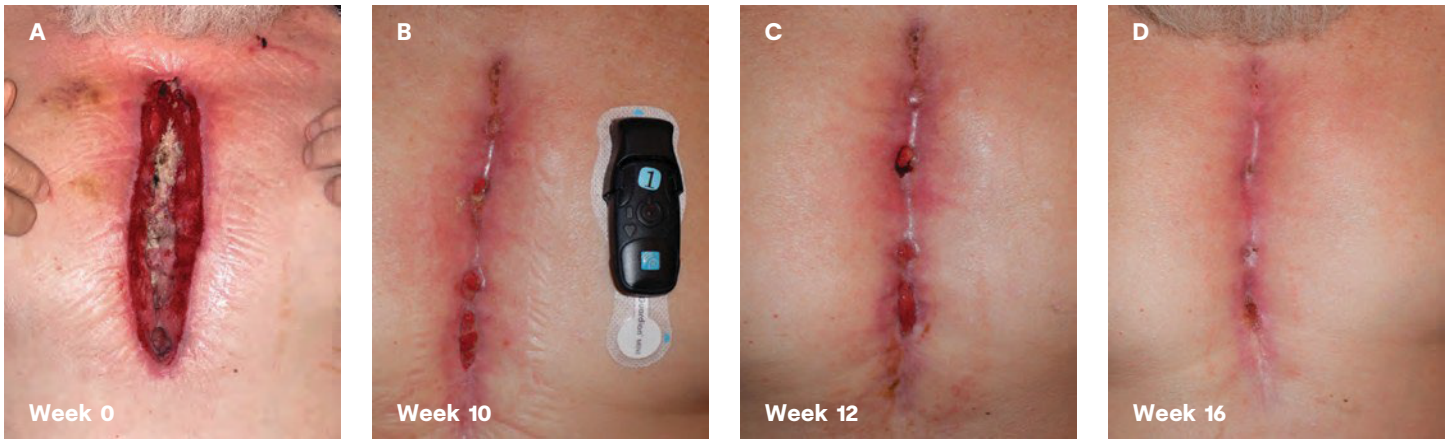


Figure 2: Wound healing progression of a post-CABG chest wound over 16 weeks. Surgaflex™ was applied from week 10 to week 16.

Imbed BIOSCIENCES

Surgaflex™

Treatment of Extensive Necrotizing Abdominal Wall Infection

Michael Schurr, MD • Mountain Area Health Education Center
Asheville, NC

Patient Presentation

- In April of 2020, a 56-year-old female presented with an incarcerated ventral hernia which led to necrosis of the strangled intestinal tissue and abdominal wall.
- Consequently, she was in septic shock.
- Extensive intestinal and abdominal surgery was performed to remove necrotic tissue and fix hernia.
- Intestines were reattached using the stapled ileocolonic anastomosis method.
- Delayed wound closure and healing by secondary intention was chosen to monitor for infection before closing.

Adjunct Therapies

- NPWT
- Systemic antibiotics

Procedure & Treatment

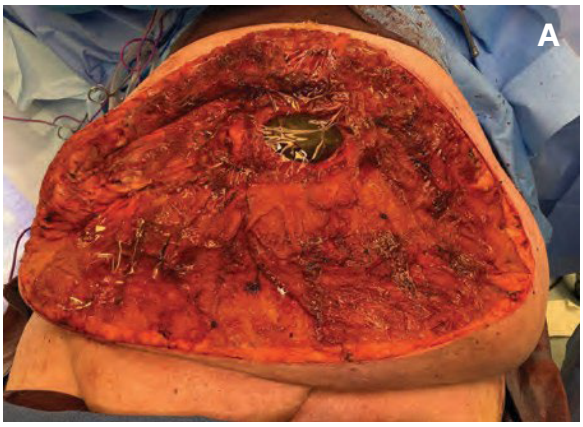
- After extensive intestinal surgery, 14 pieces of Surgaflex™ Surgical 4”x 4” sheets were placed on the wound and left to heal by second intention for approximately 2 weeks.
- When wound was confirmed as infection free, then closed with sutures.
- A wound vac was placed to manage drainage and promote healing.
- Wound was checked approximately once a month, for 3 more months.

Clinical Outcome

- One month after abdominal closure, patient’s incisional sutures were still in place and wound vac still secure. Some undermining was noted.
- One month later, patient continued to do well, and undermining was resolved. Exudate was minimal and free of purulence.
- At month three, she continued to improve with only lateral aspects of the wound open. NPWT was continued. No drainage or erythema was observed.
- Patient is free of infection and wound is greater than 90% healed with small lateral aspects remaining open which is being treated with Surgaflex™.

Conclusions

- Ventral hernia repairs have an SSI rate of up to 23%, and incarcerated hernias are associated with a poor prognosis. Necrotizing infections are severe conditions with a high mortality rate due to sepsis and the subsequent multi-organ failure. And bowel resection, as this patient experienced, adds another layer of risk.
- The addition of Surgaflex™ to the surgical protocol may have been instrumental in controlling the bioburden of the wound, thereby allowing the wound to progress out of the inflammatory stage and onto healing.
- **Surgaflex™ shows promise as an adjunctive therapy when healing by second intention is indicated.**



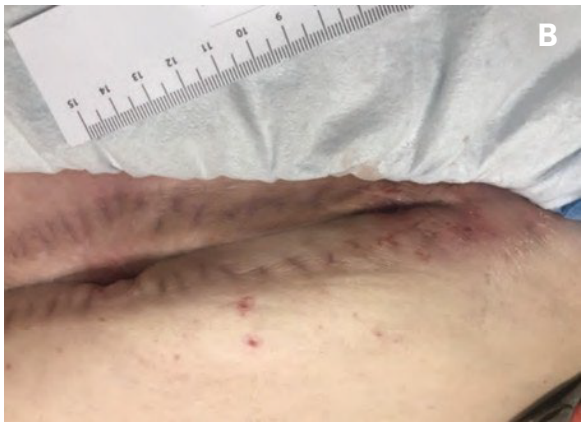


Figure 1.

A. 14 sheets of Surgaflex™ were used as the primary dressing after debridement.

B.Wound is greater than 90% healed and free of infection

Imbed BIOSCIENCES

Surgaflex™

Surgical Reconstruction and an Autologous Skin Graft using Surgaflex™

Christopher Moore, DPM Moore Foot & Ankle Specialists

Patient Presentation

A type-2 diabetic, HIV-positive male patient presented with Charcot neuroarthropathy midfoot collapse, neurotrophic foot ulcer, severe infection with abscess, osteomyelitis, and sepsis. Patient also had an unspecified autoimmune disease that was treated with methotrexate.

Adjunct Therapies

- NPWT
- Antimicrobial beads
- CROW boot
- External fixator

Procedure & Treatment

- After exhaustive conservative care and reconstructive surgery, Surgaflex™ was placed onto the deep wound bed, under flap, and primarily closed.
- Surgaflex™ was then reapplied once a week with standard wound care for 24 weeks.
- At the time of skin grafting, Surgaflex™ was applied directly onto the recipient site, below the skin graft, as well as on the donor site.
- Patient wore CROW boot or external fixator throughout this time.

Clinical Outcome

- Sixteen weeks after primary closure, skin flap necrosed and required debridement.
- The tissue revealed below was healthy, and bones were completely covered.
- Wound was debrided weekly for 7 weeks until there was enough granulation tissue.
- To promote re-epithelialization, an autologous skin graft was used, and 5 days later, the recipient site was almost healed, and the donor site was completely healed.

Conclusion

- Charcot neuropathic osteoarthropathy is a complication of diabetes that involves disorganization of bones, joints, and soft tissues of the foot, and can present with or without plantar ulceration.
- Acute localized inflammation triggers a bone resorption response which leads to mid-foot collapse.
- In this report, Surgaflex™ was able to accelerate wound closure in a patient with multiple comorbidities and high risk of infection.
- Additionally, his donor site wound was healed completely after just 5 days of Surgaflex™ application. application.

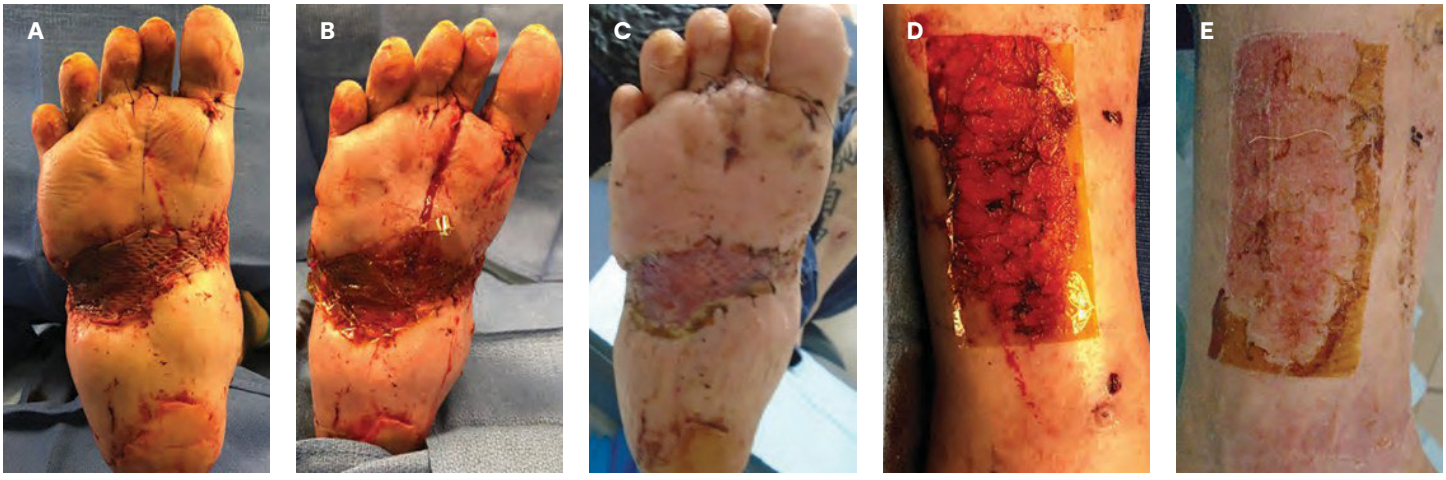


Figure 1: An autologous skin graft was used with Surgaflex™ to promote epithelialization of a plantar ulcer. A-B. Surgaflex™ was placed directly on the wound bed and under skin graft. C. Wound was almost completely healed after 5 days. D. Surgaflex™ was placed directly on top of donor site. E. Wound was completely healed after 5 days.

Imbed BIOSCIENCES

Surgaflex™

Treatment of a Pilonidal Cyst following Wide Excisional Debridement

Shannon Payseur, MD
Methodist Hospital For Surgery, Addison, Texas

Patient Presentation

- A 23-year-old male patient presented with an inflamed non-healing pilonidal cyst complicated by fistula that was re-occurring and/or open for approximately 4 years.
- Following his fourth and most recent wide excisional debridement, his full thickness wound measured 259 cm^3.
- The patient reported pain at the surgical site and was given oral pain medication accordingly.
- Surgaflex™ was used to support growth of granulation tissue within his cavernous wound, promote re-epithelialization, and manage wound bioburden.

Previous Treatments

- Antibacterial foam dressing
- Betadine wet to dry
- Chemical cautery

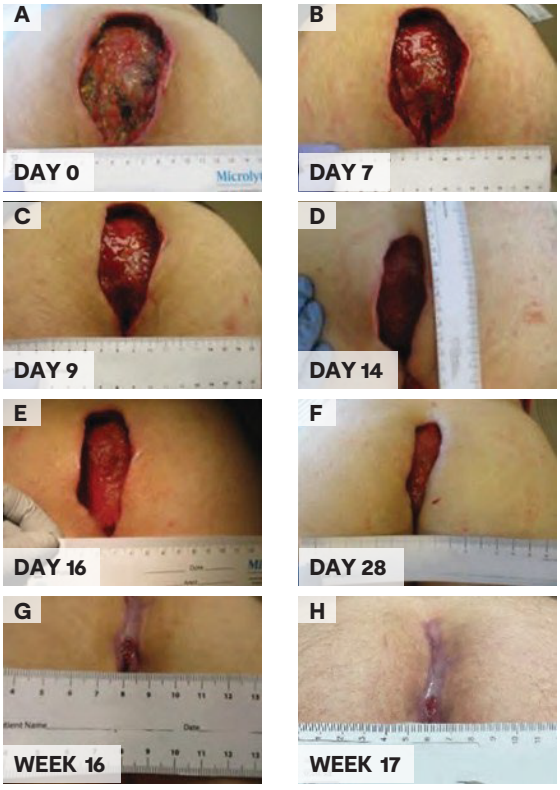


Figure 1: A-H Healing progression of pilonidal cyst treated with Surgaflex™ and NPWT over 17 weeks.

Procedure & Treatment

- The patient's wound dressing was changed every 2 to 5 days over a 17-week period and was treated with Surgaflex™ at each dressing change.
- Negative pressure wound therapy (NPWT) was placed at week 2 and reapplied every 2 to 5 days until week 4.
- The patient was also nutritionally supplemented with antioxidants and amino acids to further support wound healing.

Clinical Outcome

- After 1 week of Surgaflex™ treatment, the patient's wounds closed by 15%, and by week 2, his wound closed by 50%.
- One week after NPWT was added to his treatment plan; the patient's wound decreased by 80%, measuring 54 cm^3.
- At week 17, the patient's wound measured 0.04 cm^3, a 99% decrease in wound volume.
- Importantly, the patient reported decreased pain at the surgical site and his wound did not become infected, despite the heavy contamination of exit zones.

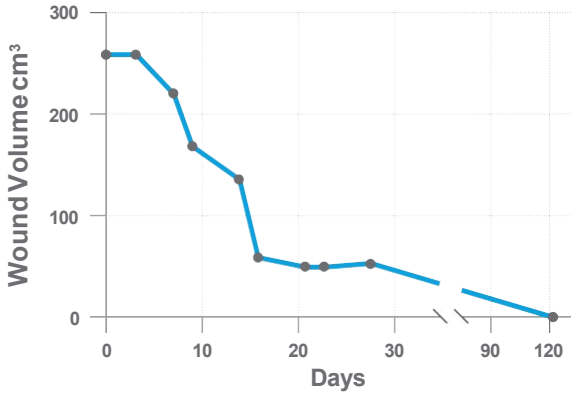


Figure 2. Graphical depiction of healing progression over 17 weeks Bright blue lines indicate period of Surgaflex™ treatment.

Conclusions

- After 4 years of wound chronicity, Surgaflex™ was able to close this patient's wound by 99% in 17 weeks, and significantly reduced the patient's levels of pain.
- Surgaflex™ therefore shows promise as an adjunct therapy in treating chronic pilonidal cysts.

Imbed BIOSCIENCES

Surgaflex™

Treatment for Chronic Contaminated Wound After Total Thyroidectomy

Thea Price, MD • Rush University Medical Center, Chicago, IL

Patient Presentation

A 59-year-old woman presented in May 2018 with delayed tracheal injury and perforation with abscess after total thyroidectomy for cancer. She returned to the OR for drainage and muscle flap complicated by dehisced surgical site infection. Comorbidities included: **papillary thyroid adenocarcinoma**

Failed Therapy

- Failed surgical repair with muscle flap

Procedure & Treatment

- Tracheal perforation closed with muscle flap
- Cultures: Group A Streptococcus Pyogenes
- Initial Thyroidectomy 5/21/2018
- Debridement and muscle flap 5/29/2018
- Surgaflex™ applied at weekly evaluations
- Non-excisional debridement during weekly evaluations
- Secondary dressing with PICO vacuum
- No additional dressing changes at home
- No oral or topical antibiotics were administered

Clinical Outcome

By the first follow-up at Day 7, the wound had closed by ~90% based on wound volume (Figure 1B). Nine days later, the wound had closed by 98% (Figure 1C) and Surgaflex™ was applied. At the 4-week follow-up, the wound was fully closed. The wound remained healed and patient retains only a small scar in the site of the original wound.

Conclusion

Faster and more complete closure of a chronically infected wound was achieved by application of Surgaflex™ than was achievable with other failed therapies. This patient had multiple risk factors for postoperative surgical site infection including poor glycemic control, polymicrobial infection, and ongoing tobacco abuse. Surgaflex™ applied weekly was associated with a positive outcome and this patient was able to resume a normal lifestyle, including attending her own wedding without the need for a bandage on her neck.

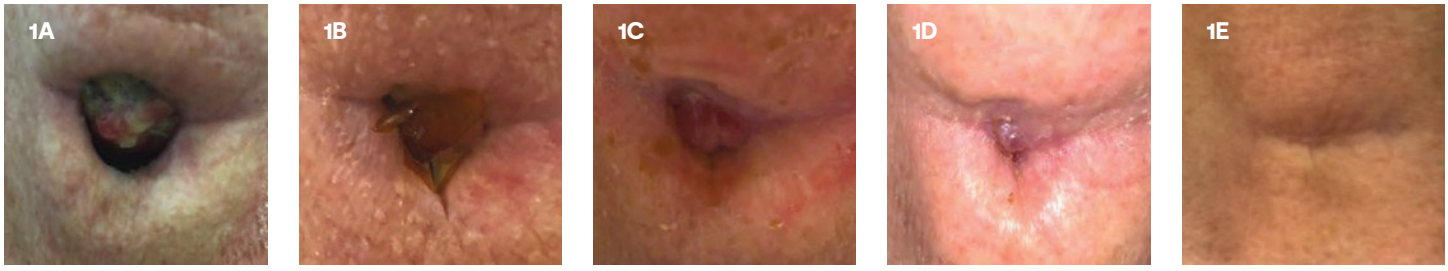


Figure 1: Accelerated wound healing in infected, malignant, and radiated chronic plateaued wound after total thyroidectomy. Surgaflex™ was applied to wound 9 days post-surgery (A). After one week (B), the wound had closed by 90% (volume). Nine days later Surgaflex™ was applied again, at which point the wound was 98% closed (C). Complete wound closure was achieved with 28 days (D). Four months post operatively, only a small amount of scarring was visible (E). Surgaflex™ was reapplied at each evaluation. All secondary dressings were standard per clinician preference and wound characteristics.

Imbed BIOSCIENCES

Surgaflex™ Product Information

	Reference	Product Description	GUDID Number	Configuration
	SF0203	Surgaflex™ 2x3 cm	00850019162189	Individual Sheet
	SF0406	Surgaflex™ 4x6 cm	00850019162196	Individual Sheet
	SF0420	Surgaflex™ 4x20 cm	00850019162202	Individual Sheet

Imbed BIOSCIENCES

REFERENCES 1 A Agarwal, et al. Biomaterials, 31 (4), 680-690, 2010. 2 Systemic Toxicity, Local Tissue Response, and Wound Healing Study of Microlyte Ag wound dressing, Following Repeated Treatment to Full-Thickness Wounds in Rats – 28 Days. Study 15T_41113_02, 2015. Data on file, Imbed Biosciences. 3 MTT cytotoxicity testing conducted at NAMSA. Data on file at Imbed Biosciences. 4 FDA 510k application. Data on file, Imbed Biosciences. 5 Measurement of Antimicrobial Activity of Microlyte Ag, Study 16C_52935_02., 2016. Data on file, Imbed Biosciences. 6 Weigelt, J.A., et al. Am J Infect Control, 38, 112-120, 2010. 7 American Health Quality Association. 56 hospitals collaborate to prevent surgical infection: QIO-led program cuts infection rate 27% in a year, 2005. 8 Anderson, D.J., et al. PLOS One. 4(12), 1-7 2009. 9 Study conducted at Mission Hospital, Ashville, NC. Data on file, Imbed Biosciences, NCT# 03204851.