



The Efficacy of a Synthetic Bioresorbable Antimicrobial Matrix as an Implantable Material for At-Risk Surgical Wounds

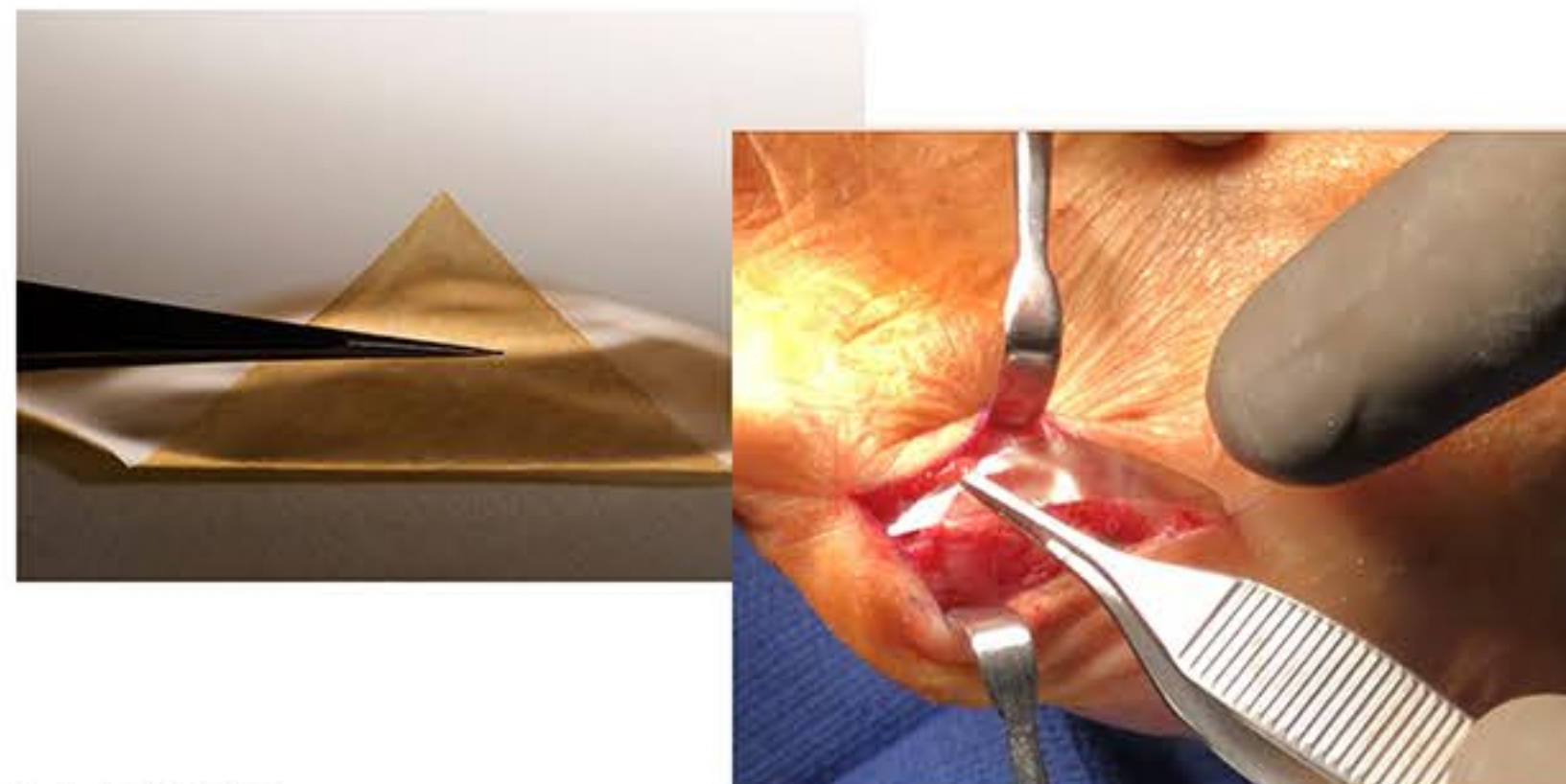
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BACKGROUND

Up to 13% post-op infection rate is noted in diabetics undergoing elective procedures versus less than 3% in nondiabetic populations.¹ Infection risk increases and can trend towards 50% with poor glycemic control,⁶ immunopathy, peripheral neuropathy, presence of an open wound,² cigarette smoking, PVD, and increased length of surgery.⁴

Recent development of a synthetic bioabsorbable polymeric multilayered matrix impregnated with silver has shown promising results in prevention of infection and acts as a scaffold allowing for cell migration, vascularization, and formation of granulation tissue in a wound bed. The matrix is 99.9% bactericidal for common infecting organisms, and lasts for at least 3 days as the entire construct bioresorbs over 1 week.⁵



METHOD

Diabetic patients undergoing non-emergent or elective surgery were included in the study. At risk subjects included those with: neuropathy, infection (treated), an open wound, or peripheral vascular disease (treated). Patients were educated on potential risks, benefits and complications of implanting the bioabsorbable silver containing matrix.

Once informed consent was obtained, patients underwent a foot or ankle surgical procedure with primary closure of the wound. The bioabsorbable matrix was implanted just deep to incision and the incision primarily closed. Nonadherent cover dressing was applied and patient was scheduled for 3-5 day routine follow up.

ACKNOWLEDGEMENT: The bioresorbable matrix used in this study is MicroLyte® AG Antimicrobial Matrix. It was provided by the manufacturer Imbed Biosciences Inc. for this study.

RESULTS

No signs of infection were noted at first post-operative appointment (between 3-5 days) in all 20 patients. All patients healed, 18 of the 20 at typical rate for the respective procedure.

Clinical Case 1

39 y/o diabetic female, history of MRSA infection, status post partial 1st and 2nd ray amputations with percutaneous tendo achilles lengthening and subsequent rupture requiring open repair



5 days post-op

2 weeks post-op

Clinical Case 2

63 y/o diabetic neuropathic male, cigarette smoker, osteomyelitis left 3rd digit.



5 days post-op

3 weeks post-op

Clinical Case 3

62 y/o diabetic neuropathic male, smoker, PVD with gangrene of great toe.



7 days post-op

Results Data

Patient #	Surgery	Wound Present at time of surgery	Infection present at time of surgery (resolved at level of closure)	Osteomyelitis (concomitant IV antibiotic treatment and removal of osteomyelitic foci)	History of MRSA / recurrent infection	Signs of Infection at First Post-Op Appointment (3-5 days)	Days to Healed	Complications	Remove from study
1	Achilles tendon repair	no	no	no	yes	no	14	none	
2	2nd toe amp	yes	yes	yes	no	no	18	none	
3	Midfoot bone removal with closure	yes	yes	yes	yes	no	22	none	
4	Great toe amp	yes	yes	yes	yes	no	132	Weight bearing dehiscence	
5	5th Met exostosis with recurrent ulceration	no	no	no	no	no	19	none	
6	5th digit amp	yes	yes	yes	yes	no	104	Weight bearing dehiscence resulting TMA	
7	3rd met elevating osteotomy with fixation	no	no	no	yes	no	24	none	
8	2nd digit amp	yes	yes	yes	yes	no	24	none	
9	Right great toe amp	yes	yes	yes	yes	no	34	none	
10	3rd met head resection	no	no	no	yes	no	n/a	Weight bearing dehiscence and later secondary infection	Not compliant with blood sugar, weight-bearing status, antibiotics, nor bandaging
11	1st MPJ arthroplasty	no	no	no	yes	no	n/a	Weight bearing dehiscence and later secondary infection	Not compliant with blood sugar, weight-bearing status, nor bandaging
12	Partial great toe amp	yes	yes	yes	yes	no	18	none	
13	Left 3rd toe amp	yes	yes	yes	no	no	19	none	
14	left 5th digit amp/left 2nd digit hammer toe repair	no	no	no	yes	no	12	none	
15	Partial first ray amp	yes	no	no	yes	no	22	none	
16	left great toe amp	yes	yes	no	yes	no	25	none	
17	Great toe amp	yes	yes	yes	yes	no	29	rescheduled suture removal appointment	
18	Left 5th met bunionectomy	no	no	no	yes	no	17	none	
19	Left 2nd digit amp	yes	yes	yes	yes	no	12	inflamed, cultures negative	
20	Left 3rd digit amp	yes	yes	yes	yes	no	29	none compliance with weight-bearing	
21	Right 4th digit amp	yes	yes	yes	yes	no	20	Slow healing from PVD	
22	Left 2nd digit amp	yes	yes	no	no	no	20	Slow healing from PVD	

DISCUSSION

In our study of 20 patients, 100% had diabetic peripheral neuropathy, 73% had open wounds and 67% had treated infection at time of surgery. Only 2 patient compliance-related complications, that of weightbearing dehiscence that resolved with revisional surgery, use of the matrix and appropriate wound care. Two patients were removed from study secondary to multiple infractions of noncompliance.

The matrix is effective for at least a 3-day period, offering the incision site protection during this important initial coagulation and healing time. This likely contributes to success seen in our study. Preliminary results are promising but a larger study is needed; further research is currently underway.

CONCLUSION

The addition of the bioabsorbable antimicrobial matrix prior to primary closure is efficacious in prevention of post-operative infection in the high-risk diabetic population.

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