NOVEL APPROACH TO FASTER HEALING OF DIFFICULT DFUs AND AMPUTATION PREVENTION WITH ENLUXTRA SMART WOUND DRESSINGS
Webinar Transcript. Wed, Sept. 30, 2017.

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1 Intro

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Vicki:

My name is Vicki Fischenich, I am the Director of clinical Affairs for OSNovative Systems. First of all, I want to start off by thanking everybody for taking time out of their day today, out of their busy schedule to attend the webinar.

Today we have a very special speaker, it's my pleasure to introduce him -

Alexander M. Reyzelman, D.P.M., FACFAS

- Senior Physician Diplomate UCSF Division of Vascular Surgery
- Associate Professor Department of Medicine California School of Podiatric Medicine, Samuel Merritt University
- Co-Director, UCSF Center for Limb Preservation

Doctor Alex Reyzelman is a fellow in the American College of Foot and Ankle Surgeons. He is a Senior Physician with UCSF Division of Vascular Surgery. He is also an Associate Professor at the California School of Podiatric Medicine at Samuel Merritt University. He is board-certified in foot surgery by the American Board of Foot and Ankle Surgery. He is a co-director of UCSF Center for Limb preservation, which specializes in treating lower extremity wounds and patients with higher risk of amputation, particularly those with diabetes and peripheral arterial disease.

Doctor Reyzelman is extensively involved in research, has published numerous papers in peer-reviewed journals and is a member of many professional associations, such as the American Podiatric Medical Association and the American Diabetes Association.

And I've personally had the pleasure of hearing Doctor Reyzelman speak on several occasions and on several topics involving wound healing and limb preservation. It is evident in his message and with his continued research development that he strives to find better, faster and more reliable ways of healing patients suffering with chronic wounds and, ultimately, the goal is limb preservation. So I will turn this over to Doctor Alex Reyzleman.

OSNovative Systems, Inc.

Novel approach to faster healing of difficult DFUs and amputation prevention with ENLUXTRA Smart Wound Dressings

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Slide 1

Alex:

Hello everybody, good evening to everyone. What I'd like to do is start this presentation and then for all of you to keep the questions, and hope you will ask those questions after the presentation.

Goals and Objectives

- Why treatments fail
- What barriers to healing exist
- Wound inflammation
- Autolytic debridement
- Why is picking the correct primary dressing important in wound healing
- Use of Enluxtra on Diabetic Foot Ulcers

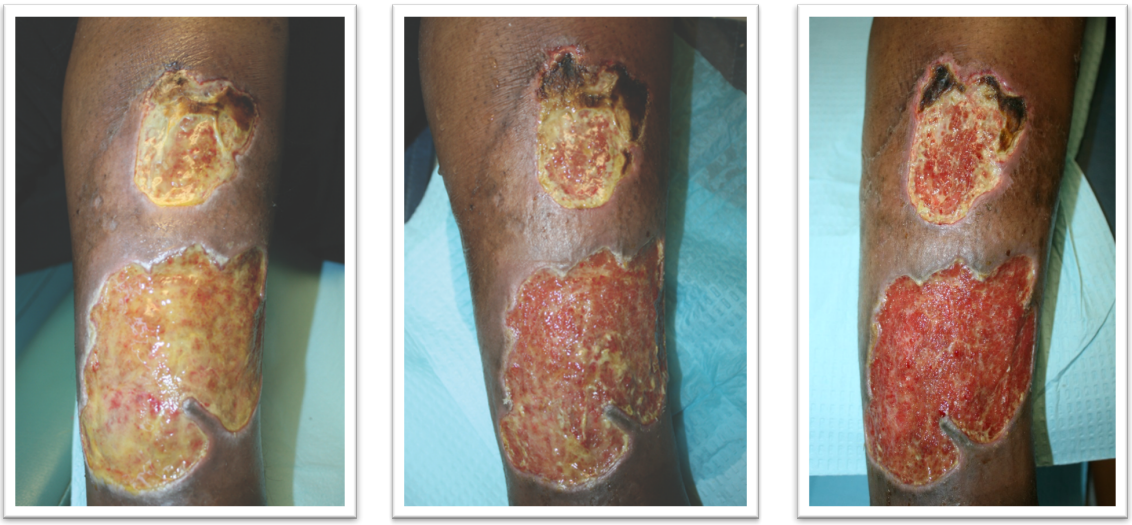
Slide 2

So what we're going to do is just go over the goals and objectives for the next 15 to 20 minutes. What I'm going to talk about are the treatments of diabetic foot ulcers and why they fail, what barriers to healing of diabetic foot ulcers exist.

We will touch upon wound inflammation and its importance to healing. Then we'll talk about autolytic debridement and follow that up with why picking the correct primary dressing is important in wound healing. And we will end with the use of Enluxtra smart dressing for diabetic ulcers.

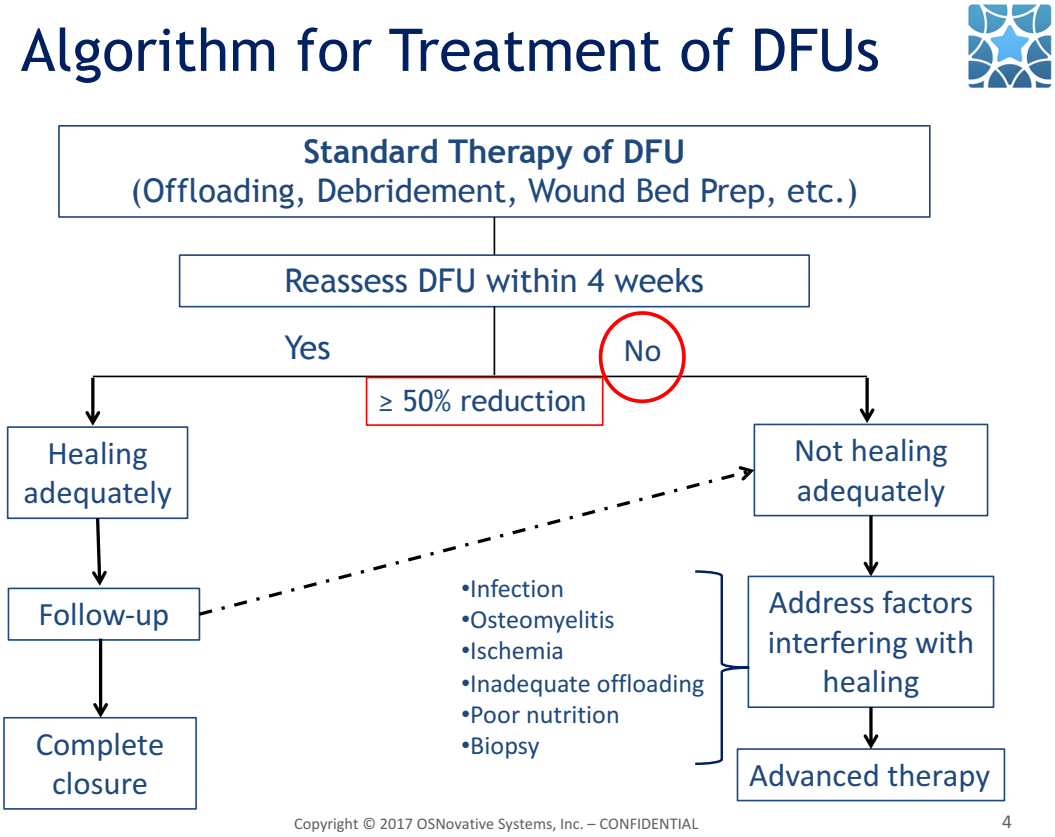
Is this possible without Surgical Debridement?

Day 0. Day 4. Day 11.



Slide 3

Before we begin the webinar, I'd like to plant a seed at this point and show you a case of mine that I've had a year ago. Patient that had this wound on the left went from Day 0, then Day 4 to Day 11 to a wound that looks like what you see on the right. And the question I'd like to pose is: “Is this possible without surgical debridement?”. And I’d like to just ponder that thought for a few minutes and we'll return to it in a little bit.

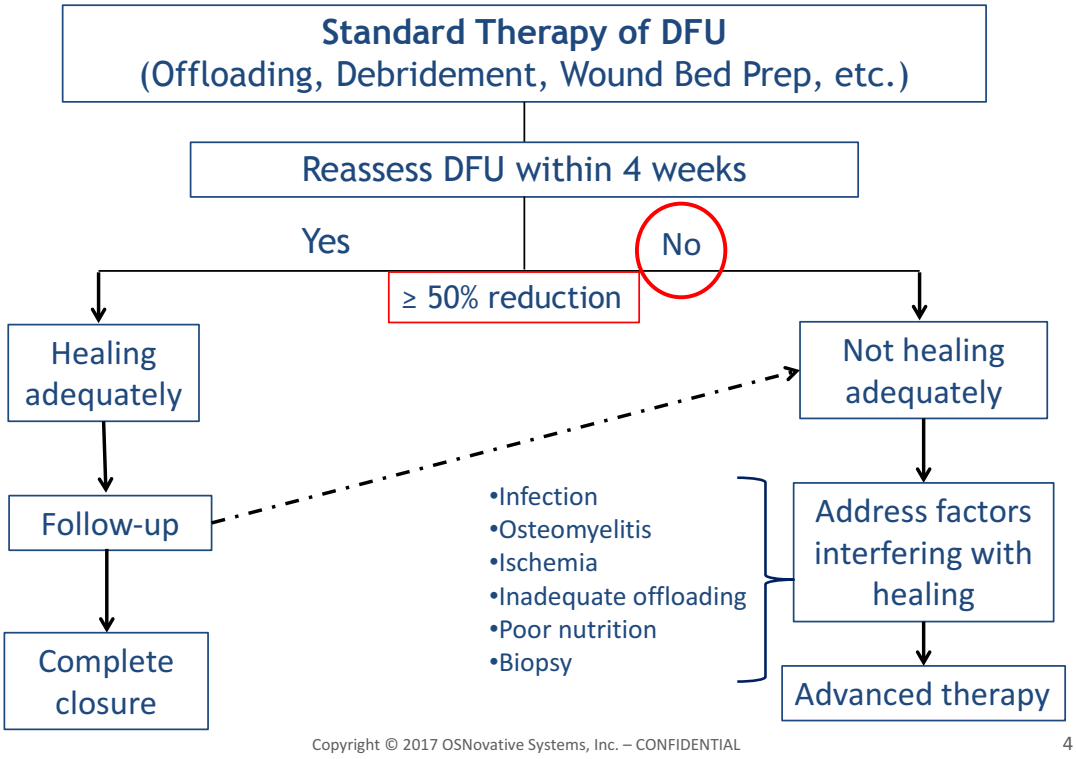


Slide 4

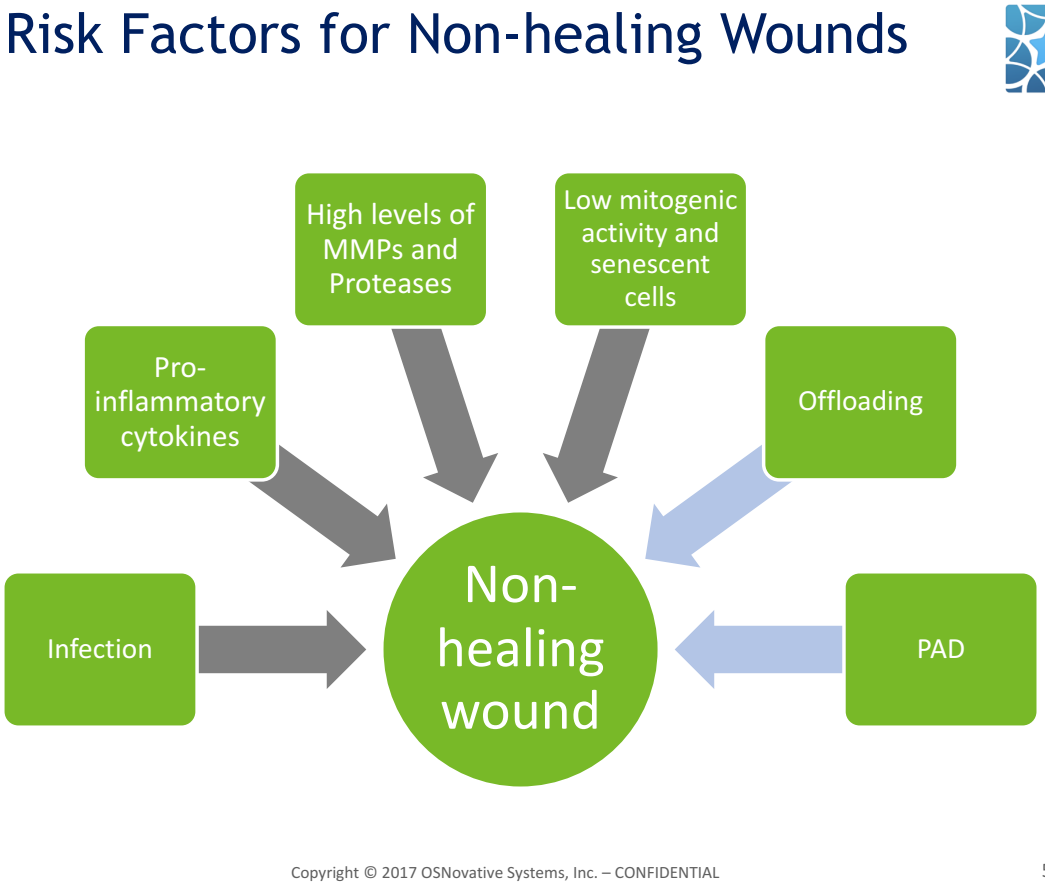
This algorithm for treatment of diabetic foot ulcers was published by Rob Kirsner from Miami in 2012. And this is somewhat standard. I think majority of us who treat diabetic foot ulcers all realize that the standard therapy for diabetic foot ulcers is offloading. It's paramount. Debridement is very important and certainly wound bed preparation in order for the wound to heal.

Now, typically, most of the clinics that I've ever been associated with, usually see patients once a week. It could be more frequent; it could be less frequent. But if your treatment regimen is working, you want to see a roughly 50% reduction in size at about 4 weeks. And if everything is going according to plan, if the ulcer is reducing in size by roughly 50% then continue the regiment and everything should heal.

Algorithm for Treatment of DFUs

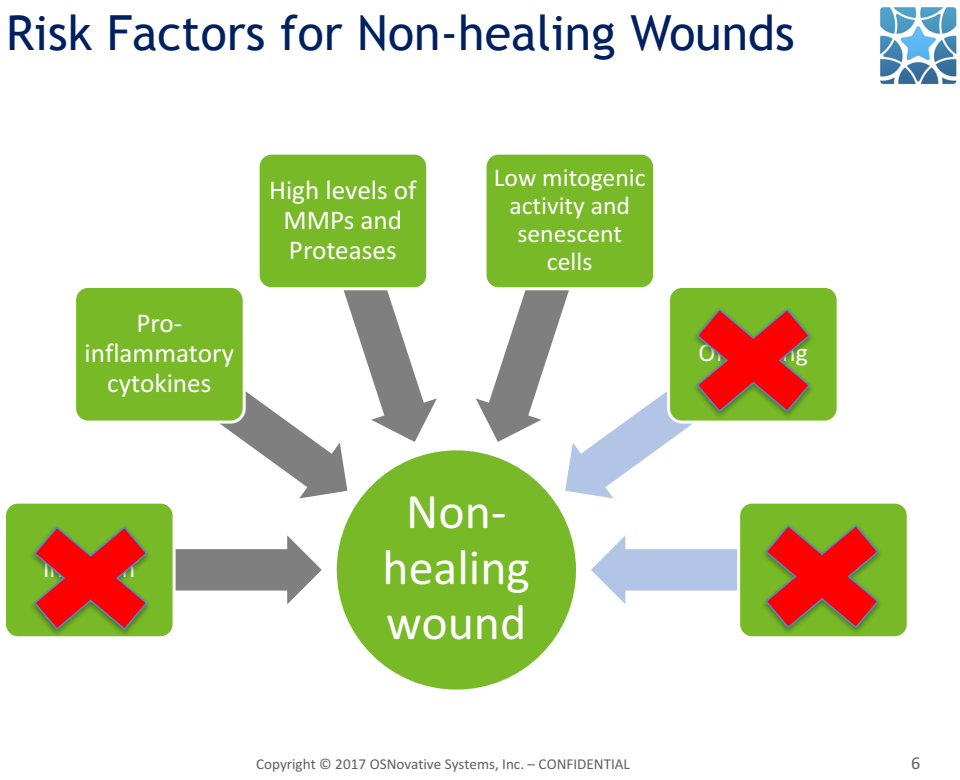


However, if the reduction in size does not reach 50% or so in 4 weeks, then we need to consider other factors that are that are playing a role in why the wound is not healing. And typically these factors (when it comes to diabetic foot ulcers) are infection, missed osteomyelitis, ischemia that goes undiagnosed and certainly inadequate offloading. And those are the main three, and sometimes we see a weird one such as malignancy, or maybe adjunctively poor nutritional status.



Slide 5

But for the most part, when we talk about diabetic foot ulcer healing issues, we're talking about offloading infection in PAD.



Slide 6

I think it's fair to say that many of us who treat diabetic foot ulcers do a pretty good job at offloading. And we think that we are pretty good at diagnosing peripheral arterial disease, picking that up and referring these patients to appropriate interventions whether it's vascular surgeon or some form of an interventionist. We also do a pretty good job at detecting infections and treating infections.

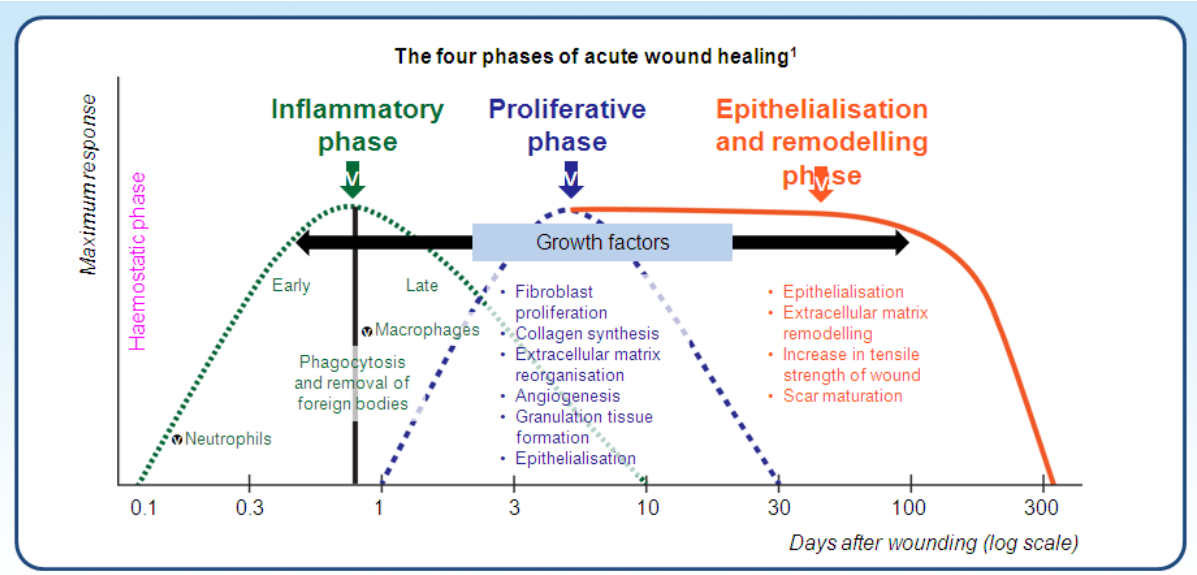
But if we mitigate all of these three factors, and the wound still goes unhealed, then we really have to focus on these three boxes that I left for you here. One of them is pro-inflammatory cytokines, increased levels of pro-inflammatory cytokines. High levels of MMPs, which are matrix metalloproteinases and low mitogenic or poorly functional cells that we call senescent cells. And all three of these should fit into the category of inflammation. And we'll talk about this in the next few minutes.

Slide 7

Now, it's easy to talk about pro-inflammatory cytokines and it sounds fancy, we talk about MMPs. The real question to the clinicians is: "How do we recognize these factors," "How do we know that these wounds are not healing?" and "What does it look like in real life?".

And here is a slide that really shows us some of these objective findings that we see on wounds that tell us that the wound is stuck and is not moving forward. Lack of pink-red granulation tissue, no decrease in size, pale white-yellow dark wound base, increase in exudate. And increase in exudate we're going to spend more time talking about, because this is paramount when it comes to inflammatory process. Certainly, foul odor or malodorous wound, peri-ulcer erythema such as what you see here around this wound. Even though this wound looks like it has good granulation tissue, the peri-ulcer erythema certainly plays a role. It tells us that something is going on, and prevents this wound from continuing to epithelialize.

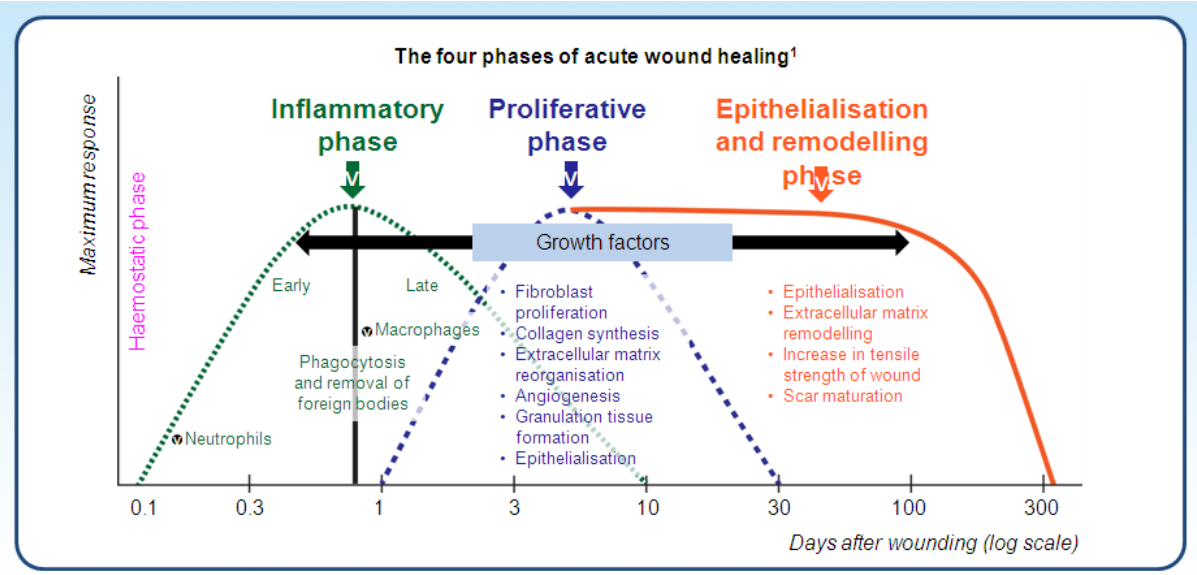
Chronic, Stalled Wound Biology



Slide 8

This slide here (and I'm not going to bore you with the biochemistry of wound healing) I think many of us, if not all of us, have seen this once or twice before. But I will tell you and point out something that is really important: inflammatory phase is typically 4 to 6 days, can go a little bit longer, and then it goes into proliferative phase. Now, characterization of proliferative phase [technical glitch] that's the only way to really think of how the wound is progressing. If it forms granulation tissue, we know it's moving forward.

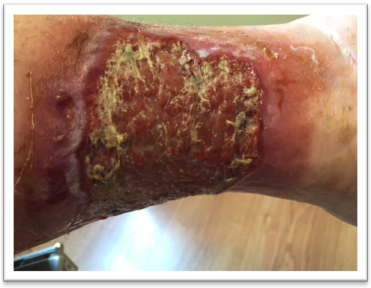
Chronic, Stalled Wound Biology

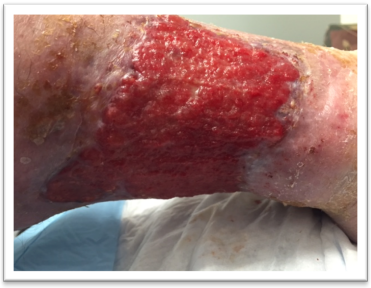


What's interesting here is this overlap between inflammatory phase and a proliferative phase, which many of us don't necessarily realize, myself included - for many years I didn't really appreciate this as much as I appreciate it now. And what this means is that wound that goes through inflammatory phase does not necessarily stop and move on to granulation tissue. It actually has this major overlap. And it also tells us that a wound that's granulating can certainly jump back into the inflammatory phase. And this is the crux of the problem for non-healing wounds.

3 Phases of Normal Wound Healing

- **Inflammatory Phase**
  - Removal of infectious agents and prevention of infection
  - PMNs, mast cells, histamine release monocytes
  - Day 0 to Day 4-6 post injury
- **Proliferative Phase**
  - Cell recruitment, migration, and proliferation of (epithelial, fibroblast, endothelial and stem cells)
  - Granulation tissue formation, Angiogenesis
  - Day 2 to Week 3 post injury
- **Remodeling Phase**
  - Matrix deposition and re-organization
  - Week 3 + post injury





Slide 9

What I'd like to show you on this slide is, I'll just point you to these two pictures. This is the same patient at different time points. The one on the bottom here has robust red granulation tissue with epithelializing borders, very little to no peri-ulcer erythema, there's minimal exudate. And the same patient here has slough, has light granulation tissue, it's not very robust, it's not very red. It has these rolled borders, it has peri-ulcer erythema, and mostly this wound just looks angry. And this is exactly what inflammatory phase looks like, and if you have a wound that looks like this - this wound cannot progress in an orchestrated fashion. And what's interesting about this slide here is this wound here actually was doing well and then 2 weeks later it became something like this. So I want you to just think about inflammation, if you take away nothing from this webinar at least take away the idea that inflammatory phase is something that we really need to focus on and we need to control and address it.

Exudate Management

Wound Fluid:

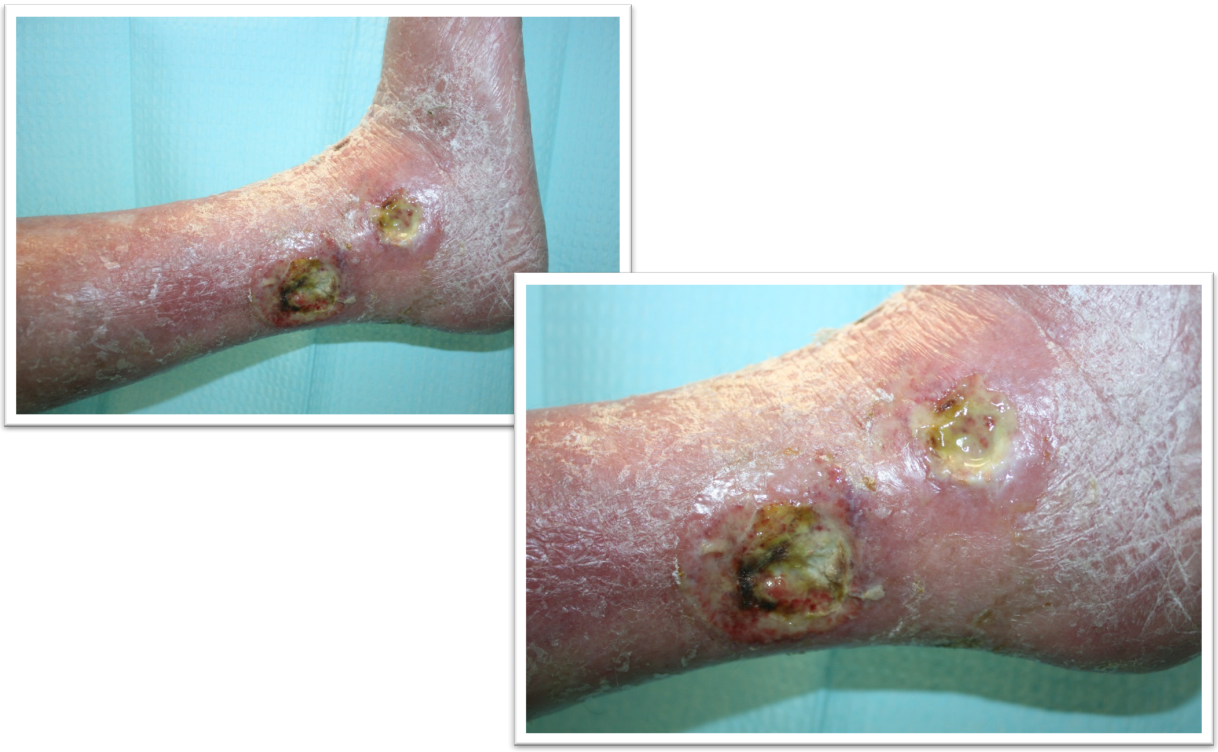
- Acute - stimulates cell proliferation
- Chronic - contributes to delayed healing
  - Increased levels of MMP's which degrades the extracellular matrix
  - Selectively inhibits proliferating cells
  - The longer a wound stays open, the more difficult it is to return to an acute state due to excessive senescent fibroblasts and an increased bacterial burden[3]

3. Cardinal M, Eisenbud D, Harding K, et al. Serial surgical debridement: a retrospective study on clinical outcomes in chronic lower extremity wounds. Wound Repair & Regeneration [serial online]. May 2009;17(3):306-311. Available from: CINAHL Plus with Full Text, Ipswich, MA. Accessed May 31, 2017.

Slide 10

One of the major inhibitory factors that promote inflammation is wound exudate. Now, we all know that exudate is normal. Almost every wound has exudate; and in small amounts in an acute wound acute exudate stimulates cell proliferation. However, in chronic wounds when there is more exudate, it contributes to delayed healing, because we have increased levels of MMPs. And these matrix metalloproteinases actually degrade/break down not only of the extracellular matrix, but they also break down the growth factors, selectively inhibit proliferating cells. So exudate in chronic wounds and heavy exudate, or moderate to heavy exudate, is actually very much of a problem in these wounds. And the longer a wound stays open the more difficult it is to return it to an acute state.

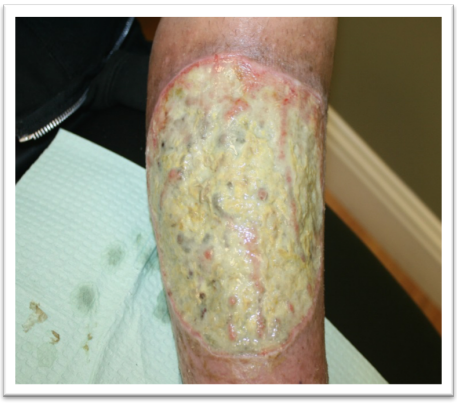
Chronic Wound Exudate



Slide 11

Here you see a couple of ulcers that are characterized by significant amount of exudate. Certainly the wound face does not look healthy and clean, but without controlling this exudate this wound has no chance of turning into a granular healthy wound. Another major inhibitory factor that promotes inflammation is bioburden.

Bioburden



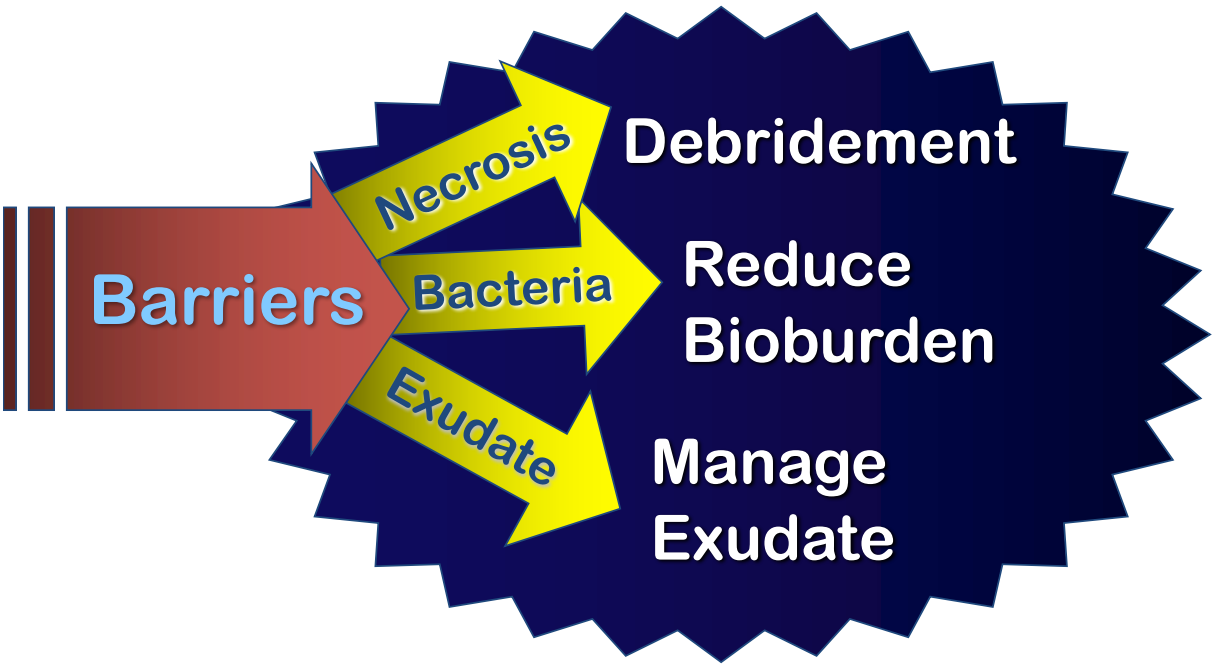
- What is it?
  - The quantitative estimation of the number of viable organisms living on a wound, implant, or other surface
- It represents contaminating organisms that can colonize and lead to infection
- It represents necrotic tissue and debris on the wound surface

Harrison-Balestra et al, Dermatol Surg. 2003
Schierle et al, Wound Repair Regen. 2009

Slide 12

Now, I think many of us have heard of bioburden. The definition of bioburden is: the quantitative estimation of the number of viable organisms living on a wound, implant and other surfaces. It represents contaminating organisms that can colonize and lead to infection. But what's interesting here is that bioburden does not necessarily mean the wound is infected. Bioburden means that the wound is increasing the number of microorganisms. This increase in microorganisms further leads to pro-inflamatory cytokines, increased level of MMPs, increase in necrotic tissue, and all of this leads to inflammation.

Clinical Management



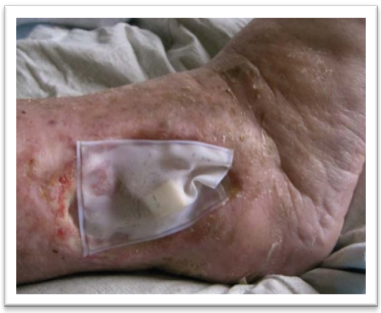
Slide 13

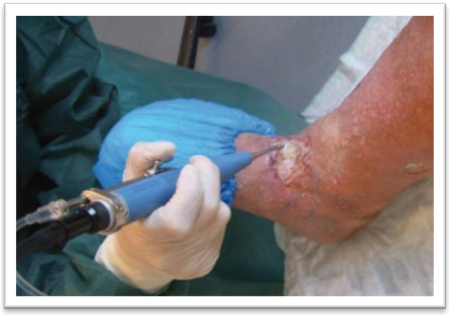
So where do we go from here? How do we manage this on a clinical level? Because that's really the bottom line: what are we going to do tomorrow, when we see these patients in the office or clinic? And I think the keys are obviously to debride the wound, reduce the bioburden and manage the exudate.

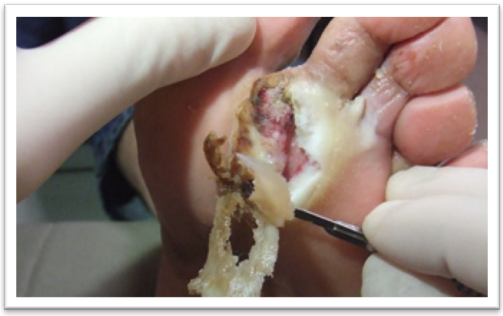
We talk about different types of debridement and when we discuss debridement, I think, many of us really believe that debridement is surgical. And, usually, everybody would say that's the only way to do it. And that's the most effective way to promote healing.

Types of Debridement

- Surgical
- Mechanical
- Enzymatic
- Autolytic







Slide 14

We talk about different types of debridement and when we discuss debridement, I think, many of us really believe that debridement is surgical. And, usually, everybody would say that's the only way to do it. And that's the most effective way to promote healing.

Serial surgical debridement: A retrospective study on clinical outcomes in chronic lower extremity wounds

Matthew Cardinal, ME[1]; David E. Eisenbud, MD[1]; David G. Armstrong, DPM, PhD[2]; Charles Zelen, DPM[3]; Vickie Driver, DPM, MS[2,5]; Christopher Attinger, MD[4]; Tania Phillips, MD[5]; Keith Harding, MBChB, MRCGP, FRCS[6]

Wound Rep Reg (2009) 17 306–311

- Retrospective analysis of 2 controlled, prospective, randomized trials
- 366 VLUs, 310 DFUs
- Serial debridement:
  - higher rate of healing
  - shorter time to healing

	Surgical Debridement	No Debridement
VLU	11.7% (SAR) 50% (12 wk closure rate)	8.7% SAR 28% (12 wk closure rate)
DFU	15.5% (SAR) 30% (12 wk closure rate)	12.5% (SAR) 13% (12 wk closure rate)

Slide 15

We do have some studies in the literature. Not that many, but there are a couple of good ones. One was published in 2009 by Matthew Cardinal, and what they did was they looked at retrospective analysis of 2 controlled prospective randomized trials. They looked at 310 diabetic foot ulcers. Patients that had serial debridement and patients that had no serial debridement. What they found was patients with serial debridement had a higher rate of healing, shorter time to heal the wounds.

EFFECT OF EXTENSIVE DEBRIDEMENT AND TREATMENT ON THE HEALING OF DIABETIC FOOT ULCERS

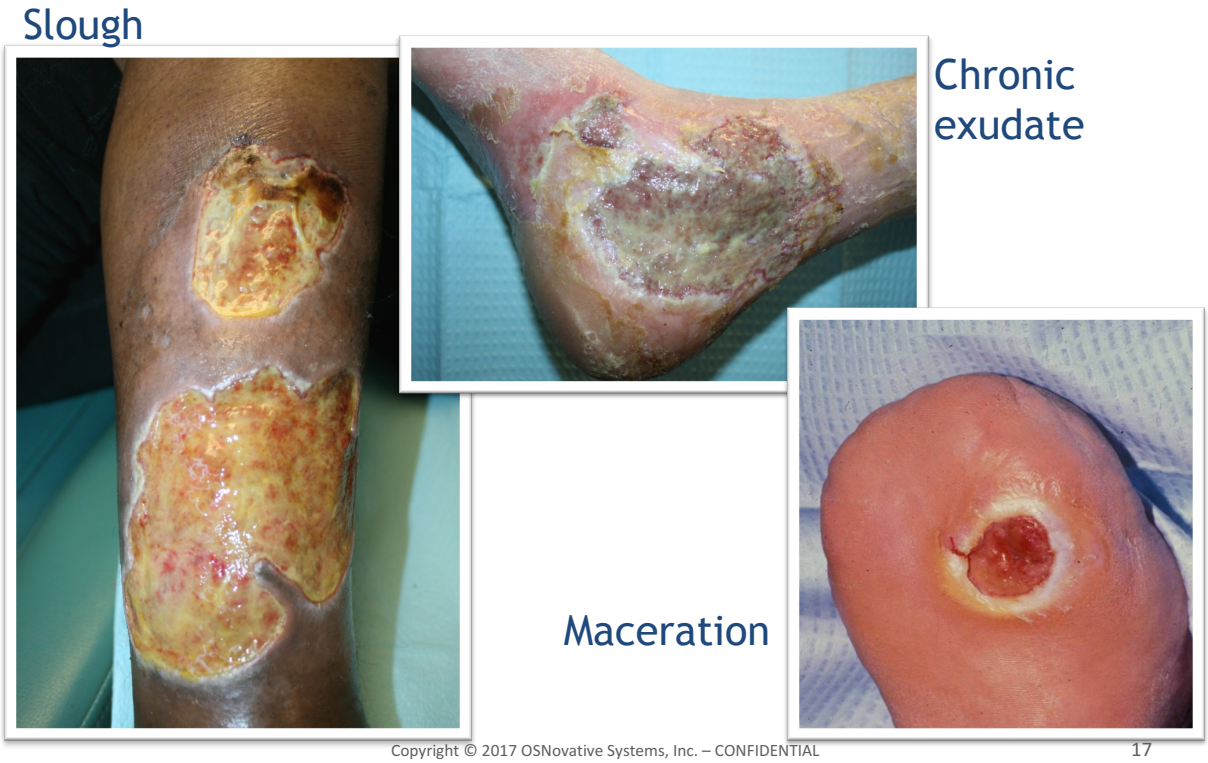
David L. Steed, MD, FACS*, Dennis Donohoe, MD†, Marshall W. Webster, MD, FACS*, Linda Lindsley, MD†, *and the* Diabetic Ulcer Study Group

- Randomized, prospective, double-blind trial
- N= 118 at 10 centers
- ALL patients had aggressive sharp debridement
- Centers with more frequent debridement = Higher rate of healing

Slide 16

Another landmark study that most people refer to when they promote surgical debridement is the David Steed article. And Steed looked at randomized, prospective trial of 118 diabetic foot ulcers over 10 centers. And he retrospectively reviewed the data. All of these patients had to have aggressive sharp debridement. However, not all centers had frequent debridement, so he compared various centres and what he found was that centers with more frequent debridement had a higher rate of healing.

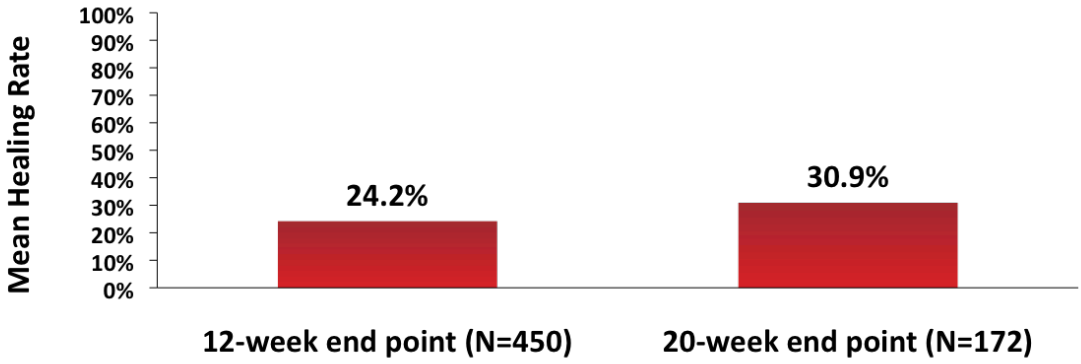
Surgical debridement weekly with no improvement



Slide 17

Well that's great, but we all know (if we're honest with ourselves) that despite our weekly debridement, and most of us do this on a weekly basis, despite our surgical weekly debridement, we still have plenty of patients that don't heal for one reason or another. And these are examples here. These are all my patients that despite debridement just don't do well. Where does that leave us? Why is that the case? Well, we have data to support that despite aggressive treatment of diabetic foot ulcers they still don't do well.

Healing of Neuropathic Ulcers: Results of a Meta-analysis



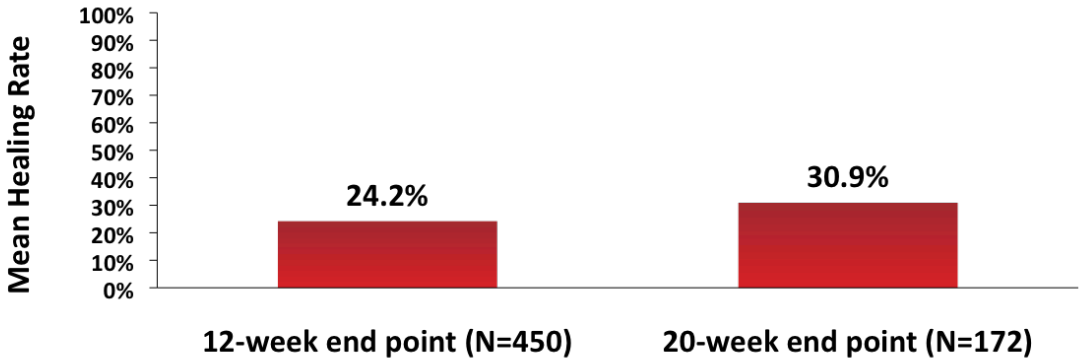
- These data provide clinicians with a realistic assessment of their chances of healing neuropathic ulcers
- Even with good, standard wound care, healing neuropathic ulcers in patients with diabetes continues to be a challenge

Margolis et al. Diabetes Care. 1999;22:692.

Slide 18

This is a study that was performed by Margolis and published in 1999. Looking at multiple prospective diabetic foot ulcer trials. And what Margolis did was he looked at all of these placebo arms of all these trials in a meta-analysis and he found that despite surgical debridement, despite offloading and despite creating a moist environment only 25% of patients healed at 12 weeks. And if he carried it out to 20 weeks only 31% of patients healed. So now we have some conflicting data. I just showed you some evidence that supports surgical debridement in terms of healing wounds and now I'm showing you that, despite surgical debridement, we still don't heal majority of our wounds.

Healing of Neuropathic Ulcers: Results of a Meta-analysis



- These data provide clinicians with a realistic assessment of their chances of healing neuropathic ulcers
- Even with good, standard wound care, healing neuropathic ulcers in patients with diabetes continues to be a challenge

Margolis et al. Diabetes Care. 1999;22:692.

So where do we go wrong? Well, maybe we need to consider that something else needs to be added to the surgical debridement. Maybe we haven't had the appropriate treatment, maybe we haven't thought of it the right way.

Autolytic Debridement: What is it?

- The process by which the wound bed utilizes phagocytic cells and proteolytic enzymes to remove debris.

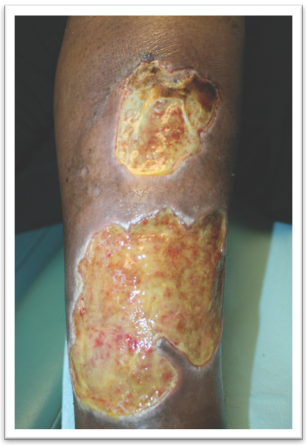
- Judicious use of occlusive and semi-occlusive dressings can promote this natural process by controlling exudate levels and maintaining a moist wound environment.

Slide 19

And that leads us into autolytic debridement. Now, if you're like me, for many years I never really understood autolytic debridement. I knew it existed but it didn't make sense to me. Yes, it's somehow the body's way of cleaning out the wound, but that's all I knew about it. And it wasn't until several years ago that it really clicked and made me understand that autolytic debridement is very powerful. Definition of autolytic debridement is: the process by which the wound bed that utilizes phagocytic cells and proteolytic enzymes to remove debris. And this can be accomplished by judicious use of occlusive and semi-occlusive dressings that can promote this natural process by controlling exudate levels and maintaining a moist wound environment. And the key here is controlling the exudate, as we will look at in a little bit.

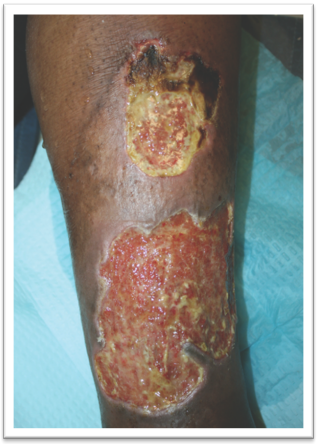
Autolytic Debridement: Benefits

- Continuous (24/7)
- Selective
- Easy to perform
- Little or no discomfort
- Performed in any setting



DAY 0.

DAY 4.



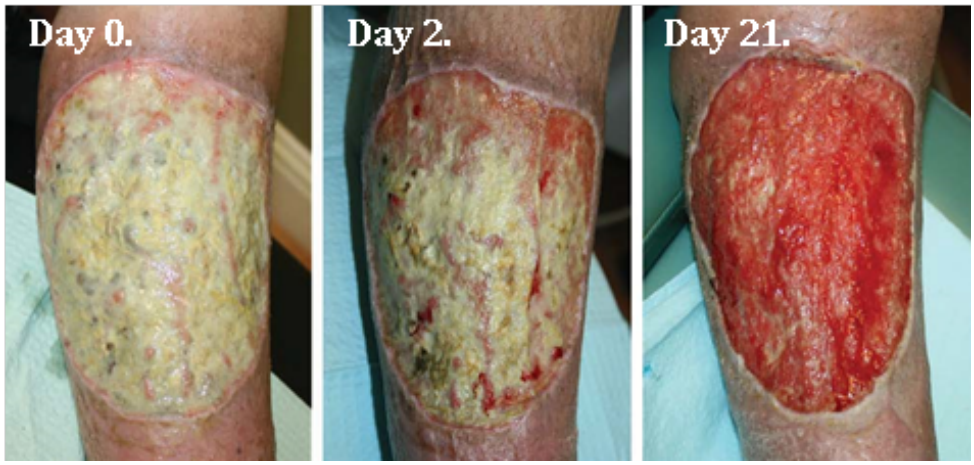
Slide 20

I showed you this case when we first started and this was the case that really drove the point across. This was when I really understood the power of autolytic debridement. This is a patient who has had this wound for over a year. She is immunosuppressed, has had multiple surgical debridements, not only in the clinic, but she had to go into the operating room on several different occasions. She's had all types of treatment and she would not let anybody take a knife to this wound. As you can see here Day 0 to Day 4 - we accomplished this improvement and granulation tissue in just 4 days with a certain dressing that we are talking about today. And the reason we did that was because of autolytic debridement. So, without doing any surgical debridement we were able to transform this wound here into this granulation tissue, this beautifully healing wound on this side of the slide.

Intensive Natural Autolytic Debridement Supported by Enluxtra

Female, 58 years old, with Hepatitis C and illicit drug abuse history.
Bilateral ulcers, pain at 7 out 10, odor, edema, copious exudate.
Previous treatments for 19 months were unsuccessful and included debridement, Medihoney, Silvadene, Unna boot, and Coban compression.

Enluxtra and compression wrap were started and changed 2 times per week. Odor disappeared by Day 16.
Wound was free of slough by Day 21 (6 dressings changes).



Slide 21

Here is another example of a similar patient who's had this wound for many many months, almost a year. You can see a lot of slough, this is a heavily contaminated wound, there is a lot of bioburden here. This wound had absolutely no surgical debridement. And you can see what happens to it within 21 days. The wound is now 100% granular. And only at this point, once it reaches this point, can it start to heal and epithelialize. And again, this was accomplished by autolytic debridement alone.

Balanced Inflammation

- **Balanced Inflammation is the "Holy Grail" of successful wound healing**
- If inflammation is unchecked and persistent, it can lead to a non-healing wound
- The goal of wound care professionals is to reduce inflammation and allow the wound to progress through the healing cascade in an orchestrated fashion

Slide 22

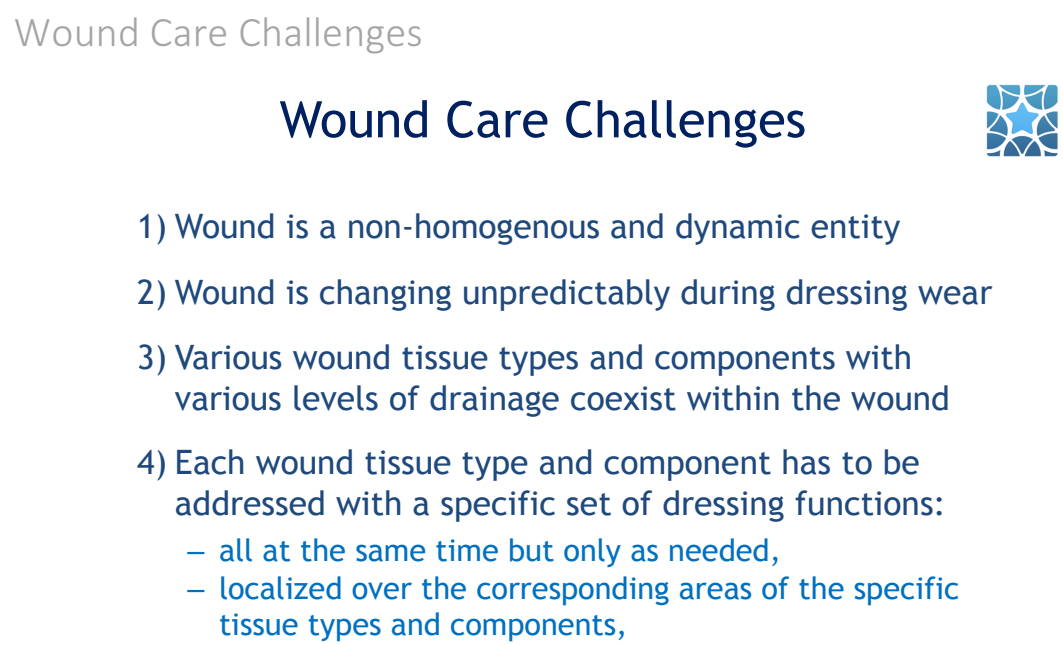
So, if we summarize so far where we are, we can really say that balancing the inflammation is the key and it's really the Holy Grail of successful wound healing. If inflammation is unchecked and persistent, it can lead to a non-healing wound. And then goal for us as wound care professionals is to reduce the inflammation and allow the wound to progress through the healing cascade in an orchestrated fashion.

Debridement is a continuous PROCESS.

Surgical and Autolytic debridement are not independent of each other.

Slide 23

So maybe there should be a paradigm shift, somewhat, of understanding the debridement and not thinking that the debridement is only once a week or once every two weeks. Debridement is a continuous process and is the combination of surgical and autolytic debridement codependent on each other. That is the way to move forward. Because if we see the patient Monday to Monday, something happens for a week between those times. And we are not controlling that. And if we can control that time between our visits then, I think, we should be able to heal more wounds.



Slide 24

So what are the wound care challenges that we're facing when we're looking at these wounds? Well, we know that a wound is non-homogeneous and it's a dynamic entity. The wound is changing unpredictably during dressing wear. Again, from Monday to Monday, or from Tuesday to Tuesday the wound has a dressing on there, but we have no idea, because we don't see the patient, what the wound looks like. Various wound tissue types and components with various levels of drainage coexist within the wound. And what that means is that, specifically with a diabetic foot ulcers, we frequently see that part of the wound has slough, fibrous tissue, part of the wound may have granulation tissue, part of the wound may be moderately to heavily exudative, while the other part may have very low exudative ability.

Wound Care Challenges

1) Wound is a non-homogenous and dynamic entity
2) Wound is changing unpredictably during dressing wear
3) Various wound tissue types and components with various levels of drainage coexist within the wound
4) Each wound tissue type and component has to be addressed with a specific set of dressing functions:
   - all at the same time but only as needed,
   - localized over the corresponding areas of the specific tissue types and components,
   - dynamically and reversibly following to evolving wound.

So, how do we accomplish all of these different things? How do we target this wound when it has all these different things going on?

We know that each wound, each wound tissue type and component has to be addressed with a specific set of dressing functions. But what's important, it needs to be all done at the same time, but only as needed; localized over corresponding areas of the specific tissue types and components and dynamically and reversibly following the evolving wound. So the wound is dynamic and the dressing needs to be dynamic, as well. And that's really the key to allow autolytic debridement to occur.

Enluxtra "Smart" Dressing Promotes Autolytic Debridement

- The first and only self-regulating superabsorbent fiber dressing with adaptive absorbency and built-in adaptive hydration function.
- Suitable for wounds with any drainage level – from lowest to highest.
- Addresses each distinct wound area individually and adjusts its properties over each area in real time in response to evolving wound environment.

Slide 25

So this brings us to Enluxtra the smart dressing. Why is it called a smart dressing? Because it is in first and only self-regulating super absorbent fiber dressing with adaptive absorbency and built-in adaptive hydration function. It's suitable for wounds with any drainage level from low to high. And it addresses each distinct wound area individually and it adjusts its properties over each area in response to involving wound environment.

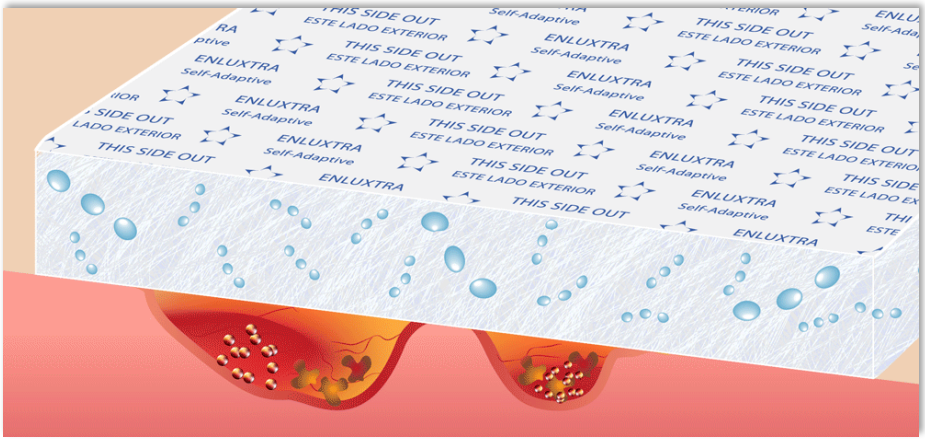
Smart Polymer Action

In exuding areas polymers sense high humidity and high moisture content – they become more permeable to fluids

>>> Enluxtra absorbs

In dry areas polymers sense low humidity and create optimal moist environment

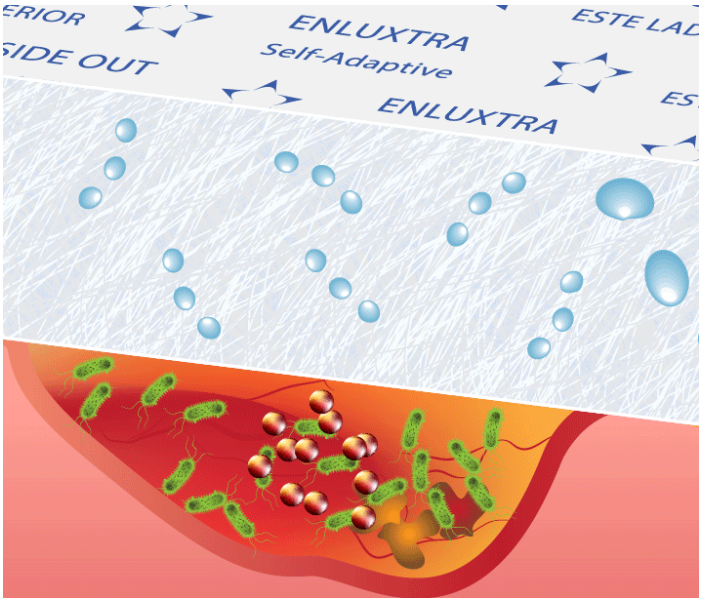
>>> Enluxtra hydrates



Slide 26

So how does it do this? Well, this smart dressing, Enluxtra, is able to detect high humidity and high moisture content and based on that it becomes more permeable to fluid and it absorbs. At the same time, in dry areas and desiccated areas it senses low humidity and creates optimal moist environment and is able to hydrate the wound.

Enluxtra's Unique Feature



Due to its porous structure Enluxtra is the only dressing that:

- Absorbs and keeps away from the wound both solid and liquid products of autolytic debridement
- Helps promote intensive natural wound cleansing.

Slide 27

Enluxtra has a unique feature: due to its porous structure it absorbs and takes away not only the solid, but also the liquefied products of autolytic debridement. It helps to promote intensive natural wound cleansing.

Enluxtra is a reliable and simple "smart" tool for faster healing

1. Continuous cleansing of the wound bed by evacuation of liquefied slough, debris, microorganisms
   - Brings the wound out of the Inflammation stage
   - Prevents a return to the Inflammation stage during the Granulation and Re-epithelialization stages
2. On-demand hydration of dry and low-exuding areas
   - Supports optimal moist microenvironment for cell multiplication and proliferation
3. Maximum absorption and retention of exudate
   - Prevents accumulation of excess moisture and skin maceration; removes MMPs

Slide 28

So if we summarize, Enluxtra... we can summarize it in a way to say that its continuous cleansing of the wound bed and evacuation of liquefied slough and debris is able to bring the wound out of inflammation stage. And I've mentioned inflammation before and I think this is really really important. Our goal is to progress the wound from inflammatory stage to the proliferative stage. But not only to progress it in that direction, but also to prevent it from returning to the inflammation stage and allow it to further granulate the wound and to further re-epithelialize the wound margins and progress to healing.

Enluxtra is a reliable and simple "smart" tool for faster healing

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   - Brings the wound out of the Inflammation stage
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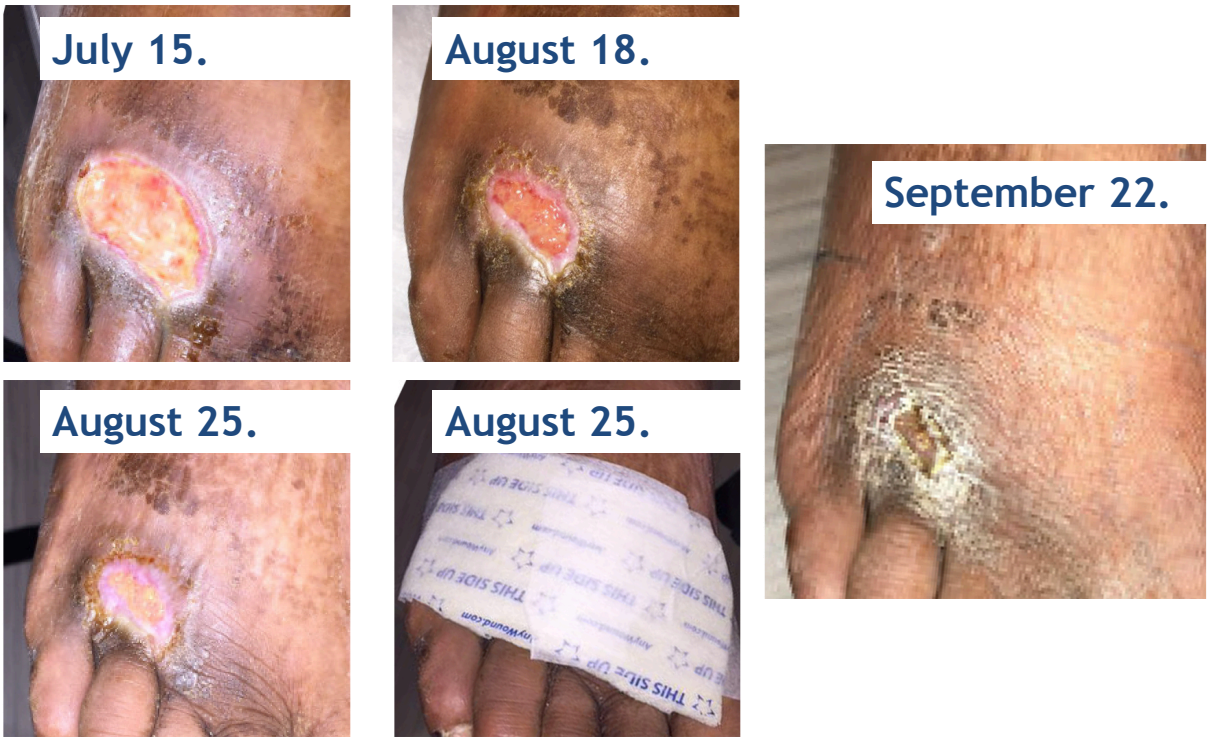
   - Prevents accumulation of excess moisture and skin maceration; removes MMPs

The second part that Enluxtra does, it has on demand hydration of dry and low-exudating wounds. It supports this optimal moist microenvironment for cell multiplication and proliferation. It's also able to maximally absorb all this fluid. Now, when you think about exudate and we talked about chronic wounds with moderate to heavy exudative properties. We talked about having MMPs. All of these things are important, because if we can't absorb it and lock it in place, then that exudate, those enzymes that are sitting on the wound, they're able to further debris and further break down the granulation tissue process that has been occurring.

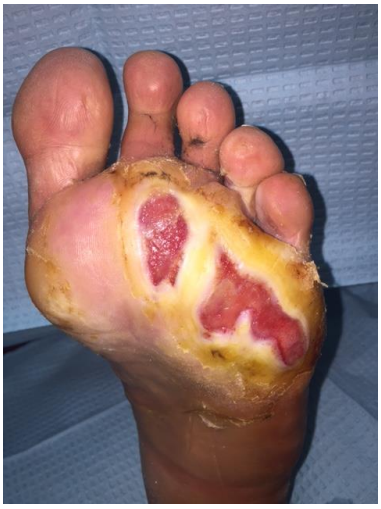
Case Study: Dorsal DFU



Slide 29

I want to show you a couple of case studies. There's nothing special about this particular patient except it's a diabetic patient with a dorsal foot wound. We did not perform any surgical debridement at this stage, and you can see how it progresses from one month to the next. What I want you to really look at is the fact that there is no periulcer inflammation. Applying Enluxtra, it is able to control not only the wound base, but also the wound margins, as well. And from one month to the next, from one week to the next we see more epithelialization and eventually this wound goes on to completely heal.

Case Study: Plantar DFU



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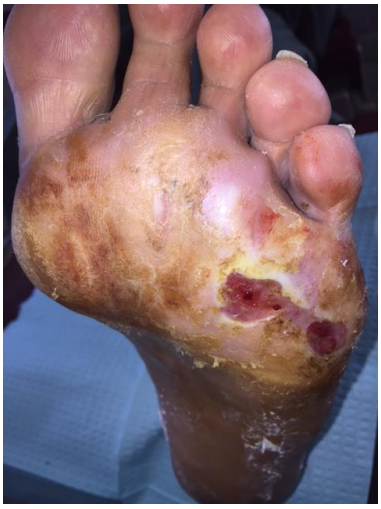

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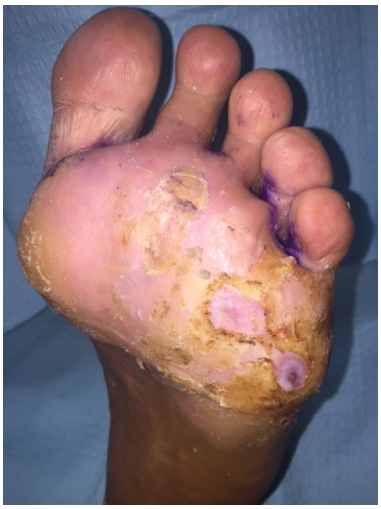
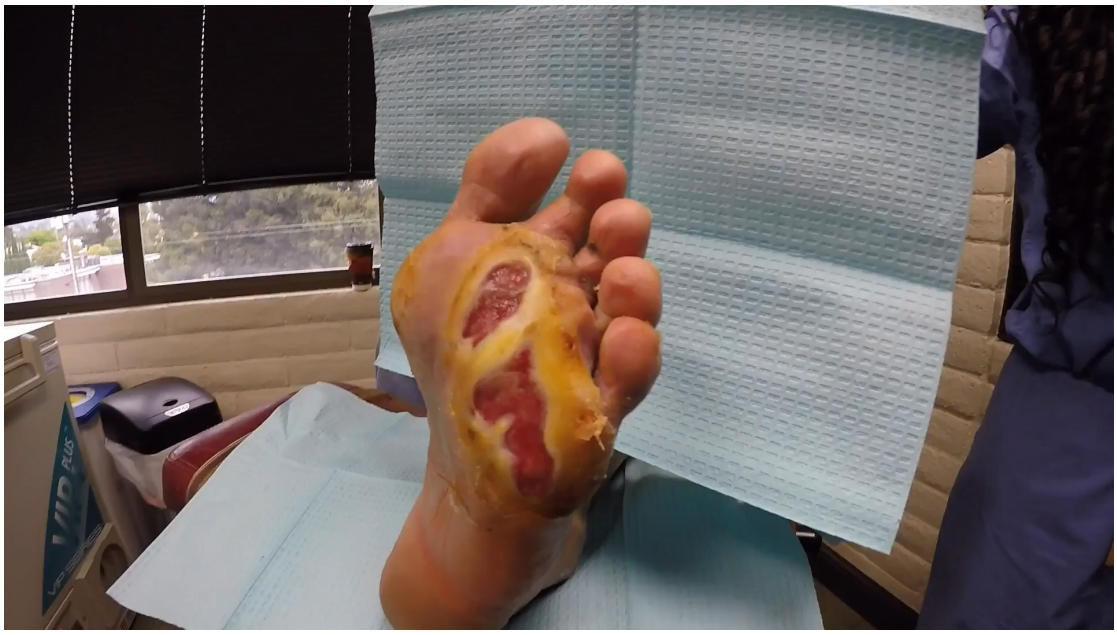


September 21.

Slide 30

This is a more classic diabetic foot ulcer, this is a plantar foot ulcer. I think this is what we typically think of when we talk about diabetic foot ulcers. What's interesting about this particular patient is that he has two ulcers separated by an island of skin. And the question is: Well, how do we dress this? Do we apply one dressing? And if we do, are we concerned about this area being macerated and breaking open?

Application of Enluxtra Video



Slide 31

And what's special about Enluxtra is that property that we talked about earlier: it can detect various zones of drainage or exudate and it can donate moisture to a dry area, and it can absorb moisture from a draining area. So even if we put one piece of Enluxtra on the entire wound that has multiple ulcers, it is not going to create more maceration. On the contrary, it's going to be able to absorb everything and provide appropriate moist environment for these ulcers to heal.

Alexander M. Reyzelman, D.P.M., FACFAS

Novel approach to faster healing of difficult DFUs and amputation prevention with ENLUXTRA Smart Wound Dressings

Alex:

So at this point what I'd like to do is turn it over to Vicki to continue the webinar and then we can open up to questions.

Application Tips

- Sizing of dressing – must cover compromised periwound skin and 1” of healthy skin
- Contact with wound bed or filler
- Removal more frequent on heavy bioburden wounds
- Removal at 7 days or before drainage reaches dressing edge
- Avoidance of co-products under Enluxtra & on wound and peri-wound

Vicki:

Thank you Alex for that great presentation. I just want to go over some quick things about Enluxtra and some of the key points Alex talked about for inflammation and the chronic inflammatory state.

With Enluxtra some of the key things to do is the sizing of the dressing. So the sizing of the dressing needs to also include the periwound tissue. So anything that's happening around the periwound area needs to be included into the sizing of the dressing. It needs to go out 1 inch to the healthy skin. Still to this day it's one of our biggest issues that I continue to see. My motto on this is: go big or go home! If you remember nothing today: go big or go home on the sides of the dressing for the first three to four changes. Make sure that you’re making good contact with the wound bed or the wound filler. You can use this on deeper wounds with cavities or undermining or tunneling. Just be sure you are using a material that does not shrink, so no alginates, no Aquacel AG. Make sure that you remove the dressing more frequently on heavy bioburden wounds. You want to remove it before 7 days or before drainage reaches the dressing edge.

Application Tips

- Sizing of dressing – must cover compromised periwound skin and 1” of healthy skin
- Contact with wound bed or filler
- Removal more frequent on heavy bioburden wounds
- Removal at 7 days or before drainage reaches dressing edge
- Avoidance of co-products under Enluxtra & on wound and peri-wound

Vicki:

Educate your patient, let them know that if they are hurting/burning/stinging/smelling more than likely the drainage has reached one of the dressing edges and it is irritating them.

One of the things that causes irritation with the use of Enluxtra is if you continue to use any kind of co-products underneath Enluxtra. If you're using any zinc paste, petroleum-based products, cream-based products, those particular products underneath Enluxtra can also cause the patients to have irritation. You want to stick to something that's water-based or not thick or viscous. So no santyl, no petroleum-based products. Those particular products are going to interact with Enluxtra.

Enluxtra Availability and Support

- Reimbursement HSPCS codes: A6196 and A6197, up to 30 dressings per month
- Information at **ENLUXTRA.com**
  - Distrubutor/DME lists
  - Free private live clinical webinar registration
  - Training and education programs
- Call for clinical support 888-519-2297, ext.7
- Call or email Vicki:
  - vickif@osnovative.com
    806-786-6902

Enluxtra is FDA-approved. It reimburses. Our HIPAA codes are: A6196 and A6197. It's a good amount of dressings. You get 30 dressings per month per wound. And you can get some of this information on how to get the distributor list and our DME list on enluxtra.com. There are other opportunities if you'd like to know a little bit more of the application process with Enluxtra, please, we encourage you to sign up for a private live webinar and get some training and education on the use of Enluxtra prior to using it.

Our numbers are listed below. That is our clinical line and my phone number directly. If you'd like to sign up from some further information.

Contact information

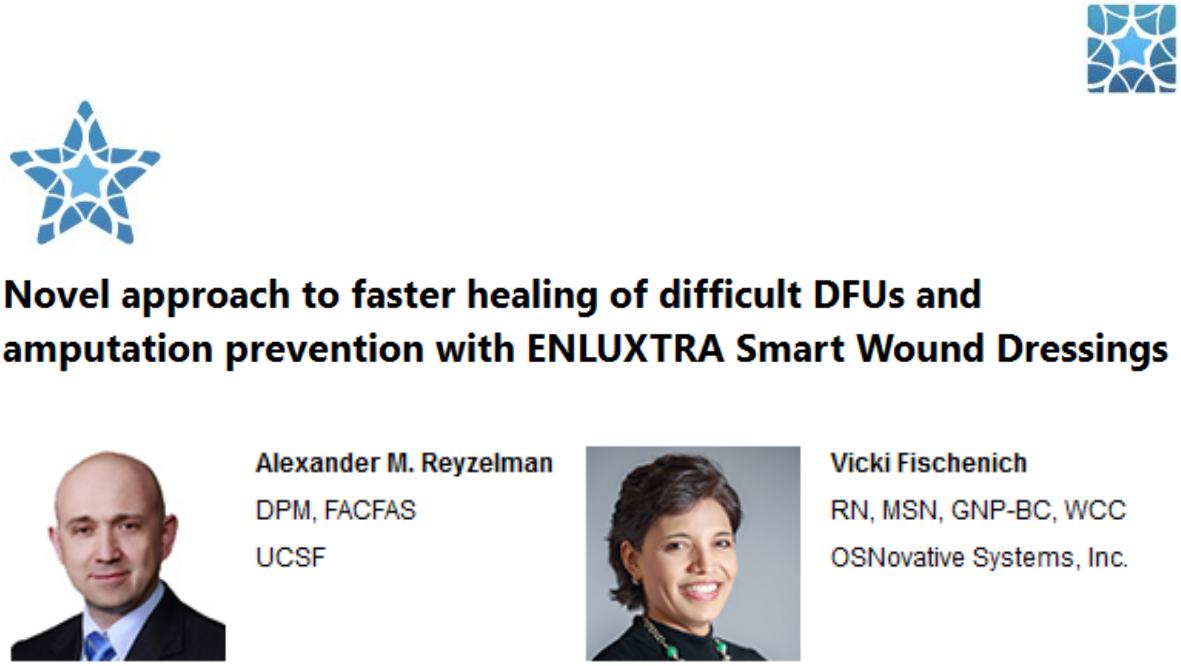
- facebook.com/osnovation

- contact@osnovative.com

- www.ENLUXTRA.com

- 888-519-2297, ext.7

There's also our Facebook. Please go to facebook.com/osnovation or contact@osnovative.com or go to enluxtra.com.



Vicki:
We want to open this up for questions right now. One of the first questions we have is:

Q: Where is Enluxtra available?

A: If you go to our website, Enluxtra is available through many distributors.

Next question we have is about manual debridement:

Q: Will manual debridement produce bleeding? Is Enluxtra good for that?

A (Alex): In terms of debridement and creating some bleeding and then using Enluxtra - we do it all the time. Of course, the bleeding has to be controlled, hemostasis to be achieved, so there is no active bleeding. But if there's some oozing it is not a big deal. We usually put Enluxtra right over it. And then the frequency of dressing changes is important. If we think there is a concern, we may change it more frequently. And if the wound is looking good and it is not bleeding, and if there is not too much exudate, then we may leave it for 3, 4, 5 or 7 days. And that's one of the advantages of Enluxtra is that we have that luxury of either changing a daily or leaving it for several days, or up to a week.

Vicki:
One of the other questions is:

Q: Can you use Flagyl crushed under Enluxtra?

A (Vicki): You could. Powder-based products can be used, but also remember Enluxtra draws in and locks in the exudate. So on frequent use if you have a heavy bioburden wound with lots of drainage what you want to do is change it more frequently at the beginning. If you would like to use the Flagyl you could underneath it. Powder Flagyl. But you would still need to increase the frequency of change early on.

A (Alex): You know, in my experience using Enluxtra we try not to put anything between the wound and the Enluxtra if we can. I'm sure powder is not going to be a big deal and it is not going to do too much. But the idea of Enluxtra is to be able to have direct contact with the wound and allow autolytic debridement to occur. If there is a need for antibiotics, we typically use oral antibiotics if we need to. And, of course, debride surgically if we need to. But we like to allow Enluxtra to perform its function and promote autolytic debridement by itself. Usually.

Vicki:
Okay. We have several other questions:

Q: I mostly treat patients with pressure ulcers. Can I use the same approach and treat them with Enluxtra?

A (Alex): Pressure ulcers, venous leg ulcers, any type of ulcers, surgical wound - it really doesn't matter - a wound is a wound. We're just following the same principles: if it's necrotic it needs to be debrided, and then autolytic debridement needs to be promoted. Enluxtra can be used for that. We found in our setting we don't have the luxury of having many options for dressing choices, so we are always looking for this universal dressing. One that can accomplish multiple things. And that's where we found the advantage of Enluxtra. We don't stock too many dressings, we tend to keep Enluxtra as one of our only absorptive dressings. And also we rarely use hydrogel. We believe that Enluxtra promotes and donates plenty of hydration to the wound. Where we don't have to use hydrogel independently and stock different dressings. So I think that's been really helpful to us.

Vicki:
Okay. We have another question:

Q: If the exudate is so great that the dressing is not lasting 24 hours, can you change it twice a day?

A (Alex): I'll start first and you can certainly give your experience, too. Of course, you can change it as often as you need to. Really, the exudate drives everything. You want to make sure that Enluxtra is not leaking and it's not breaking up on you, because if the drainage is too much for Enluxtra to carry then it defeats the whole purpose. So you want to create the best possible appropriate moisture balance for the wound base. If it's highly exudative we have to control it at all cost. If it's BID dressings then that's what it takes. But usually we find that if it's draining lot, we will change it more frequently and then we will decrease the frequency as the drainage is controlled.

Vicki:
Yes. The only thing I'm going to add to that is the use of the sizing. So when you have a high draining wound, make sure you are sizing the dressing appropriately. You definitely need to make sure to remove Enluxtra before the exudate is pouring out the edges.

One more question here:

Q: Is Enluxtra available or is it covered by prescription; or is it covered by any medical plans?

A (Vicki): Yes. Enluxtra is definitely available by prescription. If you go to our website, you'll see a list of our DME providers and our HIPAA codes. Enluxtra is available at 30 pieces per wound per month, so you could do it daily. Of course, the goal, or hopefully, the goal is to extend the wear of the dressing as you get ahead of the condition, or either the exudate or slough.

And I think we have another question:

Q: Is there a need for biofilm detection if Enluxtra is able to remove the biofilm?

A (Vicki): Okay. So, biofilm. There is a lot of biofilm detection/DNA detection available now. If you're using DNA sequencing for your detection you could still use it. Is Enluxtra going to help with the removal of the biofilm? Yes. It will decrease it in time. You have to change the frequency. There may be a need, you may want to do a DNA sequencing in order to treat empirically, or whatever type of treatment you're going to do. But, yes, Enluxtra works really well with highly infected wounds and in my opinion it should be used on highly infected wounds because it's going to help deal with that bioburden with every dressing change. Alex, do you want to add to that?

A (Alex):
Right. I think that we really underestimate the power of autolytic debridement. We tend to focus on surgical, sometimes enzymatic debridement. But really, autolytic debridement occurs 24/7. And if we just think about that for a second - 24/7 something is going on! And if we can promote an appropriate environment for that process to continue, then it can break through the bioburden, it can break through the biofilm. It can control everything and clean up that wound faster than anything else. You have to understand that surgical debridement is a one-time

thing. We take care of it and then one week later when we see the patient, that patient has had six days, and that wound has had six days to deteriorate. And sometimes it doesn't deteriorate, but many times it does. So we need to find a way to control that six day period. Or whatever that period between our visits is. I think that's really something that I never (or I poorly) understood in the past and I understand it much better.

Vicki:
We have one more question:

Q: Can you explain why alginates are not good to use with Enluxtra?

A (Vicki): Alright. So, alginates. They're really not... In my opinion, this really good wicking fibers, it's just not going to work. If you are using an alginate for a filling material, the second it gets moistened with wound drainage it's going to shrink and you're going to lose contact with Enluxtra. So the key with Enluxtra is whatever filler material you're using for tunneling, undermining or any space cavity interfiling, that material, your filler material needs to stay in contact with the undersurface of Enluxtra. We have some new techniques for that, and that's why I encourage you guys, after we get done today, to sign up for an application webinar so I can show you exactly how to use the appropriate fillers. You want a filler material that does not shrink. That stays in contact with Enluxtra at all times, it will draw off that filling material. Alginates and Aquacell AGs, any cellulose type products are actually going to block the vertical draw of Enluxtra and you will end up with a very macerated wound bed. And I've tried every one of them. I've tested every product 6 years ago and I have pictures to prove it - it does not work.

A (Alex): And I have something to add to this. I think one thing that we tend to miss - and I'm speaking more for podiatrists in the group - is the dressings usually accomplish one thing. So if you're thinking of calcium alginate or some other absorptive dressing, it absorbs, but it does nothing more than that. The difference between Enluxtra is that it's able to absorb and hydrate at the same time. So we all know that the wound has multiple zones within the wound. They're not all uniform. So when you put Enluxtra on it you can be sure that it can detect different parts of the wound in a different way. And that is why it's called a smart dressing, because it's able to do that versus calcium alginate which is only able to absorb. So then once you've done that you have to change a dressing to go somewhere else. Maybe it's now dryer and now you need to put something more like a hydrocolloid or a hydrogel or whatever. With Enluxtra you don't need to do that. That's the biggest advantage that we have seen.

Vicki:
Okay, well I am not seeing any more questions at this time, so if there are any further questions you can email and we will provide an email where we can continue answering questions throughout the week on this. And, please, I encourage you to sign up for our application webinar if you have any further questions.

So I just want to thank you today, Doctor Reyzelman, for presenting the information to everybody. And thank you everybody for attending today.

Alex: Thank you.