

Clinical Uses of **Cellerate Rx** “Activated Collagen”

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Powder and Gel

Wound Care Innovations

Ft. Lauderdale, Florida

Applications

- Ulcers with undermining
- Tunnels
- Combining with antibiotics and other biological dressings
- Skin Tears and Flaps
- Burns

Application

- Powder
- Gel – topical and injection
- Paste – topical and injection
- Combine with topical antimicrobials – tobramycin, vancomycin, polymyxin, doxycycline, gentamicin
- Combine with Collagenase Santyl, Regranex, living skin equivalents

Collagen is....

- Biocompatible
 - Does not interact with other wound products or wound tissue in an adverse way.
 - It does not need to be removed from the wound.
 - It is safe for ingestion so can be used on all ages and does not harm if ingested.
 - It does not hurt and tends to be soothing to the wound due to coverage of the open wound.
 - Rare allergy. Bovine collagen very similar.

Science

- Type 1 Collagen most abundant collagen, over 90% of collagen is type 1 and 30% of total body protein is collagen
- Collagen is synthesized by fibroblasts
- Native collagen has many cross-links of fibrils that increase resistance to breakdown – inter and intra molecular connections

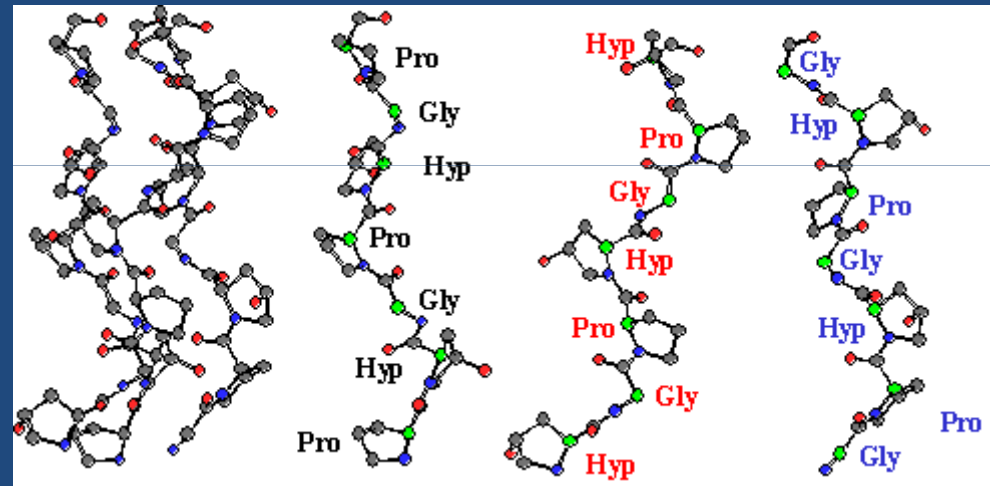
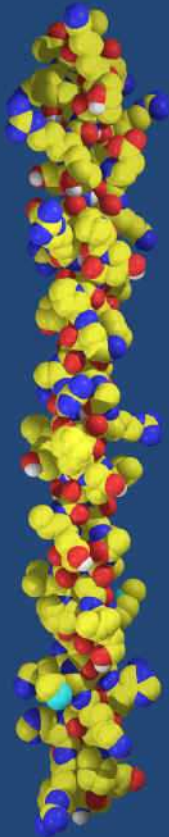
Science

- Type I Bovine Collagen from young calves
 - Water is the other ingredient- no additives
- FDA cleared for all wound types except third degree burns
- Hydrolyzed, not denatured , 1000 Daltons, maintains basic structure (usual monomer is 300,000 daltons)
- Does not support bacterial growth
- **“Activated”** proprietary version- immediately bioavailable

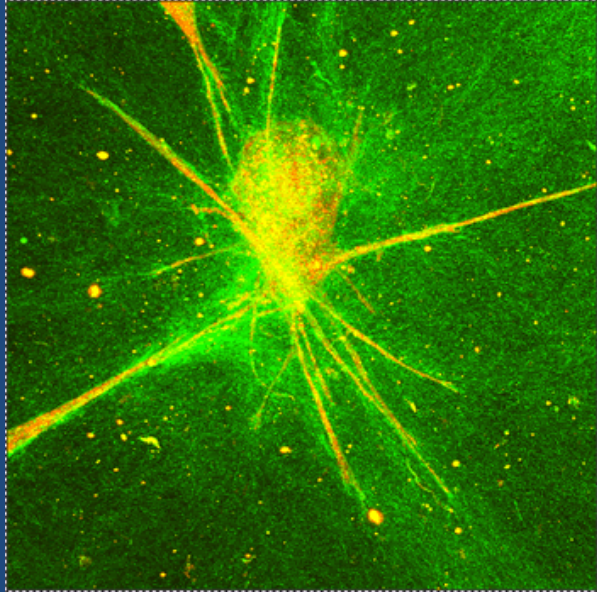
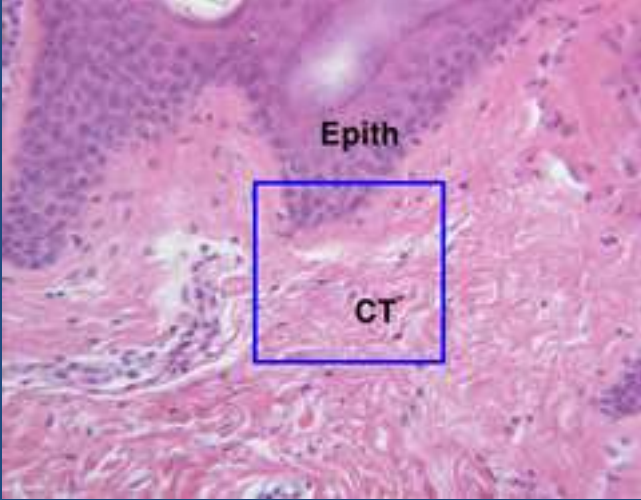
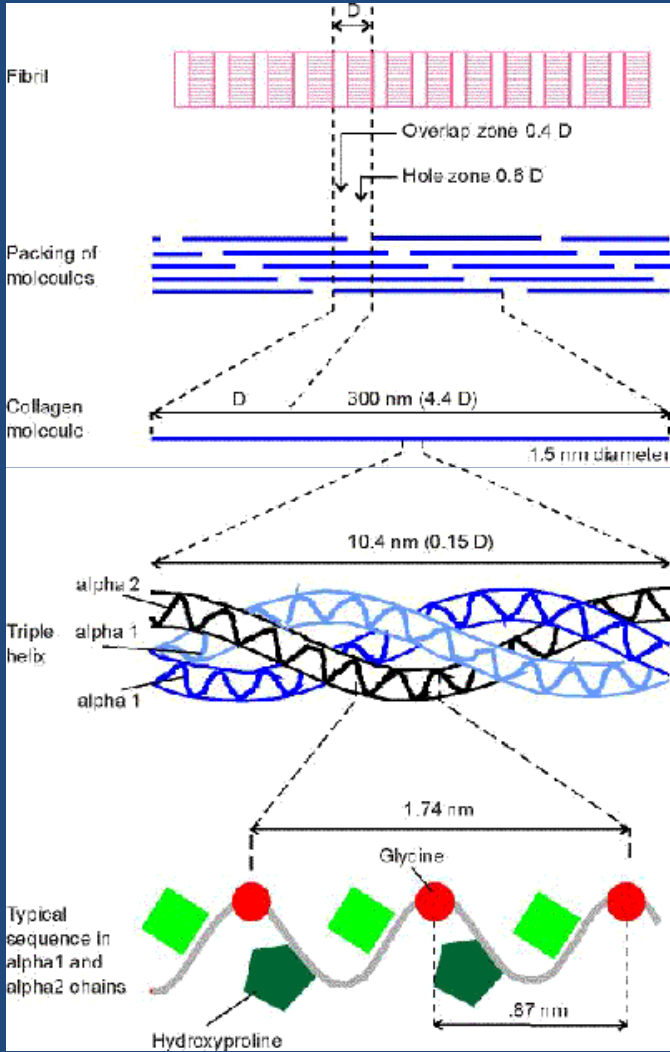
Science

- Native collagen requires the action of collagenase type 1 (MMP1) to become bioavailable for further breakdown
- No synthetic additives, non-toxic, non-allergenic
- Gel- approximately 65% “activated” collagen
- Powder- approximately 96% “activated” collagen
- No need to remove, always biocompatible and compatible with any other product okay for wounds

Basic Triple Helix



Structure



Ulcers

- Gel – less exudates, thinner application of collagen, place in curved-tipped syringe or catheter application
- Powder – “puffed” into the wound, use of a tongue blade, thicker application of collagen, use with negative pressure wound dressing
- Paste – vary thickness depending on need, easy to apply, liquid with greater percentage of collagen

Combining with antibiotics

- Delivery of antibiotics is difficult with decrease in blood supply and disruption of tissue
- Allows high concentration of antibiotic in areas where there may be a cavity
- Chemical property of collagen sustains activity of antibiotic release
- Dual activity of improvement of wound healing and antibiotic delivery in a biocompatible form

Combine with antibiotics

Vancomycin

- Use the powder and combine with powder, gel or paste of Cellerate Rx
- If pharmacist needs to formulate – 50 mg/cc of Cellerate Rx gel
- Order for nurses to apply powder to wound bed and then add the Cellerate Rx if questioned about nurses compounding
- Inject into tunnels

Combine with antibiotics

Tobramycin, Gentamicin, Polymyxin

- Done in a similar fashion as the vancomycin
- Tobramycin mixes very quickly and needs very little gel if making a paste
- Polymyxin topically combined with cellerate to the wound bed of burns is a great dressing

Combine with antibiotics

Doxycycline

- Powder, not crushed tablets, pharmacist will make up the powder capsules, open and add small amount to Cellerate Rx
- Do not combine with silver due to chelation
- Anti-inflammatory and antimicrobial
- 5-10% gels in literature, make a lightly colored gel or powder combination with doxycycline

Skin Flaps

Great salvage for skin flaps

1. Clean flap and wound bed with saline
2. Cavilon skin prep to periwound
3. Cellerate gel or powder to flap and wound bed
4. Flatten out the flap and especially edges to approximate to the skin edge
5. Secure with steri-strips
6. Cover with Mepilex foam or Telfa and cover with a film
7. Secure with comperm if needed also, helps edema and bruising and leaving dressing alone
8. Replace every seven days
9. Usually healed in seven days.

Skin Care Study

CellerateRx An Evidence Based Skin Tear Study: Interim Evaluation

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Skin tears, a common traumatic wound, often heal over a prolonged period of time. These wounds are most likely to occur in the frail, elderly population that have multiple co-morbidities and slow healing. The role of Hydrolyzed Collagen in promoting healing of these troublesome wounds is evaluated and compared with placebo controls. This study will provide evidenced based conclusions regarding the role of Hydrolyzed Collagen in the resolution of Skin Tears.

Study Method: Skin tears in at least 15 individuals, of varying Payne-Martin (1-3) scale severity and up to 48 hours old, will be treated by cleaning the wound, approximation of skin edges and coverage. Some of the group will have the additional step of an application of hydrolyzed collagen powder and/or gel to the wound bed before the skin edge approximation. Control wounds were treated identically but did not receive Hydrolyzed Collagen application. Presented herein are the interim study data on seven (7) patients enrolled in this study.

This information is presented as evidence based interim data on seven (7) patients with fourteen (14) skin tears. When possible, control comparisons were made between the treatments in the same person.

Conclusion:

The technique employing Hydrolyzed Collagen was very successful in saving the remaining skin flap seven to fourteen days sooner than those patients completed compared with controls. A majority were resolved within a week, with just one treatment. Closure with the use of hydrolyzed collagen increased the efficiency of healing. Both groups had relatively rapid resolution. Very distorted skin flaps were able to be salvaged using the collagen product in cases where the flap would normally have been felt to be a complete loss. A very effective technique for the treatment for skin tears and comparison with the additional benefit of the tested therapy will be reviewed analyzing cost, pain, time to healing, infection rate. Very distorted skin flaps were able to be salvaged using the collagen product in cases where the flap would normally have been felt to be a complete loss. The study continues in an effort to generate sufficient data points to determine statistical significance.

References:

1. Thomas DR, Gode PS, La Master K, Tennyson T, Parnell LK, A comparison of an opaque foam dressing versus a transparent film dressing in the management of skin tears in institutionalized subjects. *Ostomy Wound Management* 1999 Aug;45(8):6.
2. Ratliff CR, Fletcher KR, Skin tears: a review of the evidence to support prevention and treatment, *Ostomy Wound Management*. 2000;7:33(3):32-34.
3. Malone ML, Rozario N, Gavinski M, Goodwin J, The epidemiology of skin tears in the institutionalized elderly, *J Am Geriatr Soc* 1991 39(6):591-5.
4. Payne RL, Martin ML, Defining and classifying skin tears: need for a common language. *Ostomy Wound Management*, 1993, 39(5):16-20.

CellerateRx
ACTIVATED COLLAGEN (CRX)

*CellerateRx® Hydrolyzed Collagen Powder and Gel, Wound Care Innovations LLC.

Patient 1

- Age - 86 YO female
- Co-morbidities - chronic atrial fibrillation, unsteady gait, venous hypertension and current cellulitis and ulceration on leg, CHF, arthritis and impaired mobility so ambulates with a cane
- Medications - coumadin, furosemide, diltiazem, sertraline, hydrocodone

Wound CellerateRx



Control Wound



Patient 2

- Age - 73 YO male
- Co-morbidities - atrial fibrillation on coumadin, hepatic cirrhosis from NASH, CHF, Stage 3 CKD, CABG and MI
- Medications - coumadin, furosemide, spironolactone, metoprolol, multivitamins, hydrocodone/apap, midodrine, vit B 12

Wound CellerateRx



Follow Up



Patient 3

- Age - 78 YO Female
- Co-morbidities - Advanced PVD and healing a wound on foot, HTN, CVA
- Medications - gabapentin, plavix, estrogen, antidiopine, tramadol, etc

Wound CellerateRx



Control Wound



Patient 4

- Age - 78 YO female
- Co-morbidities - polymyalgia rheumatica, chronic significant eczema, rapidly progressive polyneuropathy and foot drop, referred for leg ulcer 3 mo non-healing.
- Medications - chronic corticosteroids with kenalog injections every 1-3 months, 60 mg, telmisartan, lctc, gabapentin
- Other - Generally appears frail

Wound #1 CellerateRx



Wound #2 & #3 CellerateRx



Patient 5

- Age - 88 YO female
- Co-morbidities - nursing home, poor functional status, depression, refractory clostridium difficile colitis, mild/moderate dementia, recurrent UTI.
- Medications - donepezil, remeron, seroquel, multivitamin, hydrocodone/apap
- Other -

Wound Placebo Control



Follow Up



Patient 6

- Age - 75 YO male
- Co-morbidities - obesity, venous hypertension and chronic edema B/E, type 2 DM on high dose insulin, PVD, diabetic polyneuropathy, stage 3 CKD
- Medications - aspirin, insulin, furosemide, spironolactone, simvastatin, vitamin D, etc
- Other - hydrocolloid dressing extra sticky and pulled off a large skin flap

Wound CellerateRx



Follow Up CellerateRx



Patient 7

- Patient 93 years of age
- Co-morbidities - Congestive heart failure, mild dementia, Type 2 DM, insulin requiring, CAD post bypass and recent angioplasty
- Medications - duragesic patch, lanatus insulin, atenolol, multivitamin, PM oxygen, lasix, spironolactone, zocor, zaroxylin, plavix

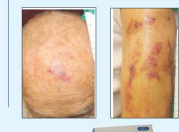
Wounds CellerateRx



Wounds Day 7



Wounds Day 14





Getting Cellerate Rx for your patient

- Part B reimbursement
- Device, not a biological, wound dressing
- Gel (A6011) and Powder (A6010)
- This is a specific collagen code
- Available and reimbursed
- Sterile products – irradiated and not heat treated

Cellerate Rx and Wound Care

“Activated Collagen”



A Great Product to Depend On For Use In the Treatment of Wounds



Powder and Gel

Call Wound Care Innovations at 1-800-205-7719, extension 140

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