AGENDA

State and Public School Life and Health Insurance Board
Quality of Care Sub-Committee
Meeting

October 10, 2017

1:00 p.m.

EBD Board Room – 501 Building, Suite 500

I. *Call to Order*.....*Margo Bushmaier, Chair*

II. *Approval of September 12, 2017 Minutes*.....*Margo Bushmaier, Chair*

III. *ACHI Updates*.....*Mike Motley, Izzy Whittington, ACHI*

IV. *Emerging Therapies*.....*Dr. David Harshfield, Morgan Pile, Regenerative Therapies*

V. *Emerging Therapies*.....*Laura Trivette, MiMedx Group, Inc.*

VI. *Wellness*..... *Chris Howlett, EBD Executive Director*

VII. *Director's Report*..... *Chris Howlett, EBD Executive Director*

Upcoming Meetings

November 14, 2017, December 11, 2017, January 8, 2017

NOTE: All material for this meeting will be available by electronic means only ASE-PSE BOARD@dfa.arkansas.gov. Please silence your cell phones. Keep your personal conversations to a minimum.

State and Public School Life and Health Insurance Board
Quality of Care Sub-Committee Minutes
October 10, 2017

Date | *time* 10/10/2017 1:00 PM | *Meeting called to order by* Margo Bushmiaer, Chair

Attendance

Members Present	Members Absent
Michelle Murtha – Vice-Chair	Frazier Edwards
Zinnia Clanton	Dr. Andrew Kumpuris
Dr. Joseph Thompson	Pam Brown
Margo Bushmiaer - Chair	Don Hollingsworth
Dr. John Vinson	Robert Boyd
Dr. Namvar Zohoori	

Chris Howlett, EBD Executive Director, Employee Benefits Division

Others Present:
Doris Brown, Eric Gallo, Shay Burleson, Jamie Levinsky, Rhoda Classen, EBD; Arlo Kahn, John Lyon, Mike Motley, Elizabeth Whittington, ACHI; Sandra Wilson, AHM; Sean Seago, Merck; Seth Pinkerton; Carl Keller, ICMC; Marc Watts, ASEA; Jennifer Vaughn, COMPsych; Marc Bagby, Lily; Jessica Akins, Takisha Sanders, HA; Robyn Keene, AAEA; Andy Davis, ADG; GeriBeth Bemberg, UAMS; Laura Trivette, MiMedx

Approval of Minutes by: Margo Bushmiaer, Chair

Bushmiaer asked for a motion to approve the September 12, 2017 minutes. Zinnia Clanton motioned for approval of the minutes. Dr. Vinson seconded. All were in favor.
Motion Approved.

Howlett stated that MiMedx was not able to attend the last meeting due to weather conditions from the hurricane, but they are here today. Just to put this in frame of reference, Dr. Harshfield and his team is a service provider on regenerative medicines, and the MiMedx team is more product offering. There is a symbiotic relationship between the two, but this distinction needed to be made since there were a lot of questions on this after the last meeting.

ACHI Updates by: Mike Motley, Elizabeth Whittington, ACHI

Whittington reported on updates for lower back imaging analysis and some follow up for the Choosing Wisely initiative. For today, we are going to revisit some background on the initiative, and Motley will present additional analytic output related to the lower back imaging. We also have a few

recommendations for the subcommittee around the Choosing Wisely initiative and adopting that as a framework moving forward and a few things for the board to take around lower back imaging.

Choosing Wisely is an initiative of the American Board of Internal Medicine (ABIM) Foundation and was named in Act 1089 of 2017 which also included the emerging therapies and therapeutic alternatives to invasive surgical procedures. By utilizing this framework, EBD will ensure reducing overuse and waste within the plan.

Examples of Choosing Wisely in Action:

- Washington Example:
    - 2016 reported determined 26% of patients in the state with upper respiratory infections were prescribed potentially unnecessary antibiotics
- Virginia Example:
    - Recent analysis of 44 low-value healthcare services revealed more than $586 million in unnecessary costs
    - Greatest amount of waste came from low-cost services
    - Preoperative lab testing for low-risk patients undergoing low-risk surgery accounted for half of unnecessary spending

With all of this in mind, Whittington proposed the recommendation to the subcommittee that the EBD Board and its subcommittees formally adopt the Choosing Wisely initiative/framework when assessing issues related to quality of care and benefit design.

Dr. Vinson asked about the proposed recommendation. Does that mean we carte blanche accept everything in the framework?

Whittington replied that this is a framework in decision making, not necessarily a carte blanche kind of approval. Use the framework as situations arise.

Howlett stated that the thought was to use this as a framework. The ACHI team has been working on this research establishing the framework to allow us to explore the various categories, and this will be ongoing.

Dr. Thompson stated the Choosing Wisely recommendations come from the specialty association in each category. There is evidence and the professional view to give a framework for necessary testing. It is not an adoption of no testing, but a framework to allow the questions of why are we paying for unnecessary testing.

Dr. Vinson stated that he is comfortable using this framework in his decision making tree and has in the past. If it is adopted, how will it impact the ability to makes decisions for operationalizing this?

Dr. Vinson made a motion to adopt this recommendation.

Dr. Zohoori stated that he needs more information, and Dr. Vinson withdrew his motion.

Motley reported nonspecific low back pain and Choosing Wisely recommendations and ASE/PSE lower back imaging analysis.

Utilization Analysis

- 4,741 members were diagnosed with uncomplicated lower back pain within a one-year period (October 2014—September 2015)
- 1,257 of those members had an imaging event within the first 4 weeks following diagnosis
- 27% of members with uncomplicated low back pain received potentially wasteful imaging

Surgery Analysis

- 8% of those who had imaging in the first four weeks of a diagnosis of uncomplicated back pain had subsequent back surgery
- Comparatively, 3% of those who did not receive imaging in the first four weeks had subsequent back surgery
- Patients who received imaging in the first 4 weeks were 2.6 times more likely to have surgery

Provider Analysis

- 469 providers were included in this analysis (individuals or groups)
- 176 providers had at least 6 patients with uncomplicated low back pain within that year
- Following slide shows distribution of patients with potentially wasteful imaging

Motley stated the recommendations for the lower back imaging are in a three tier approach.

1. Member education: Disseminate related education materials (from Choosing Wisely & Consumer Reports) in member newsletter and other outlets;
2. Provider outreach: Conduct targeted outreach to high-volume providers with higher rates of potentially wasteful imaging;
3. Prior authorization: Review existing EBD prior authorization criteria and work with vendor to refine criteria to more closely align with the Choosing Wisely recommendation.

Bushmaier asked if on recommendation 2, it would technically be Chris' team to figure out the implementation plan.

Motley stated yes, technically that is correct.

Dr. Zohoori stated that patients that receive imaging are more likely to have surgery. Are there other factors that lead to patients having more imaging? Is there more data to drill down?

Motley stated that they have claims data to use, but we do not have chart data. That is certainly a valid point.

Murtha asked if you say imaging, do you mean a MRI or CT scan?

Motley answered yes. We presented the volume type of the images last time, but we can present that again.

Dr. Zohoori stated that he is not comfortable taking this at face value, and Dr. Zohoori would advise caution.

Bushmaier said that we can ask for more data to adopt the recommendations or for more time to investigate.

Motley stated that there should be no imaging within the first 6 weeks unless there is a prior serious underlying condition.

Murtha asked if you can tell who is ordering the imaging and which type of provider.

Motley said yes, you can tell what type of provider is ordering imaging. We saw a chiropractor that had close to 100%.

Dr. Thompson stated that this is a recommendation for action.

Dr. Zohoori asked if a patient comes in with low back pain, will he be told no on imaging for the six weeks. Is that what we are saying?

Howlett said that if the PA qualifications are met, then they could have the imaging done.

Dr. Vinson asked about Choosing Wisely. If a doctor looks up Choosing Wisely, the physician will see that it specifically says it should not be used to establish coverage decisions or exclusions but to spur conversation to discuss an appropriate necessary treatment. How do we reconcile what Choosing Wisely intends to be used for versus how we will use it for the framework of our plan?

Dr. Thompson stated that the three recommendations are consistent with what is being asked. The fourth recommendation that the board could decide that is not consistent with what is being asked is no imaging for the first four weeks, and the board has done that in the past. From a board perspective, we need to try to restrict coverage on a set of benefits that work. We need to find a balance of covering what will work against the cost on the premium side.

Howlett stated a piece of this, as a non-clinician during the first four weeks, hopefully there will still be things done to help improve the patient's condition without the imaging. My only concern is they are postponing what they view as the inevitable and prolonging the patient's suffering.

Dr. Thompson said most back pain goes away in four weeks, so we are not saying we want you to be in pain for four weeks.

Clanton asked if we are making a recommendation to go with the entire Choosing Wisely list.

Howlett stated that we decided to start using these guidelines nine to ten months earlier and moving forward, but we will see a lot of clinical areas that we will explore.

Murtha made a motion to adopt the three recommendations (member education, provider outreach and prior authorization) for low back pain. Dr. Zohoori seconded. All were in favor.

Motion approved.

Howlett stated that the way we have operated so far has been that we have used the initiative and the framework as our guiding principle towards where we have arrived. The framework is there and we are building upon it with every category that is being reviewed. What stands out is the issue of quality of care and benefit design, and most of this is initiated from the plan itself and my team.

Dr. Vinson pointed out that Choosing Wisely is leading many of our discussions.

Dr. Thompson said this is a vehicle to use and it feels pretty safe.

Dr. Zohoori wanted clarity on what adopting this will mean. Are there any places where Choosing Wisely conflicts with USPSTF?

Motley responded that he did not see any differences.

Whittington stated that on the pap test change, Choosing Wisely falls right in line with US Preventative Task Force (USPSTF).

Howlett said we have been using Choosing Wisely as our guidance, but do we need this. Can we just stay with status quo?

Dr. Thompson stated the board doesn't have to decide, but the ACHI team needs some direction.

Howlett said he cannot imagine not following down this path with Choosing Wisely since it has already been approved. The pap testing alone gave us the history to continue on.

Bushmaier said we will continue to use Choosing Wisely and other sources.

Regenerative Cellular Therapies by Dr. David Harshfield, M.D. & Carl Keller, CEO

Carl Keller discussed new centers of excellence that will be located in Little Rock, El Dorado and Fayetteville. The whole idea is to have all the doctors under one roof, develop a fellowship for orthopedic medicine.

Guidelines

Regenerative Injection Therapy (RIT)

Buffered 5% Dextrose (D5W)

plus

1.Platelet Rich Plasma (PRP),

2.Hematopoietic,

3.Mesenchymal and/or

4.Amniotic Cellular Solutions

Interventional Regenerative Orthopedic Medicine Practice

6 Co's of MAXIMIZING EFFECTIVENESS OF RIT-*Avoid Competition!*

1. Collaborate with patient's Primary Care Provider (PCP)

2. Coordinate with patient's Chiropractor and/or Manual Therapist to ensure the patient the dignity of a proper diagnosis.

3. Collate existing health care records with all prior medical and surgical history with an updated pharmaceutical history, Microbiome (gut) assessment/therapy, blood laboratory and hormone status and QANS testing to determine appropriate oral and I.V. nutrition.

4. Correlate prior imaging studies with appropriate up-to-date imaging to arrive at the correct diagnosis.

5. Communicate overview of Regenerative Injection Therapy (RIT) in sync with patient's understanding of their existing health care regimen (making clear that RIT is **'**in addition to**'**, not **'**instead of**'** the patient's existing and evolving 'patient specific' integrative health care regimen).

6. Complete patient registry following RIT.

Key Points

Clinical Outcomes: IROM, with credentialed providers and certified protocols, provides safe, affordable and effective therapy resulting in improved healing and overall patient outcomes.

Financial outcomes: Lower costs to The State and Public School Life and Health Insurance Board, not only with avoidance of unnecessary pharmaceuticals and surgery, but of complications as well.

Quality of Life: IROM is not only financially beneficial, but allows patents a more rapid return to work and activities of daily living.

Treatment Acceptance: Increasing payer adoption of the use of regenerative and cellular medicine therapies, with Arkansas now playing a leadership role in the U.S.

Dr. Vinson asked if the patients are usually cash paying patients or if they were covered by insurance.

Keller said some of the early patients were covered by Medicare until about 2003, and since then the patients have been covered by hospital reimbursement and the balance of the patient would be private pay.

Dr. Thompson asked if Medicare covers it now.

Keller responded no.

Dr. Thompson asked why they did they stop covering it.

Keller said there was a physician here in Little Rock with Blue Cross that did not care for the procedure, and he filed a non-coverage. We took that back to Tommy Thompson, and we got a letter back that said we were covered. We continue to go back and forth.

Dr. Thompson asked if private companies cover this?

Keller responded yes, some do, and the government employee health coverage covers it at 100%.

Dr. Thompson asked if there is a study out there that has a good design? One patient got standard care of treatment and one patient got this treatment, and this treatment was better.

Keller said there are currently three studies being done right now across the country, but none of them are being conducted by us. The results are not back on these studies.

Dr. Zohoori asked if there were published results on this.

Keller said if you research this type of procedure, you will probably find between 4-5,000 immediate hits on information and studies done. There are few well controlled studies because this procedure was not initially understood.

Murtha asked if there is any information on a diabetic with peripheral vascular disease. After you do this procedure and it heals, how soon will the ulcer return? With minimal blood supply, how does this stay healed?

Keller responded that you create a new blood source to that area with the injection.

Dr. Thompson stated that he thinks the proposal goes much further than the skin wounds.

Keller said yes, we are looking at the low back, knee, and diabetic foot wounds.

Dr. Thompson stated that he needed more evidence on this because we are an insurance plan not a research group.

Dr. Zohoori agreed, and stated he would like to see more scientific evidence in these areas.

Keller said if you would like to see more evidence and papers on this, I can provide that.

Dr. Thompson said to be clear, it needs to be peer reviewed published literature, not a patient advocating for the product.

Dr. Zohoori would like to know what convinced the federal government to accept it.

Keller said he was not sure what all is available with that.

MiMedx Presentation: Laura Trivette, MiMedx

Trivette stated that MiMedx is a manufacturer of regenerative medicine. There are several categories, and we fall into the amniotic category.

Trivette stated that at the end of August, we had distributed 1 million allografts and have 800 employees. We are the amniotic tissue of choice by providers across the country. We have had Medicare coverage since 2014 for Epifix for treatment lower extremity wounds, and we have solid coverage with commercial payers as well as state Medicaid plans. Here in Arkansas, we have seen close to 2,000 allografts distributed.

Literature shows amniotic membrane enhances healing:

- Immunologically privileged
- Modulates inflammation
- Reduces scar tissue formation
- Contains essential growth factors

MiMedx has distributed **1,000,000** allografts to date with **no adverse reactions** attributed to our products.

MiMedx is a Regenerative Medicine Company with an Extensive Product Portfolio

Sheet dHACM:
Flagship bioactive Amnion/ Chorion grafts containing 226 proteins and growth factors with proven enhanced healing power

- Smaller wounds
- Various surgical applications
- As a barrier membrane

Micronized dHACM:
Same dHACM in an injectable configuration

- Smaller wounds
- Various surgical applications

Umbilical Cord Products:
Provide a protective environment for the healing process.

- Smaller wounds requiring a graft that can hold a stitch
- Longer site coverage timeframe
- When a thicker graft is needed for coverage/ padding

Placental Based:
Our NEW bioactive placental tissues containing Growth Factors found in PURION® Processed tissues that modulate the activity of the recruited cells to enhance healing **+** an extracellular matrix (ECM) that provides a scaffold for recruited cells to attach, populate, and proliferate.

- Larger and uneven surface areas >25cm^2
- NOT injectable

Diabetes in Arkansas: We are focused on the 364,000 people in Arkansas who live with diabetes

Diabetic Patients with Non-healing Wounds

- Mean one year cost from a health care public payer perspective was $44,200 for diabetic foot ulcer (DFU), and $11,000 for leg ulcer (LU)[1]
- 33% of the cost of diabetes directly linked to the care of lower extremity complications[2,3]
- The majority of non-traumatic lower limb amputations can be avoided with education, monitoring and early treatment. [4]

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[1]Chan; "Cost-of-illness studies in chronic ulcers: a systematic review." Journal of Wound Care Vol 26. No.4, April 2017
[2]Rogers LC, Lavery LA, Armstrong DG. The right to bear legs – an amendment to healthcare: How preventing amputations can save billions for the US health-care system. J Am Podiatr Med Assn 2008;98:3-5
[3]Driver VR, Lavery LA. The costs of the diabetic foot: The economic case for the limb salvage team. J Vasc Surg
[4]American Diabetes Association http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/arkansas.pdf

MiMedx

We believe using EpiFix in combination with existing Standard of Care treatments, can enhance the treatment and safe healing of chronic, non-healing lower extremity wounds.

Safety and Testing

Major Process Step	Criteria that Ensures Tissue Safety
Donor Screening	Performed per 21 CFR 1271 domestically.
Infectious Disease Testing	Negative results for all FDA approved and **CLIA Certified** tests that includes HIV, Hepatitis B and C, Syphilis, and Human T-cell lymphotropic virus (HTLV)
PURION® Process	A validated process with proven Bacterial/Spore reduction capabilities that range from 1.4 –5.6 Logs
Terminal Sterilization of all grafts	A validated process per **ISO 11137** standards providing at least a 10-6SAL with irradiation dose monitoring linked to the release of every tissue distributed
Double sterile barrier product packaging	A validated process per FDA recognized **ASTM D4169** standards that ensures sterility is maintained post distribution

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MiMedx

MiMedx Value Proposition

- Promotes Healing- Scientific data shows dHACM ability to draw stem cells toward the site to modulate inflammation, reduce pain and accelerate healing
- Proprietary PURION Process preserves 226+ different growth factors
- Superior Published Clinical Data - 6 Randomized Control Trials (RCTs) showing statistical significance
- Patient Safety – Terminal Sterilization
- Stem Cell Magnet - Scientific data shows dHACM ability to draw stem cells toward the site
- USP Monograph - Rigor in processes ensure consistent product quality
- Storage and Ease of use - Ambient conditions with 5-year shelf life

Dr. Vinson asked if the product comes from one patient.

Trivette responded that this comes from one patient; we do not mix placenta.

Dr. Vinson inquired about the donors. Is there something that makes one donor more desirable such as age, diet or genetics? Is one product equal to another one with different hosts?

Trivette responded that there was rigorous screening done beforehand, and the amniotic and the chorion layer are separated. Each allograft is minimally manipulated the same way. Epifix is considered homologous use, human to human use, so there have been no adverse events reported to date.

Dr. Thompson asked for clarification on the homologous statement.

Trivette stated that she has had questions about matching blood types, and that is not necessary since mother and baby can have different blood types. We do not have to match a blood type to the donor.

Dr. Zohoori asked what is left (the active agent) at the end of this process.

Trivette said since the allograft contains the amnion and the chorion; we minimally manipulate the product and do not add to or take away any raw material.

Dr. Thompson mentioned the FDA, and this is not a drug but a product.

Trivette stated the FDA oversight is listed as a biologic 361 product, and they are paid by Medicare part B.

Dr. Thompson asked which commercial companies pay.

Trivette stated that over 800 commercial payers across the country, and currently Blue Cross Blue Shield Arkansas has them on their policy.

Murtha asked about a patient that is diabetic or someone with peripheral vascular disease. How will this still get a good blood supply to the area?

Trivette stated that the physician would decide if that was an issue and use other treatment.

Murtha and Bushmaier stated they would like to know the long term effects and if these patients are healed and stay healed.

Trivette stated that since she is not a physician it is hard to answer. She is not trying to avoid the question, but a physician has a lot of things to evaluate if Epifix would be the right treatment.

Dr. Zohoori asked how much it cost.

Trivette said the injectable vial is $300, and the 18 mm discs up to an allograft are typically reimbursed at $169 per square centimeter.

Wellness & Director's Report by: Chris Howlett, EBD Executive Director

Howlett stated that Dr. Vinson chairs the wellness committee, and there were several meetings to define wellness, such as BMI, tobacco and the flu shot. Part of the mechanism that was discussed was the flu shot component being attached to that wellness benefit. In hindsight, we did a lot of operational pieces and assessments, and to that we will struggle with capturing to high success the participants that will receive the flu shot. Howlett requests here, as in Benefits, that we release the flu shot component from the defined wellness program that will go back to the Board but keep the other components that ACHI and wellness put together, such as BMI and tobacco. Howlett may have to come back with some more defined guidance.

Bushmaier stated that we no longer have a quorum, so we cannot make a motion.

Dr. Vinson mentioned that with the wellness, the things that were driving the costs were from cardiovascular disease, tobacco use, obesity, and diabetes not the cost of influenza. The thought was that flu shot was more of an outcome rather than lab values. If it is removed, Dr. Vinson does not think it will make a huge difference on the cost side of things, but he does think we should encourage state employees to still promote flu shots and encourage their use. There is data especially about giving flu shots at the work sites. Dr. Vinson knows there is a National Injury Compensation Program around vaccines, and any kind of injuries would be covered under that program first and foremost. Dr. Vinson would love a legal opinion on that. If the flu shot is taken out of the wellness, Dr. Vinson would like to look at other avenues to improve our flu vaccination rates.

Howlett stated that he does not disagree, and he will reposition this as he stated Friday. Howlett was operating with the legal assumption and just a verbal, and this is now having a legal opinion reviewed by legal counsel internally. There is some case law that has been established that even in a voluntary setting there could be a potential for assumed liability because we are offering the workspace and it is still tied to, or stresses the importance of the flu shot. Howlett is aware of the national program, but until he gets a full piece on that he needs to take a step back to assess that. We will still have the flu shot as readily available as legally possible.

Clanton motioned to adjourn. Brown seconded. All were in favor.

Meeting adjourned.

EBD Quality of Care Subcommittee Updates

Mike Motley, MPH
Assistant Health Policy Director

Elizabeth Whittington, MPA
Policy Analyst

ACHI
Arkansas Center for Health Improvement

October 2017

Objectives for Presentation:

- Review background on Choosing Wisely Initiative
- Review additional analytic output related to low back imaging
- Discuss recommendations for improvement and Subcommittee/Board consideration

Choosing Wisely Initiative Background

Choosing Wisely Background

- **Choosing Wisely is an initiative of the American Board of Internal Medicine (ABIM) Foundation**

- **Aims to promote conversations between clinicians and patients by helping patients choose care that is:**
  - **Supported by evidence**
  - **Not duplicative of other tests or procedures already received**
  - **Free from harm**
  - **Truly necessary**

Source: Choosing Wisely Initiative Website, "About" Section.

Choosing Wisely Background

- Intended to spark discussion about the need—or lack thereof—for many frequently ordered tests or treatments

- Consumer Reports has developed patient-friendly materials based on these recommendations for consumer use

- Provider-oriented materials available to assist with patient engagement on these issues

Source: Choosing Wisely Initiative Website, “About” Section.

Choosing Wisely In Action

- **Choosing Wisely was named in Act 1089 of 2017:**

- ***"By the end of plan year 2017, the State and Public School Life and Health Insurance Board shall explore the evidence supporting opportunities for benefit modification information by:***
  1. ***The Choosing Wisely Initiative;***
  2. ***Emerging therapies; and***
  3. ***Therapeutic alternatives to invasive surgical procedures, such as regenerative injection therapy."***

Source: Washington Health Alliance, "Less Harm. Less Waste. Choosing Wisely in Washington State," 2016

Choosing Wisely In Action

- **Opportunity for EBD to utilize Choosing Wisely framework when assessing issues related to quality of care and benefit design**

- **States are using this initiative to uncover areas of wastefulness in their healthcare systems**

- **<u>Washington Example</u>:**
  - **2016 reported determined 26% of patients in the state with upper respiratory infections were prescribed potentially unnecessary antibiotics**

Source: Washington Health Alliance, "Less Harm. Less Waste. Choosing Wisely in Washington State," 2016

Choosing Wisely In Action

- **Virginia Example:**
  - **Recent analysis of 44 low-value healthcare services revealed more than $586 million in unnecessary costs**
  - **Greatest amount of waste came from low-cost services**
  - **Preoperative lab testing for low-risk patients undergoing low-risk surgery accounted for half of unnecessary spending**

Source: Mafi, J., et. al. "Low-Cost, High-Volume Health Services Contribute The Most to Unnecessary Health Spending," Health Affairs, October 2017 vol. 36 no. 10, 1701-1704.

Recommendation to Subcommittee

- **The EBD Board and its Subcommittees formally adopt the Choosing Wisely initiative/framework when assessing issues related to quality of care and benefit design**

- **All Choosing Wisely Lists**

Choosing Wisely Recommendation: Imaging Tests for Low Back Pain

Choosing Wisely Recommendation-Nonspecific Low Back Pain (AAFP)

- **Don't do imaging for low back pain within the first six weeks, unless serious conditions are present**

- **These include, but are not limited to:**
  - **Severe or progressive neurological deficits**
  - **When underlying conditions such as osteomyelitis (infection in a bone) are suspected**
  - **Trauma**

Source: American Academy of Family Physicians, Choosing Wisely Recommendation-Lower Back Imaging.

Choosing Wisely Recommendations- Nonspecific Low Back Pain

- **Rationale: Imaging of the lower spine before six weeks does not improve outcomes, but does increase costs and increases the likelihood of surgery**

- **Low back pain can be addressed without imaging through pain management and/or physical therapy as first courses of action**

Source: Redd, S. Institute for Clinical and Economic Review Baseline Report-Choosing Wisely Recommendation Analysis: Prioritizing Opportunities for Reducing Inappropriate Care-Imaging for Nonspecific Low Back Pain.

Top 20 ASE/PSE Diagnoses: Potential to Impact Through Intervention 2016

Clinical Classification Category	Total Plan Paid	Unique Patients
Spondylosis; intervertebral disc disorders; other back problems	$14,694,262	16,614
Medical examination/evaluation	$14,383,565	75,200
Maintenance chemotherapy; radiotherapy	$12,005,758	731
Osteoarthritis	$9,859,450	7,026
Other screening for suspected conditions (not mental disorders or infectious disease)	$8,581,436	40,557
Coronary atherosclerosis and other heart disease	$8,278,458	6,724
Cancer of breast	$8,137,618	2,156
Other connective tissue disease	$5,624,911	16,647
Cardiac dysrhythmias	$5,590,183	6,877
Chronic kidney disease	$5,550,786	1,758
Residual codes; unclassified	$5,539,904	13,476
Septicemia (except in labor)	$5,486,604	656
Leukemia	$5,312,409	257
Immunizations and screening for infectious disease	$5,275,877	39,770
Complication of device; implant or graft	$5,208,682	1,268
Nonspecific chest pain	$5,148,580	8,580
Other nervous system disorders	$4,746,518	7,712
Diabetes mellitus with complications	$4,176,209	5,912
Other ear and sense organ disorders	$4,130,922	6,037

Known Consequences

- **Patients who received an MRI during the first month of diagnosis were eight times more likely to have surgery**
- **Five-fold increase in medical expenses**
- **No observed gains in recovery time as compared to patients undergoing no imaging**

Source: Webster, B., & Cifuentes, M., "Relationship of Early Magnetic Resonance Imaging for Work-Related Acute Low Back Pain with Disability and Medical Utilization Outcomes." *Journal of Occupational and Environmental Medicine*. 52(9):900-907, September 2010.

ASE/PSE Lower Back Imaging Analysis

Utilization Analysis

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- 1,257 of those members had an imaging event within the first 4 weeks following diagnosis

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- 8% of those who had imaging in the first four weeks of a diagnosis of uncomplicated back pain had subsequent back surgery
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Provider Analysis

- 469 providers were included in this analysis (individuals or groups)
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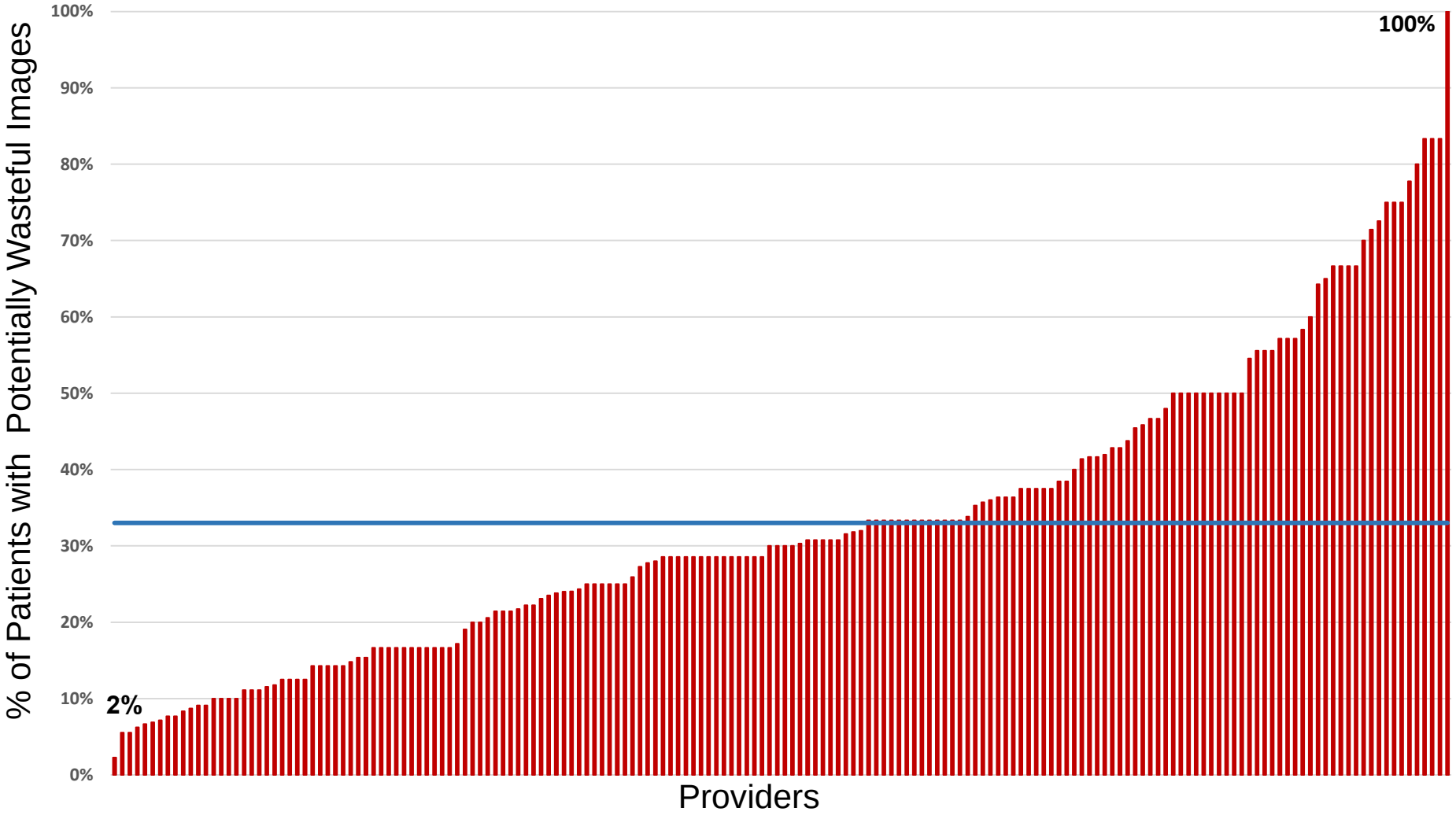
- Following slide shows distribution of patients with potentially wasteful imaging

Potentially Wasteful Images by Providers (2014-2015)



Recommendations to Subcommittee

1. **Member education: Disseminate related education materials (from Choosing Wisely & Consumer Reports) in member newsletter and other outlets;**
2. **Provider outreach: Conduct targeted outreach to high-volume providers with higher rates of potentially wasteful imaging;**
3. **Prior authorization: Review existing EBD prior authorization criteria and work with vendor to refine criteria to more closely align with the Choosing Wisely recommendation.**

MEASURE DESCRIPTIONS

The following is a brief description of each of the ten Choosing Wisely measures found in this report. More detailed information on the technical specifications is available upon request.

- **Antibiotics for upper respiratory infections:** The ratio of patients 18 years and older with an upper respiratory infection who were prescribed antibiotics within three days of the index (initial) visit, divided by the population of patients with an upper respiratory infection diagnosis.
    - **2014 measure description: Antibiotics for sinus infections:** The ratio of patients who were prescribed antibiotics within 21 days of a primary diagnosis for acute sinusitis, divided by the population of patients with a primary diagnosis for acute sinusitis.
- **Imaging for uncomplicated headache:** The ratio of patients who received CT or MRI imaging within 30 days of the index (initial) visit, divided by the population of patients with a visit for a primary diagnosis of an acute headache.
- **Too frequent Pap tests:** The ratio of female patients who had a Pap test performed within the measurement year that was within 30 months from a prior Pap test, divided by the population of female patients who had a Pap test performed within the same measurement year.
- **Pap tests for patients with a previous hysterectomy:** The ratio of female patients who previously had a hysterectomy for a non-cancer related disease that had a Pap test performed within the measurement year, divided by the population of female patients who previously had a hysterectomy for a non-cancer related disease during the same measurement year.
- **Pap tests for young women under 21 years old:** The ratio of female patients between the ages of 13 to 20 years old who received a Pap test within the measurement year, divided by the population of female patients between the ages of 13 to 20 years old during the same measurement year.
- **Imaging for uncomplicated low-back pain:** The ratio of patients with a primary diagnosis of low back pain who received an imaging study (plain X-ray, MRI, CT) within 28 days (4 weeks) of diagnosis, divided by the population of patients with a primary diagnosis of low-back pain.
- **Imaging for simple syncope:** The ratio of patients with a primary diagnosis of syncope (code: 7802) who received a CT or MRI performed within 30 days of the initial diagnosis, divided by the population of patients with a primary diagnosis of syncope.
- **CT for appendicitis:** The ratio of patients under 18 years with a primary or secondary diagnosis of appendicitis who received a CT performed and who did not receive an ultrasound within 30 days prior to the index (initial) visit, divided by the population of patients under 18 years with a primary or secondary diagnosis of appendicitis.
- **Adnexal Cysts:** The ratio of patients with simple adnexal cysts (codes: 6200-2) who received a follow-up (two or more) echography imaging test within 60 days of the index (initial) visit, divided by the population of patients with simple adnexal cysts.
- **Spirometry testing for asthma:** The ratio of patients 11 years and older with a primary or secondary asthma diagnosis code who did not received a spirometry test performed within 3 years of the asthma diagnosis, divided by the population of patients 11 years and older with a primary or secondary asthma diagnosis code.

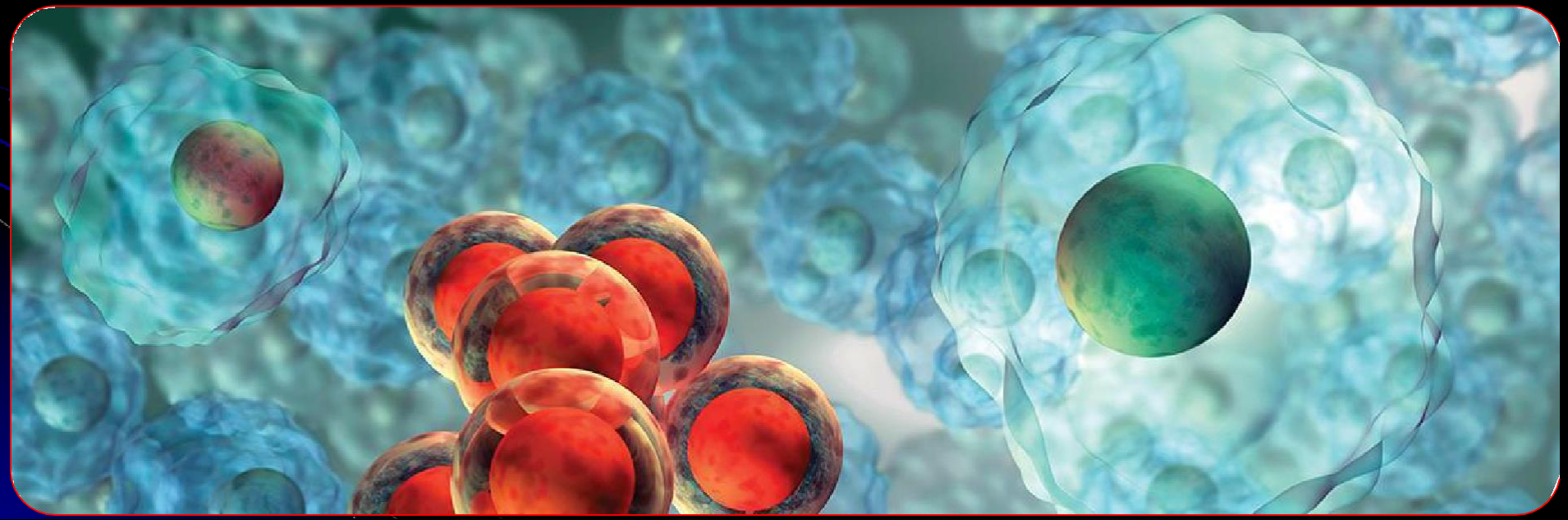
Regenerative Medicine is now a first line treatment to avoid or delay Pharmacological or Surgical treatments

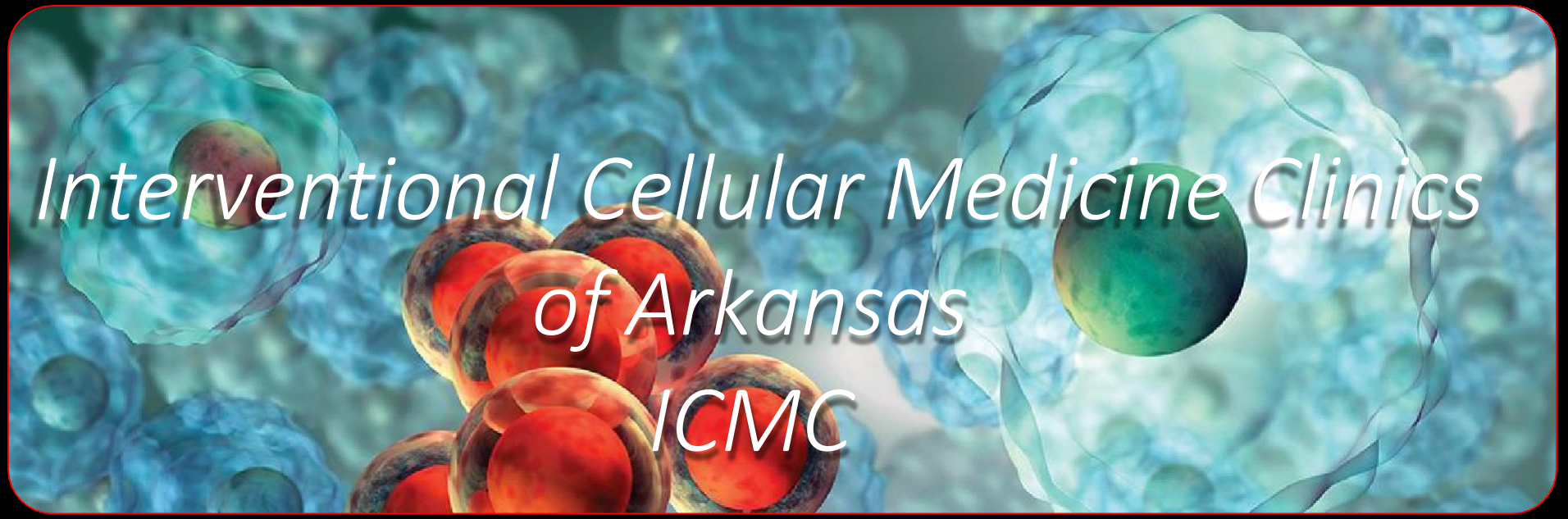
OCTOBER 6, 2017

Using the Body's Natural Healing Process

PRESENTATION

BENEFITS SUB COMMITTEE OF
THE STATE AND PUBLIC
SCHOOL LIFE AND
HEALTH INSURANCE BOARD





ICMC Physicians are Certified in IROM

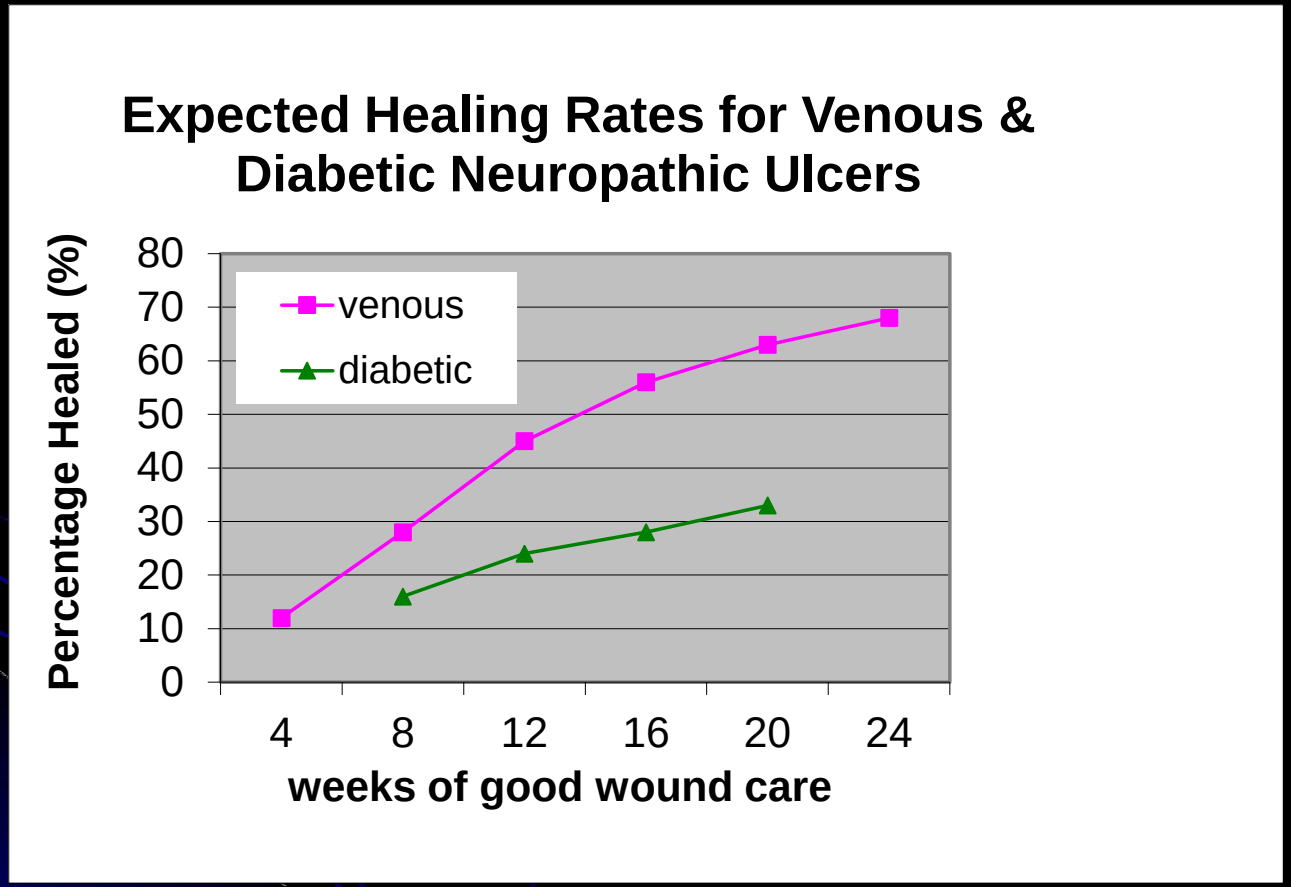
(Interventional Regenerative Orthopedic Medicine)
through the AAOM

(American Association of Orthopedic Medicine)

Clinics are certified by the ICMS

(International Cellular Medicine Society).

Normal Healing Rates?

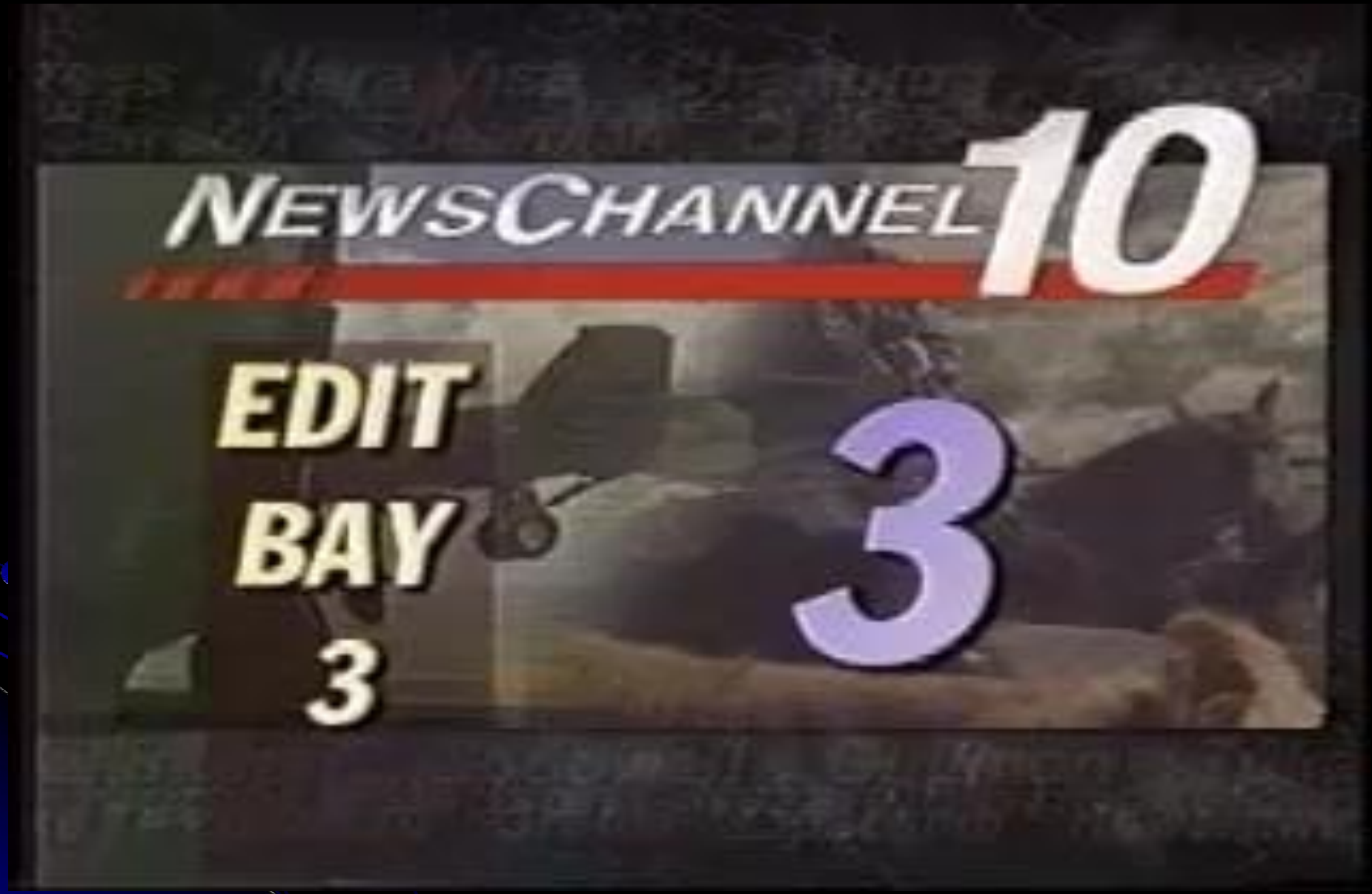


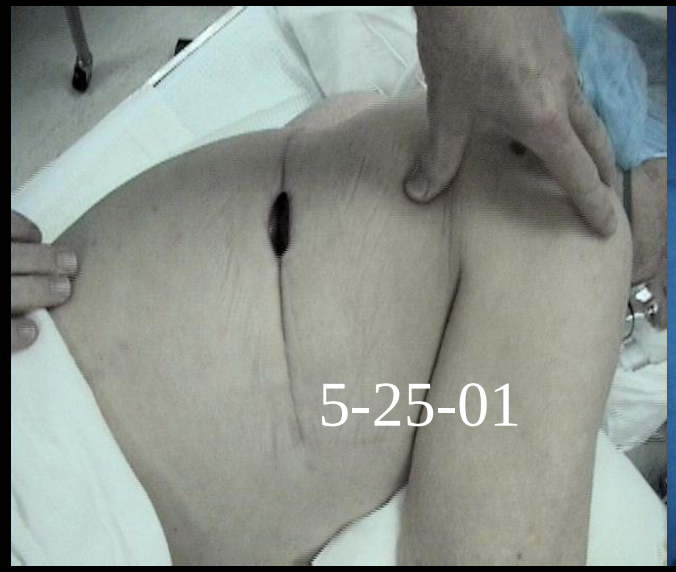
32% Venous ulcers not healed at 24 wks

67% Diabetic ulcers not healed at 20 wks

Kantor & Margolis,
WOUNDS,
Vol. 12, No. 6, 2000

Use of Autologous Platelet Rich Plasma

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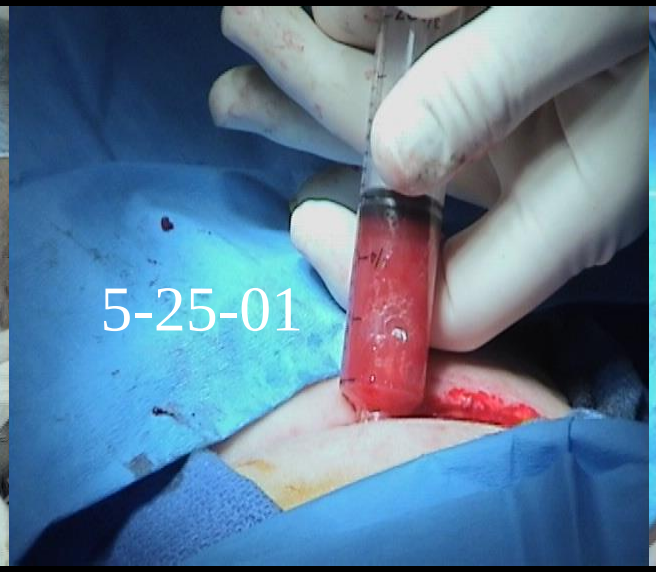
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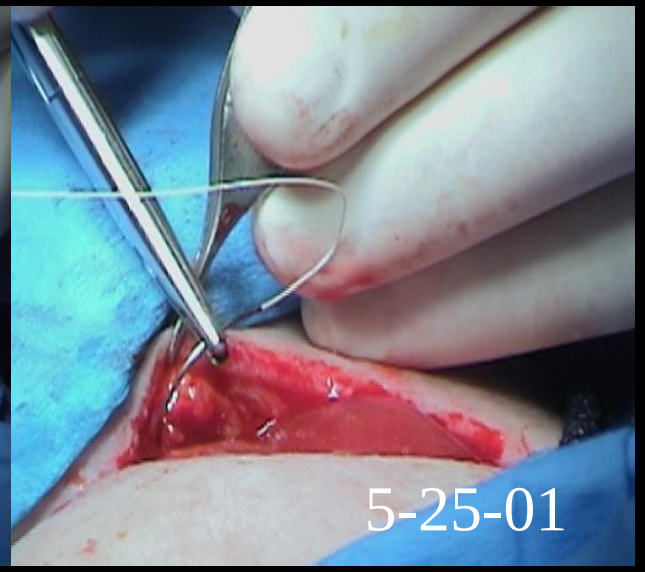
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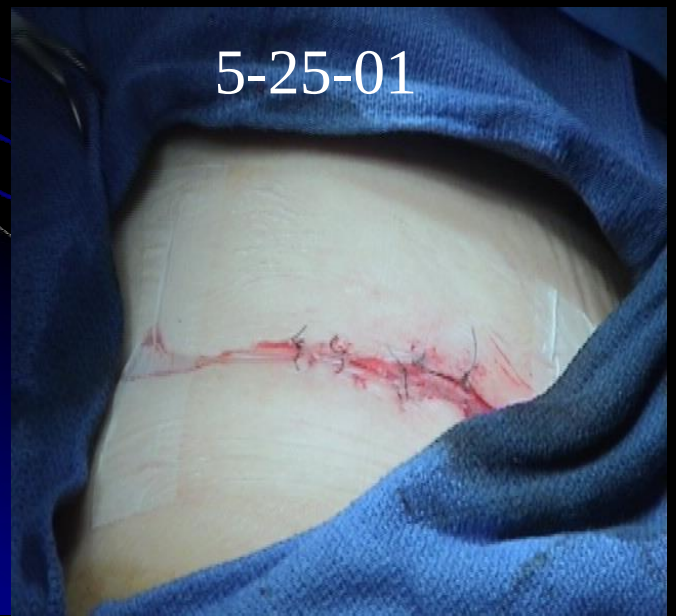
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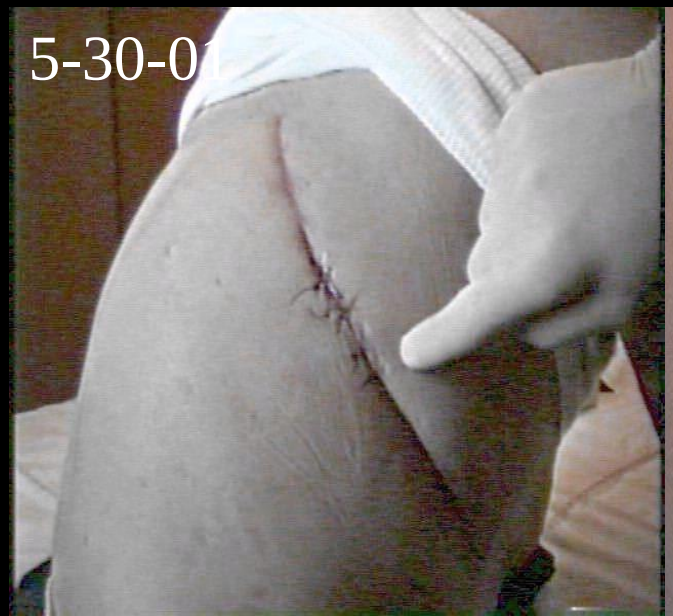
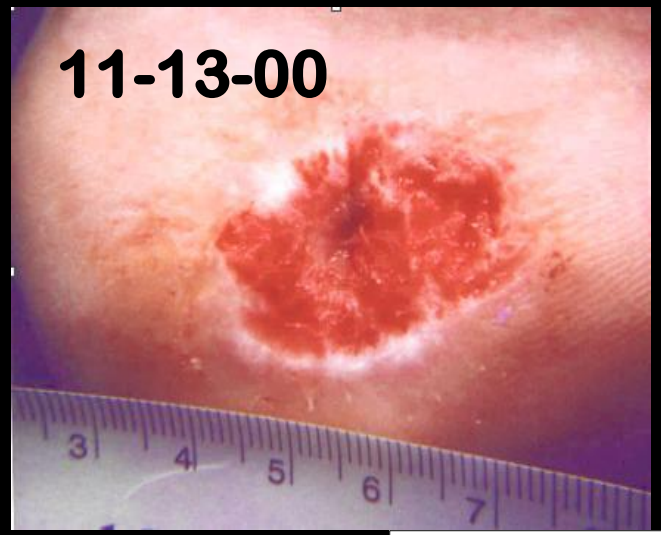
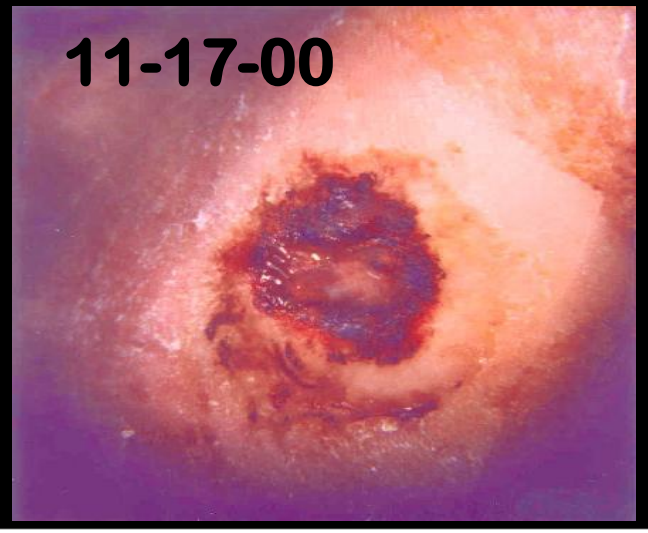
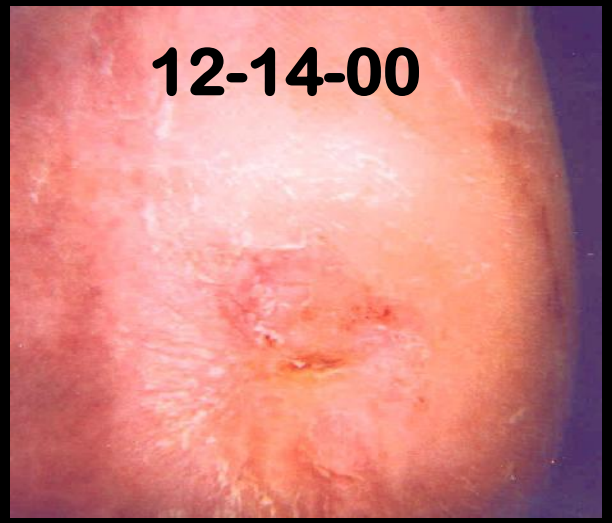

5-30-01

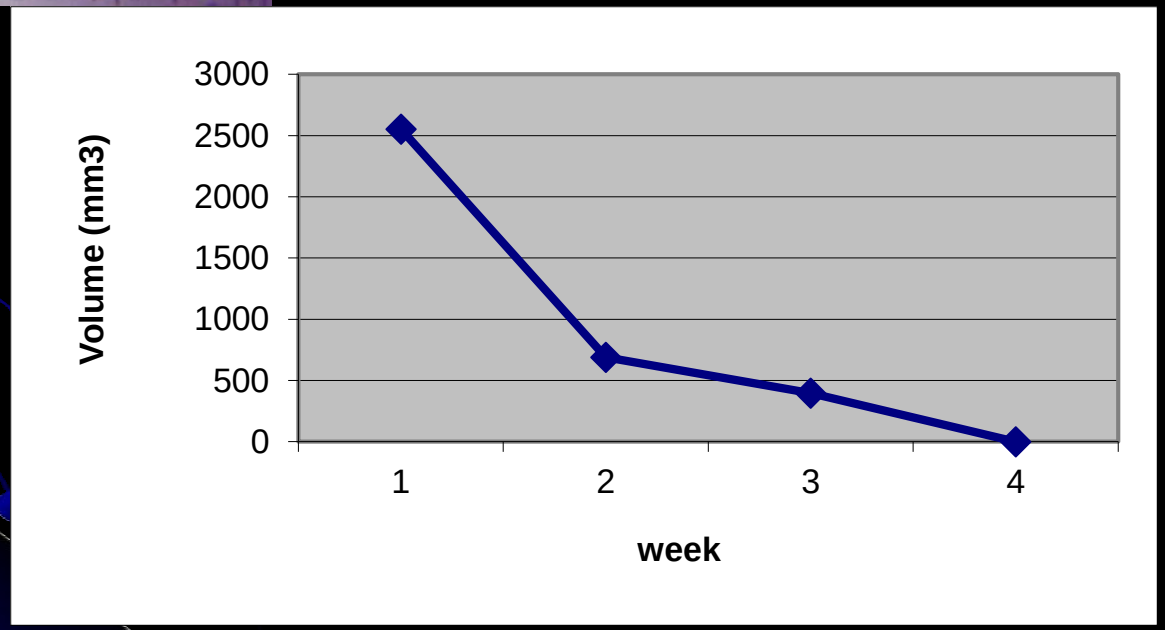

6-06-01
DAY #12

RA is a 52 y.o. white male with a hx of non-healing ulceration plantar lateral R. heel x 3 years. He has a hx of a STJ injury with lack of eversion/inversion motion. He is diabetic with neuropathy. Pedal pulses were intact. **<u>One PRP treatment</u>**.
PMH: (+) IDDM x 20 yrs. (+) MI in 1996 with CABG x 5. (+) smoker 1.5 ppd x 30 yrs.
MEDS: Humulin 70/30.

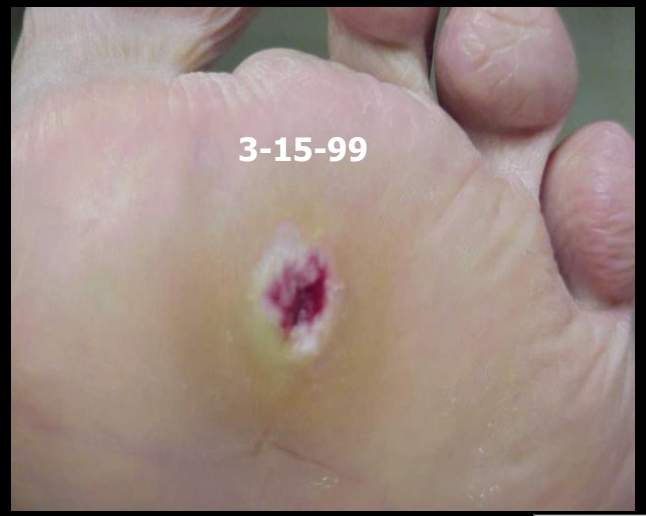


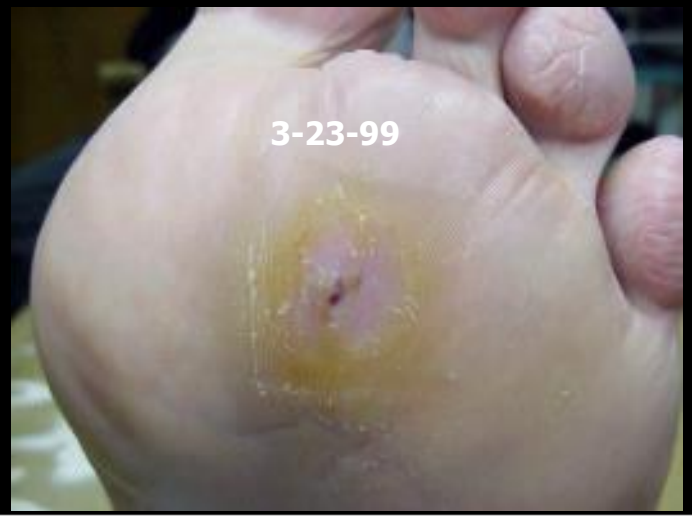


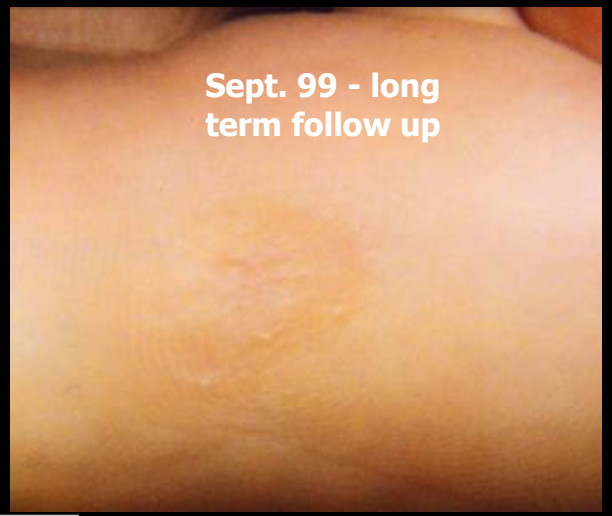


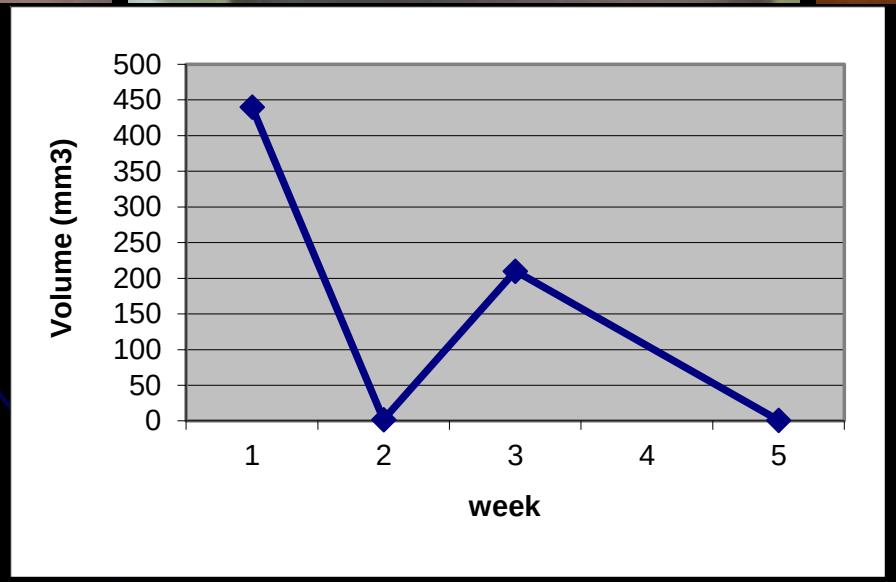


56 y.o. white male with 5 mo. hx of ulceration sub 2 secondary to 2nd digit amp. Long standing hx of IDDM with profound neuropathy. (+) PVD. (+) lower extremity vessel calcinosis. Ulcer had been present almost 1 year. He had been NWB casted, Regranex®, weekly wound care without improvement. Ulcer improved in 8 days. We in error allowed him weight bearing too soon. His ulcer enlarged. We repeated the procedure, kept him NWB x 2 weeks with resolution and no recurrence. **MEDS**: humulin, fosamax, prednisone.

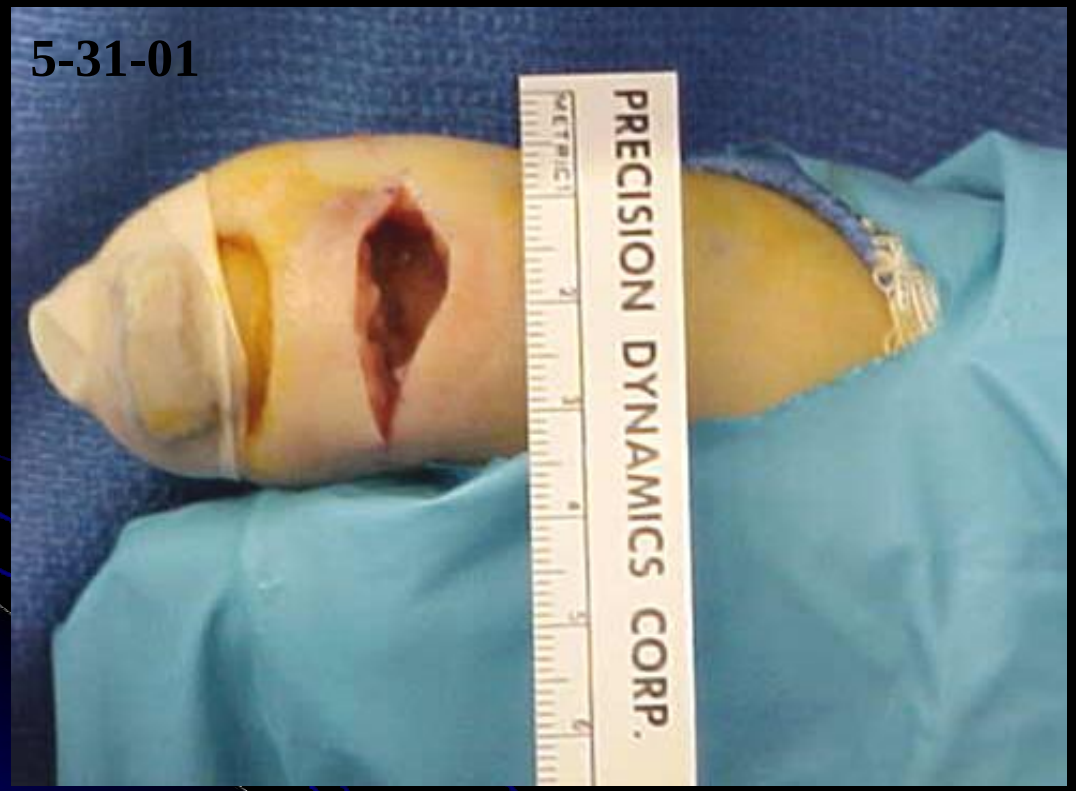


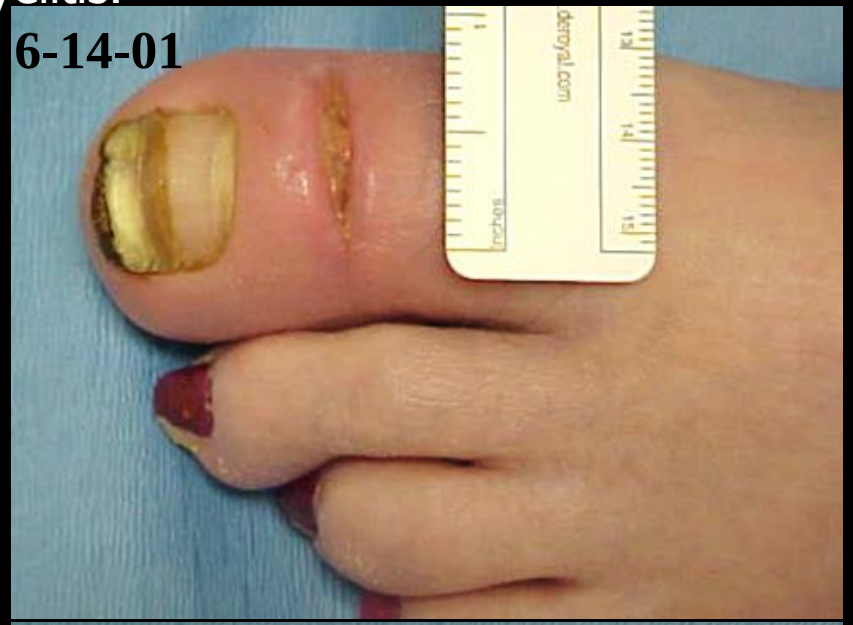


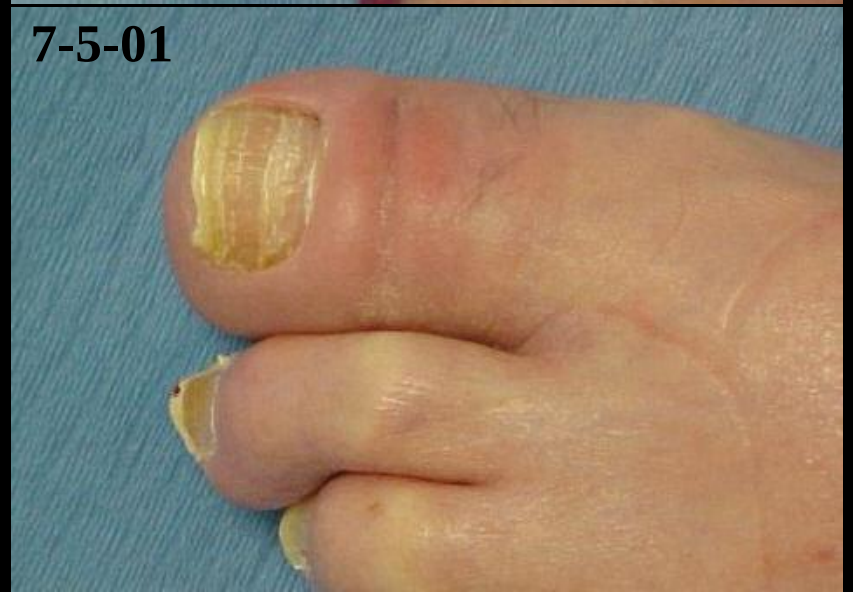




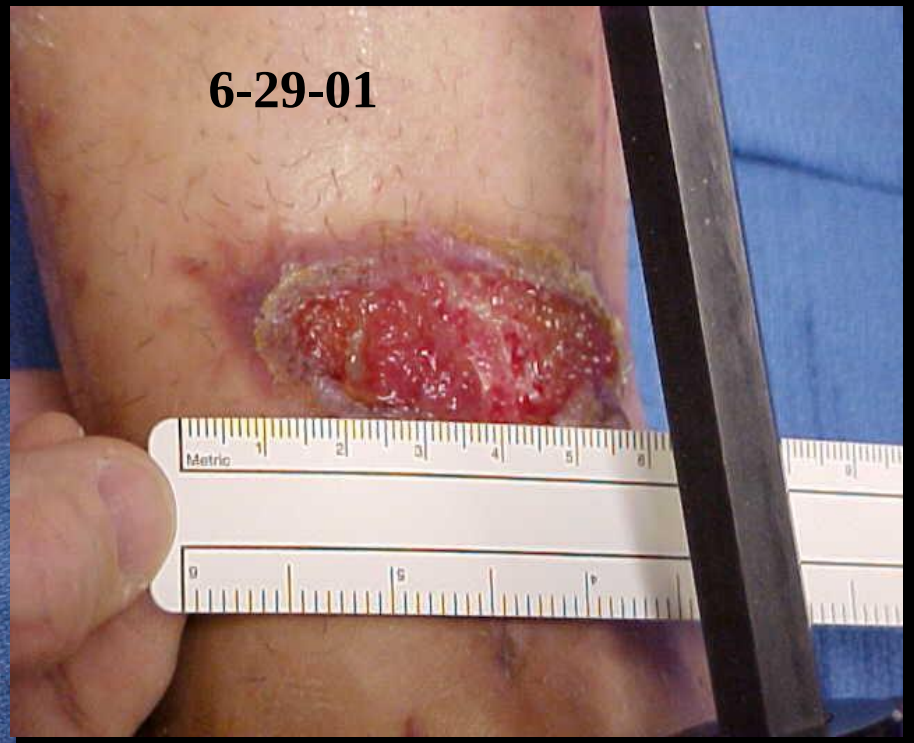
55 y.o. diabetic female with a chronic plantar-medial hallux interphalangeal ulcer. Osteomyelitis was confirmed in both the distal and proximal phalanges. Amputation was recommended by 3 different doctors. She refused and wanted to try the Autologous PRP. She healed and with no evidence of osteomyelitis.

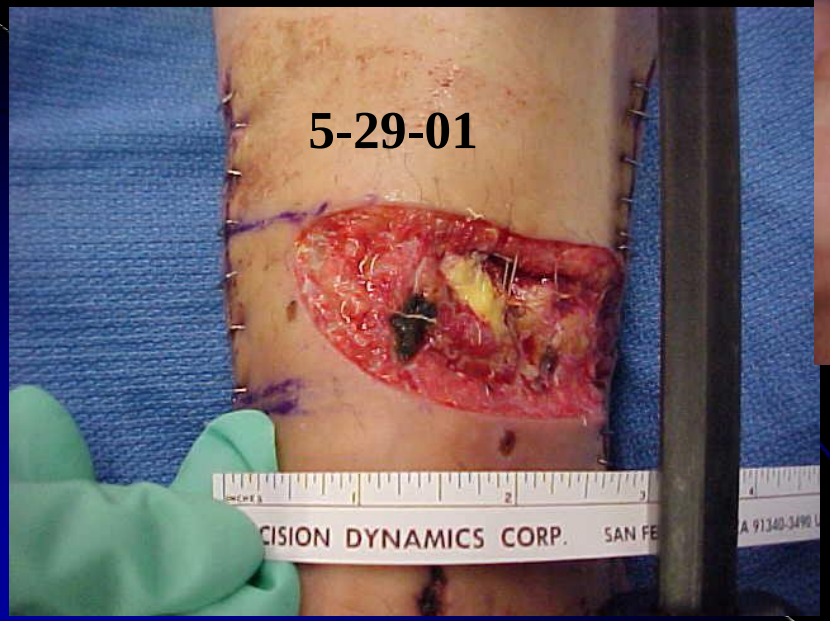


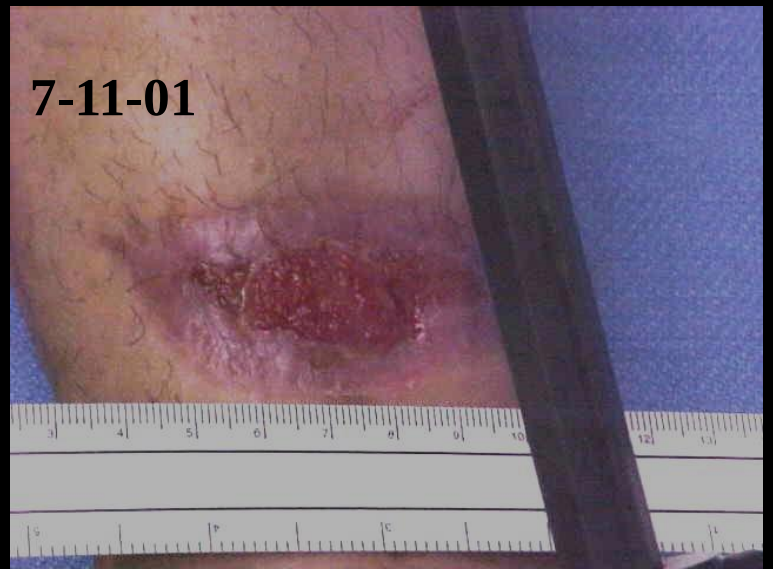




BR is a 39 y.o. female, s/p injury to right leg. Her right ankle was injured in a work related accident and she had an open reduction, internal fixation with an exterior fixator placed on her right lower extremity. She was admitted to an acute care facility for a gracilis free flap to her right ankle which was not done because the vessels in the lower leg were too damaged.
Instead, she was brought to the Center for an Autologous PRP Graft. The platelet graft was to assist in tissue granulation with the goal to prepare the site for a skin graft.
Patient was reevaluated on 06/18/01 and it was decided to postpone the skin graft at that time.
The patient completely healed.







35 Diabetic Foot Ulcers

	LENGTH WOUND PRESENT(wks)	(mm3) START VOL.	(mm3) END VOL.	WEEKS TO OUTCOME	# PROCEDURES REQUIRED
Averages*:	32.38	679.91	-0-	7.79	1.47
Fastest to heal:	24	48	-0-	0.71 (5 days)	1
Slowest to heal:	96	1360	-0-	22.71 (159 days)	5
	18	1496	-0-	22.71 (159 days)	1

* Irrespective of Glucose levels, PVD status, Compliance.

Patient and
Family Centered Functional Medicine

Guidelines

Regenerative Injection Therapy (RIT)

Buffered 5% Dextrose (D5W)

plus

1. Platelet Rich Plasma (PRP),
2. Hematopoietic,
3. Mesenchymal and/or
4. Amniotic Cellular Solutions


NEWS
KSLA-TV
12
HEALTHCAST

Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy

Significant improvements in pain and function as well as overall subjective improvement.

Key study highlights:

- No serious adverse events
- Over 90% of patients reported overall improvement at 3 years
- Numeric pain scores (NPS) improved from an average of 5.2 prior to treatment to a range of 1.2 to 3.7 post treatment
- Functional rating index (FRI) improved from an average of 60.5 prior to treatment to a range of 31.1 to 44.9 post treatment
- 85% of patients displayed a decrease in posterior disc bulge dimensions

https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-1015-5

Journal of Translational Medicine

RESEARCH Open Access

Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy

Christopher Centeno[1,2], Jason Markle[1], Eileen Dodson[1*], Ian Stemper[1], Christopher J. Williams[1], Matthew Hyzy[1], Thomas Ichim[3] and Michael Freeman[4]

Abstract

Background: Degenerative disc disease (DDD) is a common cause of lower back pain with radicular symptoms and has a significant socioeconomic impact given the associated disability. Limited effective conservative therapeutic options result in many coming to surgical alternatives for management, which vary in the rate of success and also carry an increased risk of morbidity and mortality associated with the procedures. Several animal based studies and a few human pilot studies have demonstrated safety and suggest efficacy in the treatment of DDD with mesenchymal stem cells (MSCs). The use of bone marrow derived MSCs for the treatment of DDD is promising and in the present study we report on the safety and efficacy findings from a registry based proof of concept study using a percutaneous intradiscal injection of cultured MSCs for the management of DDD with associated radicular symptoms.

Methods: Thirty-three patients with lower back pain and disc degeneration with a posterior disc bulge diagnosed on magnetic resonance imaging (MRI) met the inclusion criteria and were treated with culture expanded, autologous, bone marrow-derived MSCs. Prospective registry data was obtained at multiple time intervals up to 6 years post treatment. Collected outcomes included numeric pain score (NPS), a modified single assessment numeric evaluation (SANE) using functional rating index (FRI), measurement of the intervertebral disc posterior dimension, and adverse events.

Results: Three patients reported pain related to procedure that resolved. There were no serious adverse events (i.e. death, infection, or tumor) associated with the procedure. NPS change scores relative to baseline were significant at 3, 36, 48, 60, and 72 months post treatment. The average modified SANE ratings showed a mean improvement of 60% at 3 years post treatment. FRI post treatment change score averages exceeded the minimal clinically important difference at all time points except 12 months. Twenty of the patients treated underwent post treatment MRI and 85% had a reduction in disc bulge size, with an average reduction size of 23% post treatment.

Conclusions: Patients treated with autologous cultured MSCs for lower back pain with radicular symptoms in the setting of DDD reported minor adverse events and significant improvements in pain, function, and overall subjective improvement through 6 years of follow-up.

*Correspondence: E.Dodson@regenexx.com
Regenexx Clinics, LLC, 850 Summit Blvd Suite 300, Broomfield, CO 80021, USA
Full list of author information is available at the end of the article

6 Co's of MAXIMIZING EFFECTIVENESS OF RIT- *Avoid Co-mpetition!*

1. Collaborate with patient's Primary Care Provider (PCP)
2. Coordinate with patient's Chiropractor and/or Physical / Manual Therapist to ensure the patient the dignity of a proper diagnosis.
3. Collate existing health care records with all prior medical and surgical history with an updated pharmaceutical history, Microbiome (gut) assessment/therapy, blood laboratory, hormone status and QANS testing assessing sympathetic system & appropriate oral and I.V. nutrition.
4. Correlate prior imaging studies with appropriate up-to-date imaging to arrive at the correct diagnosis.
5. Communicate overview of Regenerative Injection Therapy (RIT) in sync with patient's understanding of their existing health care regimen (making clear that RIT is **'in addition to'**, not **'instead of'** the patient's existing and evolving 'patient specific' integrative health care regimen).
6. Complete patient registry following RIT.

Regenerative therapies for Degenerative Arthritis and Diabetic Neurovascular therapy

Proposed study groups

1. Low Back Pain
2. Osteoarthritis (OA) of the Knee
3. Neuropathic & Vascular Lower Leg
4. Diabetic Extremity Wounds

Year 2014

Category:	Amount Paid (1)	Amount Paid (2)	Total Amount Paid
Superficial Ulcer	$ 10,975,190.55	$ 10,988,752.21	$ 21,963,942.76
Disorder of Knee's Articular Surface	$ 2,502,007.63	$ 3,396,545.05	$5,898,552.68
Lumbar/Low Back	$ 33,969,909.51	$ 33,004,371.63	$66,974,281.14
Lower Leg	$ 62,212.55	$ 155,728.63	$217,941.18
Other: Ulceration	$ 457,091.88	$ 443,089.03	$900,180.91
Plantar Fascitis	$ 3,863,864.53	$ 3,144,211.14	$7,008,075.67
Diabetic Foot Ulcer	$ 2,901,464.90	$ 3,097,735.37	$5,999,200.27
Complications Due to Diabetes	$ 7,782,001.82	$ 6,614,720.08	$14,396,721.90
Est. Total Spend for Catagories	$ 62,513,743.37	$ 60,845,153.14	$123,358,896.51
Regenerative Intervention Potential:	70%		$86,351,227.56
Estimated Costs of Regenerative Care	40%		$34,540,491.02
Projected Savings Net of Costs & Fees:			$51,810,736.53

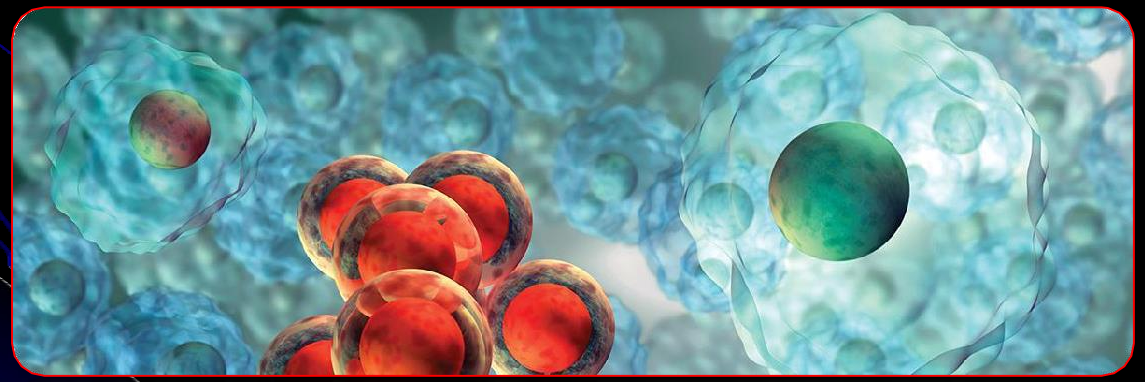
Key Points

Clinical Outcomes: IROM, with credentialed providers and certified protocols, provides safe, affordable and effective therapy resulting in improved healing and overall patient outcomes.

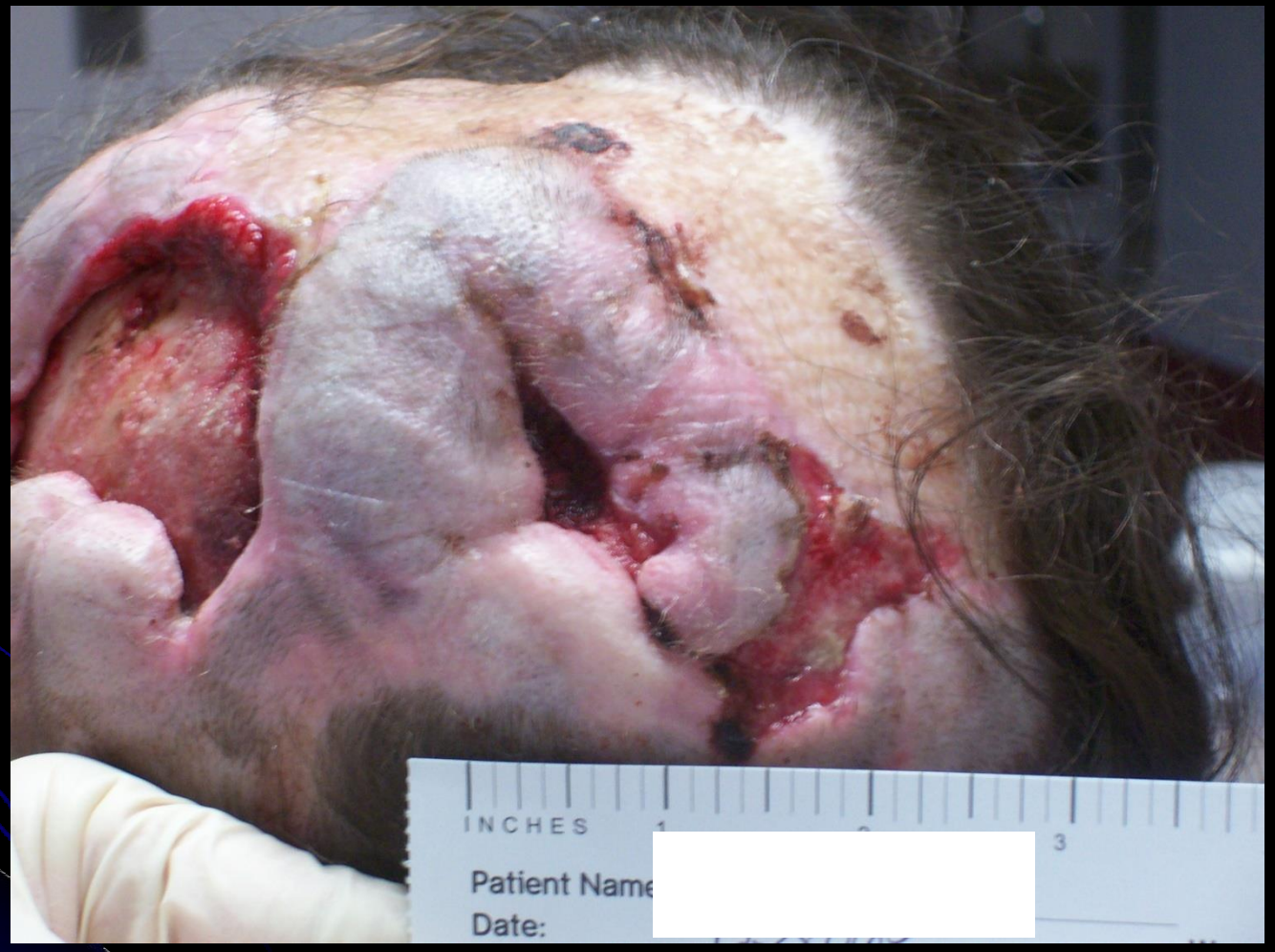
Financial outcomes: Lower costs to The State and Public School Life and Health Insurance Board, not only with avoidance of unnecessary pharmaceuticals and surgery but of complications, as well.

Quality of Life: IROM is not only financially beneficial, but allows patents a more rapid return to work and activities of daily living.

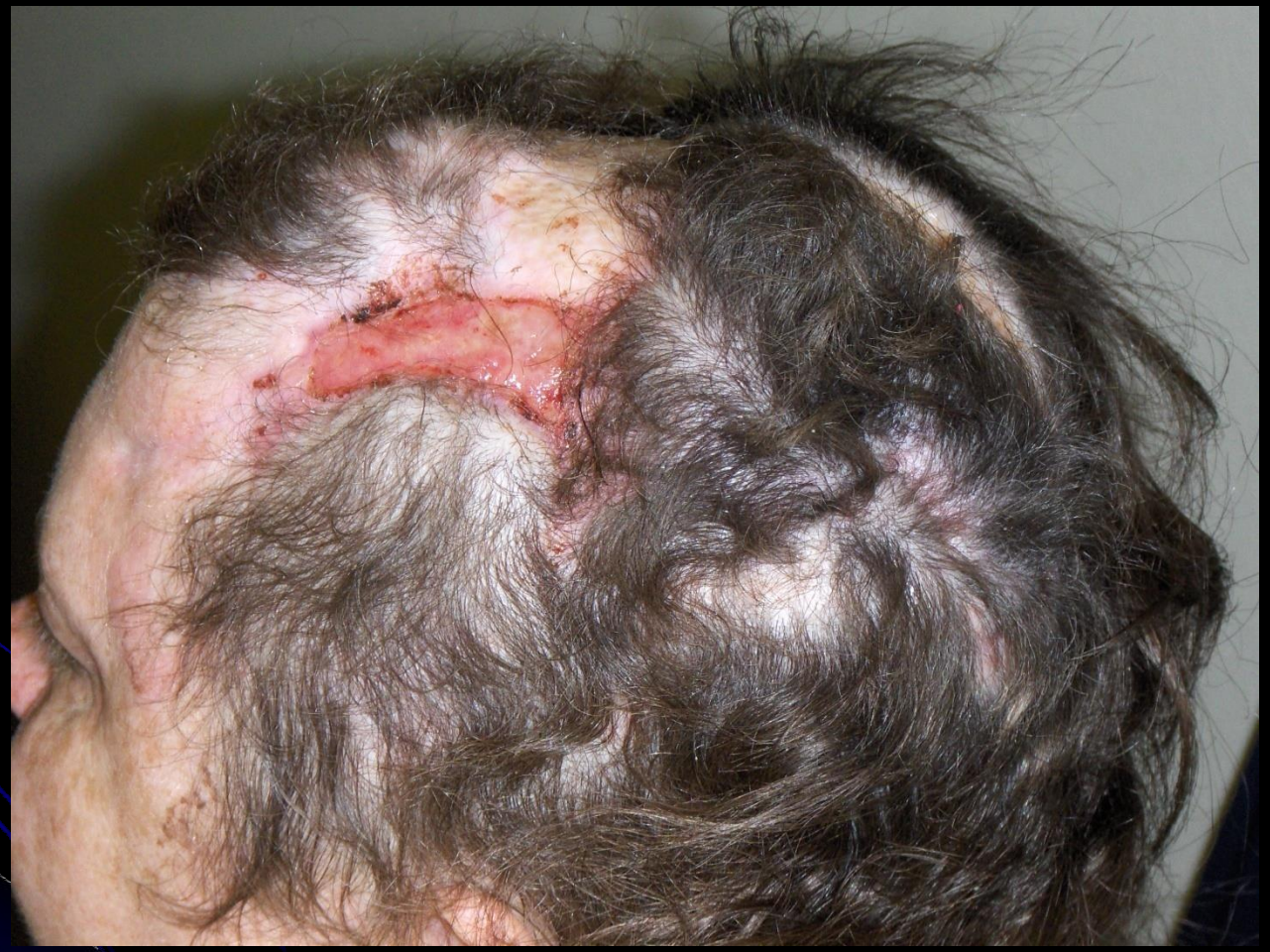
Treatment Acceptance: Increasing payer adoption of the use of regenerative and cellular medicine therapies, with Arkansas now playing a leadership role in the U.S.



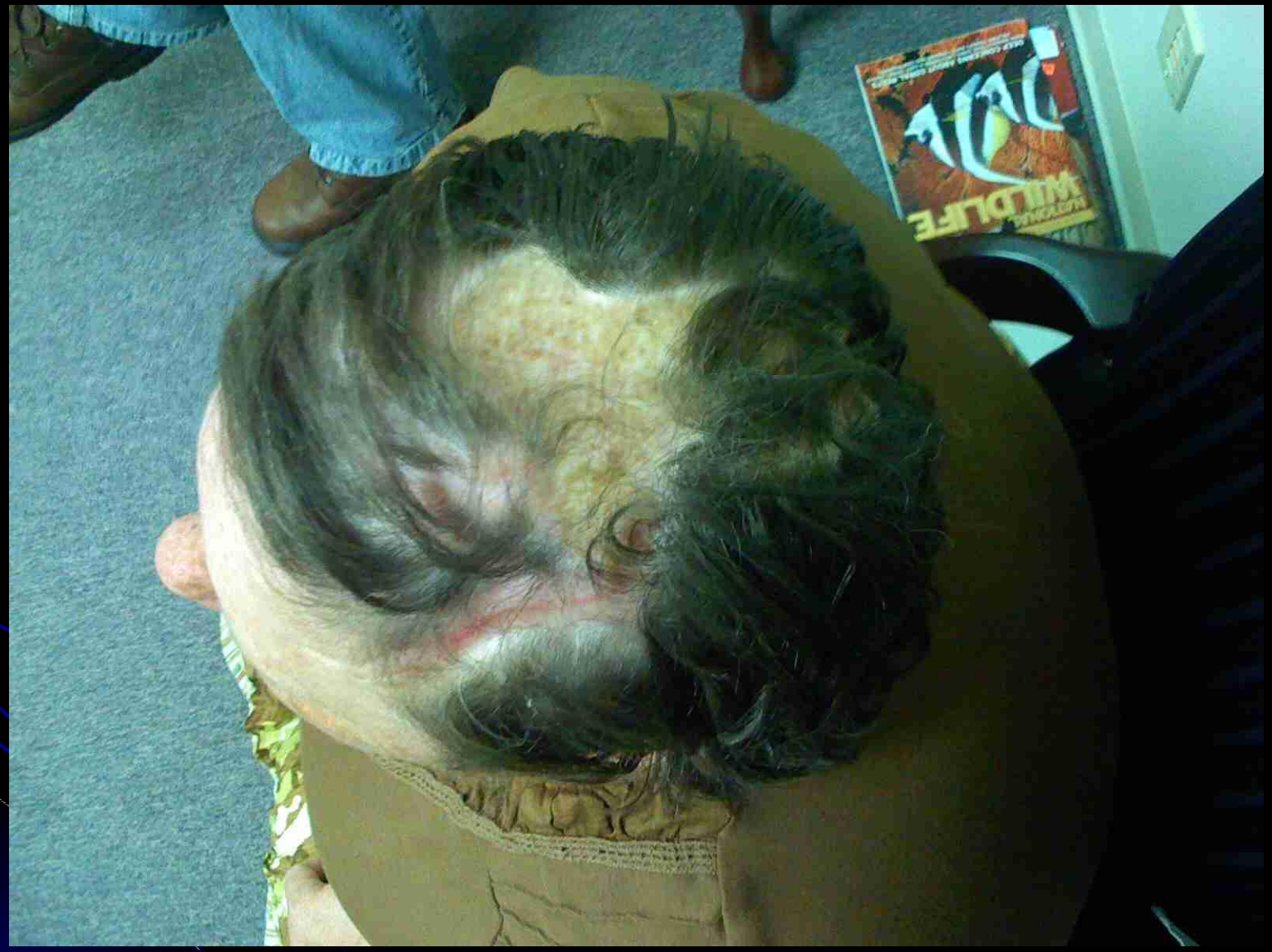
Six Years of Unsuccessful Wound Care

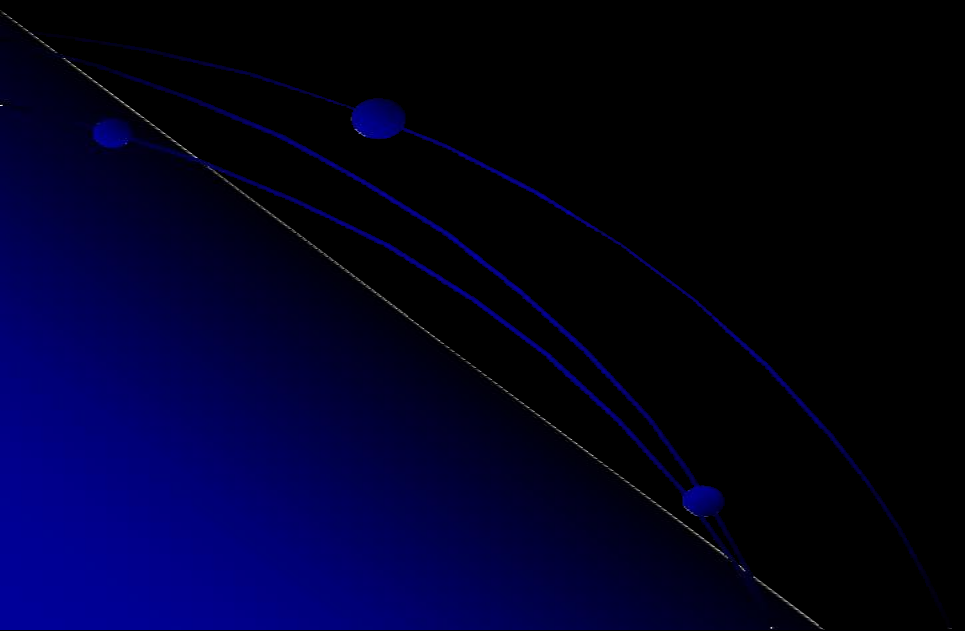


Eight Weeks of Comprehensive Team Management



Three Month Follow Up





A Hospital Corporation's Clinical Review Comparing Platelet Rich Plasma Therapy to VAC

32 Wounds treated

Patients healed an average of 71% over a three week period

Hospital cost decreased an average of 60% compared to VAC therapy

Comprehesive Regenerative care requires less nursing time

England & Associates

Rehabilitation Services & Vocational Evaluations

1979 - 2003 : 25+ Years Experience Specializing in Private Sector Rehabilitation & Case Management Services

February 4, 2003

Carl Keller, Vice President
SafeBlood Technology, Inc.
11100 North University, Suite # 202
Little Rock, Arkansas 72207

SUBJECT: Success in West Central Florida

RE: SafeBlood Technology Therapy & Client Progress

Dear Carl Keller:

After over 15 years of traditional wound care treatment, including surgical repair, 'flap procedure', skin grafting, use of Regranex and Procuren; my paraplegic Client in West Central Florida has seen success and found hope.

He has had a persistent left hip wound for many years. He has been a paraplegic since 1979. Like many paraplegics the practical difficulty with healing pressure sores and wounds of the ischial region are problematic. His concern with multiple debridements, surgical attempts to remove the wound and subsequent failures were an emotional, practical and medical concern.

In July of 2002 he had his first surgical treatment with the SafeBlood's Autologous Platelet Grafting procedure. His surgeon was instructed by SafeBlood technicians. Results were apparent within the first 1- 2 weeks.

Wound closure and healing were dramatic. A second procedure was conducted with similar positive results. Debridement, prior to application of the autologous procedure and subsequent wound care was definitely preferred to previous more invasive surgical procedures. Again, the wound closure and healing were obvious within the first 1- 2 weeks and have continued. There is hope for wound care!

In the past my practice has seen paraplegic Clients view surgical procedures, the 'skin flap procedure' skin grafting and even amputations as an eventuality with failed wound care. The autologous platelet therapy is a medically efficient and cost effective alternative to traditional medical routine treatment.

Sincerely,

Bill R. England, MS, CRC, CDMS, CCM
Medical & Vocational Disability Case Manager

England & Associates • P. O. Box 47535 • St. Petersburg, FL • 33743-7535
Phone: (727) 435-0664 • Fax: (727) 345-6126 • Cell Phone: (727) 432-9851
E-Mail: BRENGLAND@MSN.COM • Web Site: HTTP://WWW.BREARFHAB.COM

CORVEL

January 31, 2003

Charles Worden, Jr.
SafeBlood Technologies
1100 North University, Suite 109
Little Rock, AR 72207

RE: medical cost savings

Dear Charles:

During 2002, we provided case management services for a claimant who had a severe leg injury, which compromised circulation to the leg. This increased the risk with doing a rather complicated skin grafting procedure to repair the area.

We were able to use Autologous Platelet Gel treatment at a cost of approximately $1750. This treatment was successful in accomplishing healing. This resulted in significant savings including reducing the cost of hospitalization and preventing a surgical procedure, which would increase risks for the claimant and reduce the healing period. We calculated those savings at $25,920.

I feel that the aspects of this treatment, which are sometimes difficult to measure, also contributed significantly to overall savings both in amount of the claim and potential risks and complications to the claimant. We will certainly be evaluating future claimants to identify those who would benefit from this excellent method of treatment.

Sincerely,

Shugie Scroggin

Shugie Scroggin, RN, CCM
Branch Manager

CorVel Corporation
www.corvel.com

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Suite C
Fayetteville, AR 72703

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FARA HEALTHCARE MANAGEMENT
204 Winchester Drive
Lafeyette, LA 70506
(337) 988-4008 * (800) 215-3272
FAX: (337) 988-9866
www.fara.com

January 7, 2003

Charles Worden, Jr.
SafeBlood Technologies
1100 North University, Suite 109
Little Rock, AR 72207

Re: Medical Cost Savings

Dear Charles:

The estimated cost per year for our workers' compensation patient with conventional care for diagnosis of decubitus ulcers is approximately $200, 000.00 as compared to the Autologous Platelet Gel treatment which is approximately $15,000. An approximate savings of $185,000.00 per year. This total includes previous treatment of inpatient hospitalization for complications associated with the decubitus ulcers, surgical interventions, daily home health visits for wound care, rental of wound vac devices, purchase of Clinitron bed, specialty physician visits, medications and wound care supplies for dressing. The decubitus ulcers were treated with little to no success for a period of three and a half years. There was a continual worsening with increase size and depth of the ulcers with previous treatment.

With the Autologous Platelet Gel treatments the decubitus ulcers are almost healed. The results have been excellent and would highly recommend your treatment for other patients.

Sincerely,

Brenda McDaniel, RN, CCM, CPUR
Supervisor FARA Healthcare

PRP Therapy: Clinical Data

Patient	Beginning Volume CM	PRP Application CM	Week One CM	Week Two CM	Week Three CM	Week Four CM	Ending Volume CM	Volume Reduction %	PRP Cost x 3 Weeks	VAC Cost x 3 Weeks
1 Ha	252	10x9x2.8	?				0	100	688.44	1,967.13
2 BM	21	21x.5x2	15x.3x.4				1.8	92	688.44	1,967.13
3 BT	33.85	6.2x7.8x.7	6.3x8.3x.4	6.5x7x.2	6.8x7x.2		9.52	72	1,376.88	1,967.13
4 Ed	13.37	3.8x3.2x1.1	?				13.37	0	688.44	1,967.13
4 Fe	3.85	2.5x2.2x.7	2.2x2.3x.5				2.53	35	688.44	1,967.13
5 Fo	99.96	16.8x3.5x1.7	14.7x3.3x1	15.2x2.5x.8			30.4	70	688.44	1,967.13
6 GA #1	6.96	5.8x3.x.4	6x2.7x.1	5.8x2.5x.2			2.9	59	688.44	1,967.13
7 GA #2	0.09	.8x.4x.3	1x.4x.1	.6x.4x.1			0.024	74	688.44	1,967.13
8 Hb #1	1.4	1.9x1x.6	2.4x.6x0				0	100	688.44	WTD -BID
9 Hb #2	0.78	1.3x.6x1	1.1x.9x0				0	100		WTD -BID
10 Hb #3	0.3	1.1x.4x.7	.8x.7x0				0	100		WTD -BID
11 Hb #4	1.4	1x.5x2.8	.9x.7x1.5				0.94	33		WTD -BID
12 Hs #1	3.02	2.8x.6x1.8	1.9x.8x1	1.8x.9x.5	1.7x.8x1	1.7x.8x1	1.36	65	688.44	1,967.13
13 Hs #2	94.5	13.5x2.5x2.8	9x2.4x2.7	6x3x1.7	4.8x3x1	4.8x2.5x.7	8.4	92	688.44	1,967.13
14 Hm	28.5	3.8x7.5x?					0	100	688.44	1,967.13
15 Ha #1	54	10x3x1.8	9x2.8x1.8	5.3x1.3x.4	4.7x2x.5	4x1x.4	1.6	98	688.44	1,967.13
16 Ha #2	23.22	4.3x4.5x1.2	1.8x2.0x5.8	1x1.5x.6	1.5x.8x4	1x2x3	6	75	688.44	1,967.13
17 Ha #3	30	5x6x1	6.8x11x1	3.8x4.5x.7	4x4x.2	4x2x.1	0.8	98	688.44	1,967.13
18 Ha #4	0.56	.8x.5x1.4	1x.3x1	.7x.4x1.3	.4x.3x1.1		0.132	77	688.44	1,967.13
19 Th	11.61	4.3x9x.3	3.3x8x.2	1.5x6.7x.1			1.005	92	688.44	1,967.13
20 Me	0.45	2.5x1.8x.1	2.5x1.9x.1	1.7x.8x.1			0.136	70	688.44	1,967.13
21 Mi #1	27.82	10.5x5.3x.5	10.5x4.7x.3				14.8	47	688.44	1,967.13
22 Mi #2	5.21	4.7x3.7x.3	4.5x3x.2				2.7	49	688.44	1,967.13
23 RG	4.36	3.9X5.6X.2	4.7x5.6x.1	3.5x5.2x.2			3.64	17	688.44	1,967.13
24 BF	4347	13.5x46x7	13.5x42x5.5	10.7x44x5.8	10x43x3.6	8.7x37.4x2.7	878.52	80	688.44	1,967.13

PRP Therapy: Clinical Data

25 CC	1.05	3.5x.5x.6	2x.4x.6	1.9x.4x.4	1.9x.7x.2	2x.5x.2	0.2	81	688.44	1,967.13
26 FC #1	135.72	8.7x12x1.3	7.7x11x1	8.5x10x1.1	8x10x.4		32	76	688.44	1,967.13
27 FC #2	24.81	3.3x4.7x1.6	2.6x4x1.3	2.5x3.9x1.4			13.65	45	688.44	1,967.13
28 HD	63.6	5.3x6x2	3.8x5.7x1.5				32.49	49	688.44	1,967.13
29 Mc	10.16	6.2x4.1x.4	6.4x4.5x	6x6x.4	6x4.4x1	6.9x4x.6	16.56	-62	688.44	1,967.13
30 Mu	21.56	5.5x4.9x.8	5x5x.3	5.2x4.6x1		4x4x.2	3.2	86	688.44	WTD - BID
31 WG	1057.42	9.8x13x8.3	11.5x11.8x7.5	9x12x7			756	29	1,376.88	1,967.13
Beginning Volume	**6379.53**					**Ending Volume**	**1834.677**		**21,341.64**	**53,112.51**
			Total Volume Reduction	**71.25%**				**VAC**	53,112.51	
								PRP	21,341.64	
								Savings	**$31,770.87**	
			Total Cost Reduction	**60%**						

The total volume reduction is a cumulative total on the above patient population.

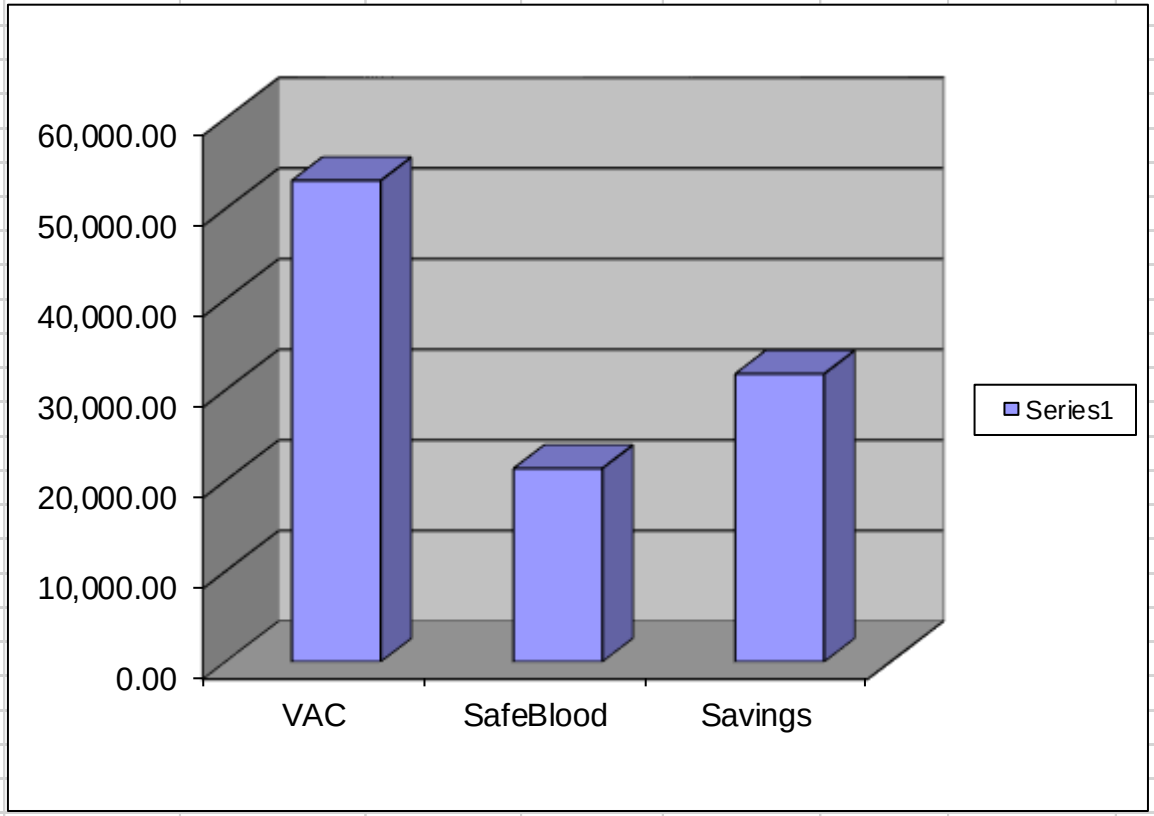
The total cost reduction is actual cost of PRP vs. projected cost of the VAC as estimated by Charlotte Martin WOCN.

These totals do not include nursing time which is generally 3 to 1 comparing VAC vs PRP.

Clinical Data

60 % Cost Reduction vs VAC

(3 weeks of supply and kit costs)



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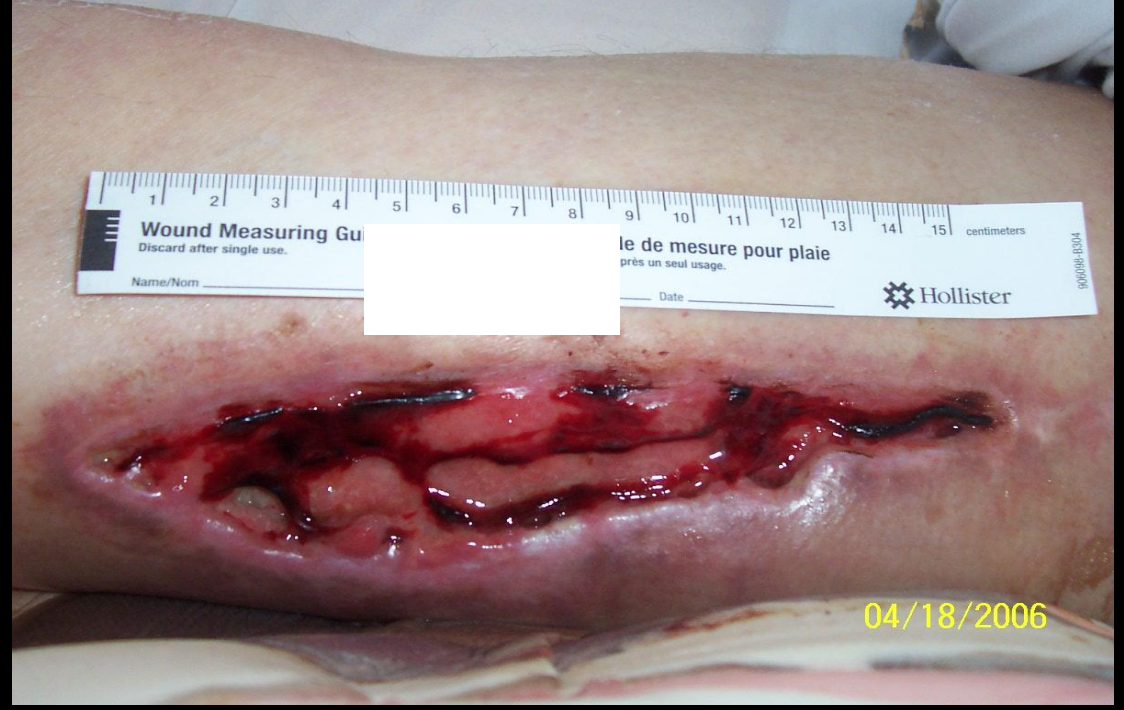
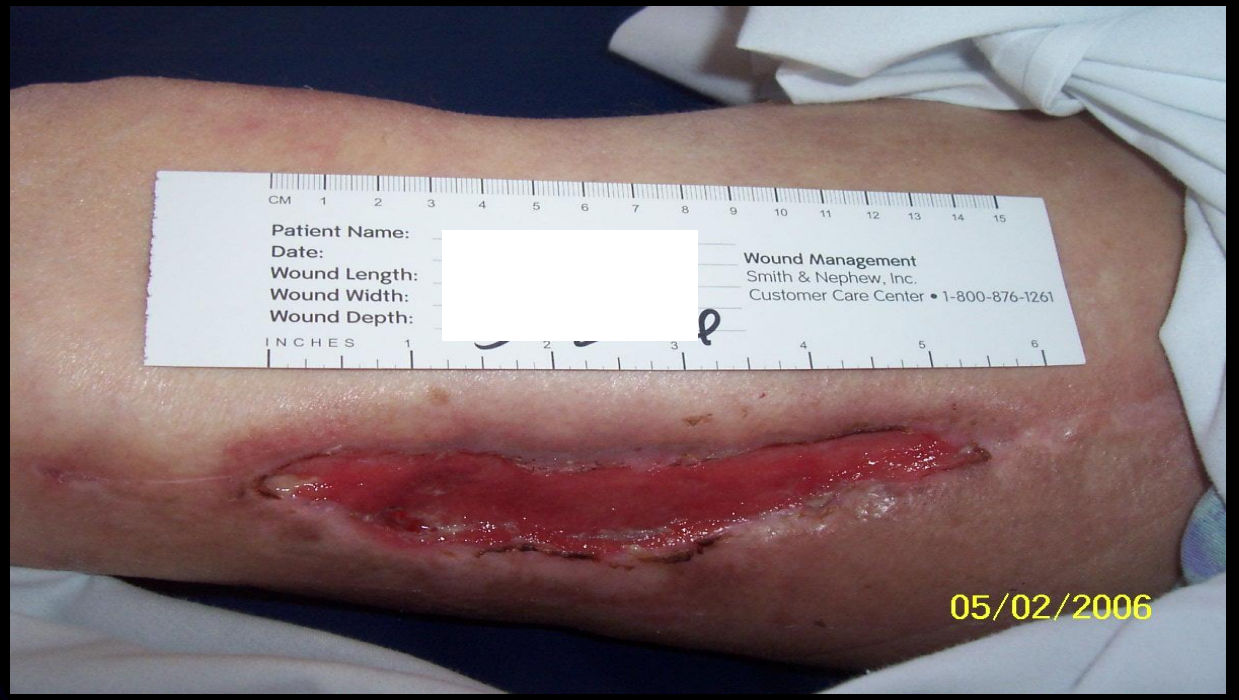


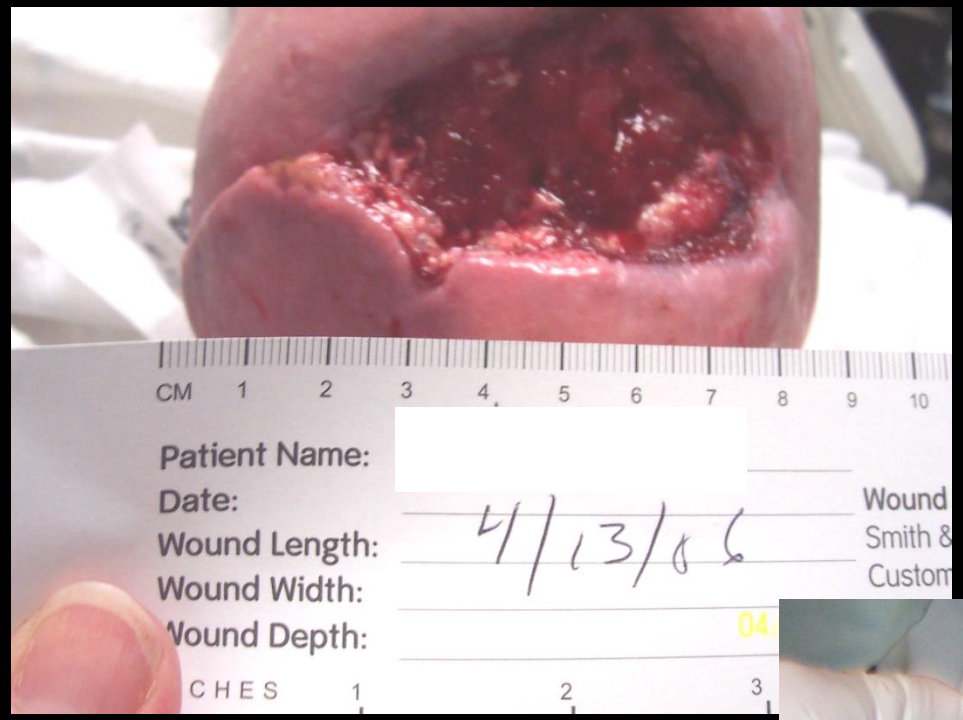
16.8cm x 3.4cm x 1.7



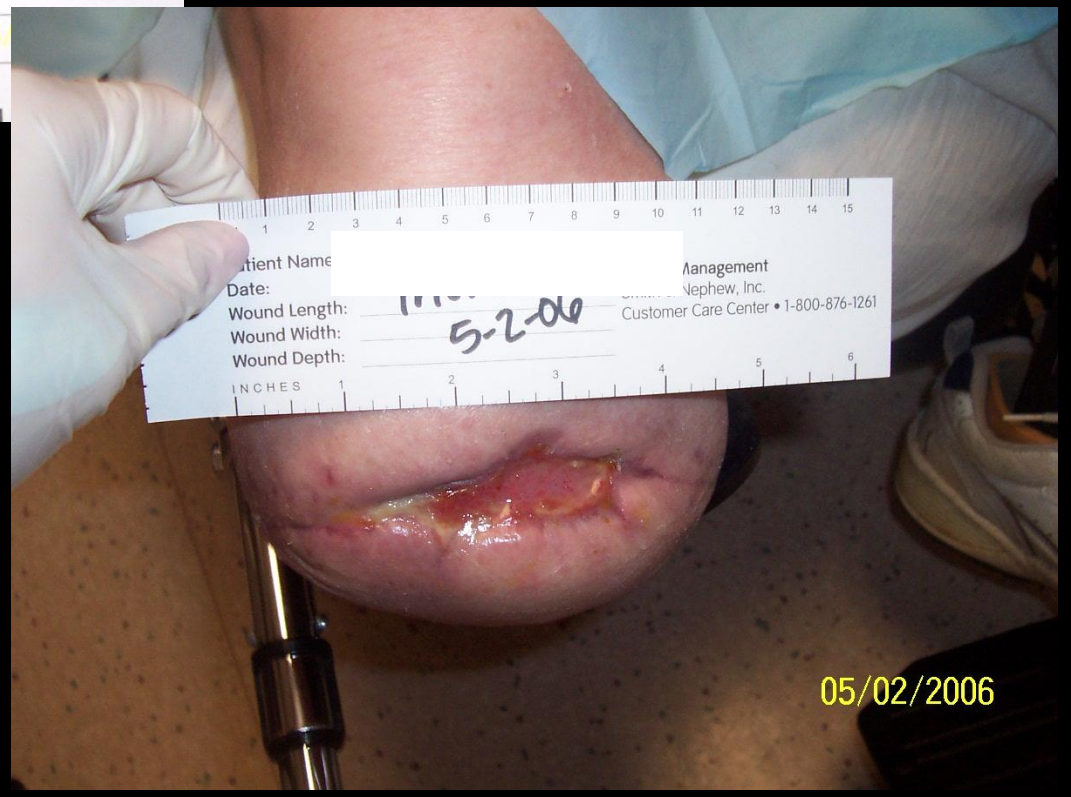
15.2cm x 2.5cm x .8cm

70% Volume Reduction
In 14 days

Stump



8.3cm x 2.4cm x 1.2cm



6.7cm x 1.5cm x .1cm

80% Volume Reduction
In 19 days

Select
Specialty® Hospital

Carl Keller
Vice President
SafeBlood Technologies, Inc.
1100 North University Avenue
Little Rock, AR 72207

RE: The SafeBlood Graft protocol at Select Specialty in Little Rock

Dear Carl:

Select at St. Vincent has worked with SafeBlood since April of 2002 and I have personally experienced your commitment and efforts in serving our physicians and patients since 2004. During that time the coordinated efforts between our facility, physicians and SafeBlood have made a significant difference not only for many of our patients, but for our facility as well.

The SafeBlood Graft procedure and protocol consistently helps us to reduce and close chronic dehiscence, pressure ulcers, and wounds with which our patients have presented. In fact, under the direction of Dr. Holland, our wound care director, we are now regularly referred wound patients for treatment with the SafeBlood Graft who have not responded to other regimens or care.

By using your protocol we have experienced more rapid closure of deep, complicated or hard to treat wounds; fewer dressing changes and complicated nursing care, and a significant cost savings over the use of other prevalent chronic wound treatments or equipment.

In summary, we appreciate the professionalism and care you have shown our patients and staff, and would encourage our other facilities to consider implementing your protocol for their patients where appropriate. They are welcome to contact me, or I am sure that Dr. Holland would be happy to discuss his experience as well.

Sincerely,

Maureen Hanneken, MHA,
Chief Executive Officer
Select Specialty Hospital

#2 St. Vincent Circle 6th Floor Little Rock, AR 72205
Referral 501 961-4198 Fax 501 905-9041
www.selectmedicalcorp.com

REGENCY HOSPITAL COMPANY

RHC

April 23, 2008

Charles Worden, Jr.

SafeBlood Technologies

1100 North University Suite 109

Little Rock, Arkansas 72207

Dear Charles,

Below is my overview of our wound care program as presented at our quarterly meeting:

Wound care for the first three months of this year has been very exciting a Regency Hospital of Cincinnati. We have started our new wound team consisting of our director of wound care, Dr. Louis Thibodeaux, wound nurse, pharmacy, case management, dietary, quality management and physical therapy. It has proved to be a very helpful tool in providing patient care.

We have started to use the new grafting system, SafeBlood, for the healing of wounds. We have done 17 treatments since the first of the year with amazing results in a short time frame. It is a non-invasive treatment using the patient's own blood to graft blood components such as growth factors directly to the wound to promote healing. Pictures are available to those who are interested in seeing firsthand how promising this treatment has been for us.

By using this method of treatment we have been able to cut our use of the KCl wound vac completely. Financially, this has cut our expenses in half. Our costs last year for KCl wound vac were $ 81,472.50. Last year first quarter we spent $ 22,950.00 for wound vac rental. This year we have cut our use of the wound vac related to our abilities to treat wounds by different means. Our vac expense in Jan. was a little over $ 2,000.00, Feb. was $ 185.00 and March was $ 0.00. Our SafeBlood expense is proving to be substantially less. This quarter we spent $ 11,008.00 for SafeBlood. If you projected for the rest of this year times 4 quarters it would show a saving of 50%.

We are extremely happy with the results of SafeBlood and those results are improving our referral base as word has "gotten out" regarding those results and we are beginning to see patients being referred for this treatment. We are the only facility to offer SafeBlood in this region.

Best Regards,

Kathy Nicholas RN WCC

Kathy Nicholas RN WCC

REGENCY HOSPITAL COMPANY

February 14, 2008

Charles Worden Jr., Vice President
Sales and Training Manager
SafeBlood Technologies, Inc.
1100 N. University Avenue
Little Rock, AR 72207

Dear Charles:

Regency Hospitals of Arkansas have been working with the SafeBlood graft since 2005. No other wound treatment modality has been as effective.

The SafeBlood graft procedure and protocol have been very successful in treating chronic ulcers, dehiscence and wounds that have been present for extended periods. The clinical outcomes our patients have received have been observed by physicians in several states and they are now referring their chronic non-healing wound patients to our facility for this procedure.

One of the more striking features of using the SafeBlood graft is the cost savings to the patient, hospital and third party payor. One study that we did showed a 60% cost savings over the use of conventional wound care related equipment. Our patients have experienced more rapid closure of their wounds and have been able to be discharged sooner.

The clinical team at Regency Hospitals of Arkansas along with SafeBlood has experienced phenomenal success in healing wounds that did not respond to any other treatment. We would be happy to discuss the clinical outcomes our patients have had with other case managers or third party payors.

Sincerely,

Mike McLean

Mike McLean, R.N.
Chief Executive Officer

MM/sr

1125 North College Avenue • Fayetteville, AR 72703 • Phone: (479) 713-7000 • Fax: (479) 713-7003

STATE AND PUBLIC SCHOOL LIFE AND HEALTH INSURANCE BOARD – QUALITY OF CARE COMMITTEE

OCTOBER 10, 2017

Meeting Objectives

Discover MiMedx as a leading Biopharmaceutical Company

Demonstrate value of patented differentiation that leads to positive patient outcomes

Dialogue regarding alignment with the Emerging Therapies Act Pilot

Discuss the merits of amniotic tissue based technology

MiMedx

MiMedx® Overview

MiMedx® is a biopharmaceutical company developing, manufacturing and marketing regenerative biologics utilizing human placental allografts for multiple sectors of healthcare.

"Innovations in Regenerative Medicine" is the framework behind our mission to provide physicians with products and tissues to help the body heal itself.

Literature shows amniotic membrane enhances healing:[1, 2, 3]

- ✓ Immunologically privileged
- ✓ Modulates inflammation
- ✓ Reduces scar tissue formation
- ✓ Contains essential growth factors

1,000,000 allografts distributed to date with **no adverse reactions** attributed to our products†

†As of September 1, 2017

>40 Peer Reviewed, Published Scientific and Clinical Studies

[1]Litwiniuk M1, Grzela T "Amniotic membrane: New concepts for an old dressing." Wound Repair Regen. 2014 Jul;22(4):451-6. (22)4. 2014 Jul. pp 451-6.
[2]Akle, C; Adinolfi, M; Welsh, K; Leibowitz, S; and McColl, I "Immunogenicity of Human Amniotic Epithelial Cells after Transplantation into Volunteers." The Lancet. (318)8254. 7 November 1981. pp 1003-1005.
[3]Parolini, O et alHuman Term Placenta as a Therapeutic Agent: From the First Clinical Applications to Future Perspectives, in Human Placenta: Structure and Development, Circulation and Functions. Pregnancy and Infants: Medical, Psychological and Social Issues Series. Nova Biomedical Books, 2010.

FDA Regulatory Classifications for Tissue, Cell Based Products, and Other

351 HCT/Ps (Human Cell Tissue/ Products)	Human Tissue (Allograft) or Cells	May be more than minimally manipulated, and/ or may or may not be for homologous use. Pre-market clearance or approval required. Requires FDA Current Good Manufacturing Practice (cGMP).
361 HCT/Ps (Human Cell Tissue/ Products)	Human Tissue (Allograft) or Cells	Minimally manipulated, intended for homologous use. No clearance or pre-market approval required. Requires FDA Good Tissue Practices (GTP)
510(k) Clearance	Medical Device (Example: decellularized human dermis, xenografts, collagen dressings, bovine filler)	Requires FDA Substantial Equivalence, shorter submission and less required verses PMA. Based on predicate device. Requires FDA Current Good Manufacturing Practice (cGMP)
Premarket Approval (PMA)	Medical Device (Example: human living skin substitutes, bone substitute)	Requires extensive FDA Pre-Market approval process, including comprehensive clinical trials. Requires FDA Current Good Manufacturing Practice (cGMP)
Biologic License Application (BLA)	Biological product (Example: Section 351 HCT/Ps, cell products, such as those containing hematopoietic progenitor cells, vaccines, and blood components)	Requires extensive FDA Investigational New Drug (IND) and BLA approval process, including comprehensive pre-clinical and clinical trials. Requires compliance to FDA Current Good Manufacturing Practice (cGMP)
New Drug Application (NDA)	(Example: living stem cells non-autologous, second degree relative, or autologous stem cells that are expanded in the laboratory)	Requires extensive FDA Investigational New Drug (IND) and BLA approval process, including comprehensive pre-clinical and clinical trials. Requires FDA Current Good Manufacturing Practice (cGMP)

United States Pharmacopeia Monograph

USP and the National Formulary (NF) are the public pharmacopeia standards for drug substances, dosage forms, compounded preparations, excipients, dietary supplements and medical devices.

- The "Tissue Human Amnion Chorion Membrane Dehydrated" USP Monograph outlines the definition of the products covered, as well as the specification, packaging, storage, and labeling requirements with which a product must conform. Validated tests, procedures for the tests, and acceptance criteria make up the specification.
- All products must have the stipulated strength, quality, and purity if they expect to conform to the requirements of this Monograph.

MiMedx dHACM is the first human amnion/chorion dehydrated membrane to meet requirements of the United States Pharmacopeia (USP) monograph.

Source: http://phx.corporate-ir.net/phoenix.zhtml?c=213465&p=irol-newsArticle&ID=2219390

Source of MiMedx PURION® Processed Amnion and Chorion Membranes

LIVE BIRTH Via Planned C-section

Microbiological and Viral Testing of Donor Tissue and Blood

purion® process

PURION® Processed Amnion/Chorion Grafts and injectables

MiMedx

MiMedx is a Regenerative Medicine Company with an Extensive Product Portfolio

Sheet dHACM:
Flagship bioactive Amnion/ Chorion grafts containing 226 proteins and growth factors with proven enhanced healing power

- Smaller wounds
- Various surgical applications
- As a barrier membrane

Micronized dHACM:
Same dHACM in an injectable configuration

- Smaller wounds
- Various surgical applications

Umbilical Cord Products:
Provide a protective environment for the healing process.

- Smaller wounds requiring a graft that can hold a stitch
- Longer site coverage timeframe
- When a thicker graft is needed for coverage/ padding

Placental Based:
Our NEW bioactive placental tissues containing Growth Factors found in PURION® Processed tissues that modulate the activity of the recruited cells to enhance healing **+** an extracellular matrix (ECM) that provides a scaffold for recruited cells to attach, populate, and proliferate.

- Larger and uneven surface areas >25cm^2
- NOT injectable

CLINICAL EFFICACY
PATIENT OUTCOMES

MiMedx

Diabetes in Arkansas:

We are focused on the 364,000 people in Arkansas who live with diabetes*

- Approximately 363,781 people in Arkansas, or 14.8% of the adult population, have diabetes.
- Every year an estimated 25,000 people in Arkansas are diagnosed with diabetes.
- People with diabetes have medical expenses approximately 2.3 times higher than those who do not have diabetes.
- Total direct medical expenses for diagnosed and undiagnosed diabetes, prediabetes and gestational diabetes in Arkansas was estimated at $2.3 billion in 2012.
- In addition, another $798 million was spent on indirect costs from lost productivity due to diabetes.

*American Diabetes Association
http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/arkansas.pdf

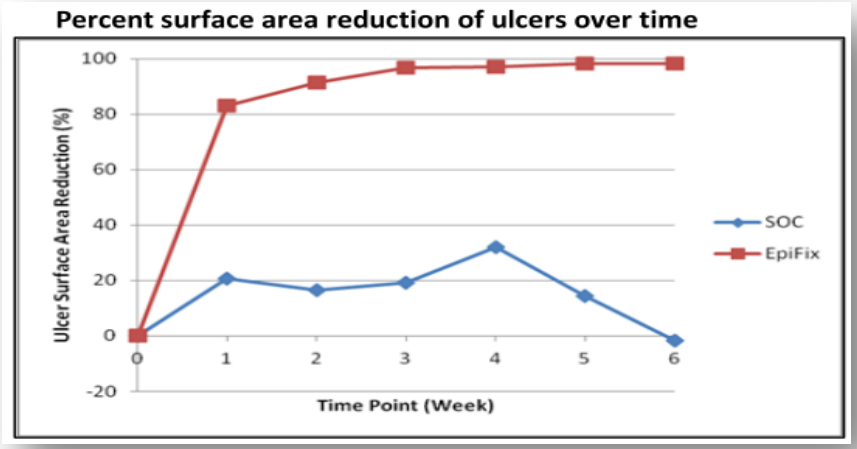
Diabetic Patients with Non-healing Wounds

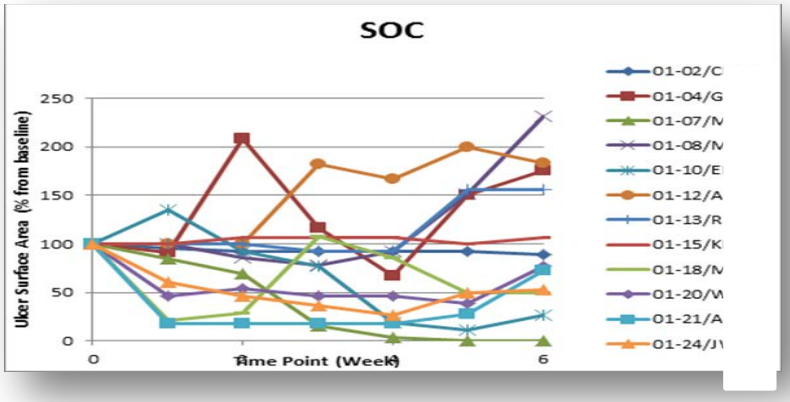
- Mean one year cost from a health care public payer perspective was $44,200 for diabetic foot ulcer (DFU), and $11,000 for leg ulcer (LU)[1]
- 33% of the cost of diabetes directly linked to the care of lower extremity complications[2,3]
- The majority of non-traumatic lower limb amputations can be avoided with education, monitoring and early treatment. [4]

[1]Chan; "Cost-of-illness studies in chronic ulcers: a systematic review." Journal of Wound Care Vol 26. No.4, April 2017
[2]Rogers LC, Lavery LA, Armstrong DG. The right to bear legs – an amendment to healthcare: How preventing amputations can save billions for the US health-care system. J Am Podiatr Med Assn 2008;98:3-5
[3]Driver VR, Lavery LA. The costs of the diabetic foot: The economic case for the limb salvage team. J Vasc Surg
[4]American Diabetes Association http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/arkansas.pdf

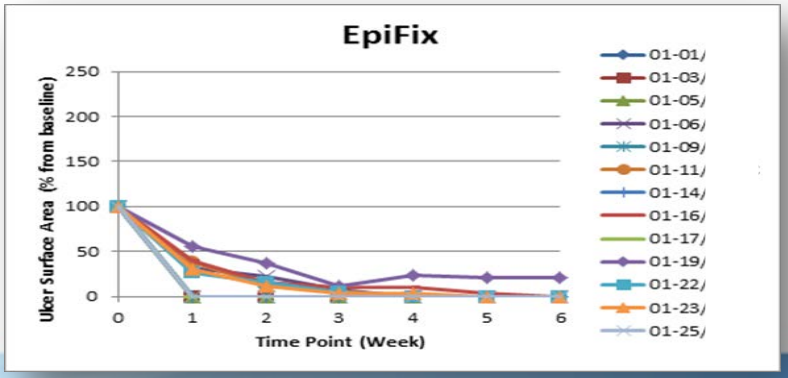
Diabetic Foot Ulcer Randomized Clinical Trial (RCT) Outcomes

- EpiFix® with Standard of Care vs. Standard of Care alone
- 92% healed in 6 weeks compared to 8% for control group
- Average of ***2.5*** grafts to closure





Ulcers healed	SOC (n=12)	EpiFix® (n=13)	P value
4 Weeks	0 (0%)	10 (77%)	<0.001
6 Weeks	1 (8%)	12 (92%)	<0.001

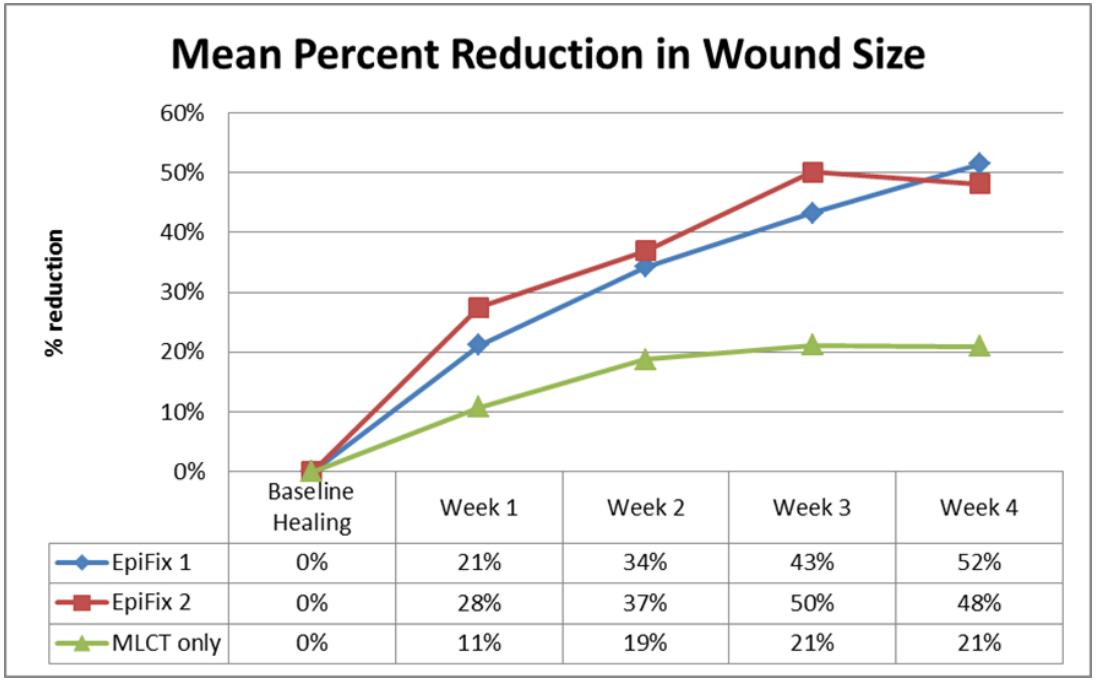


Zelen CM, Serena TE, Denozière G, Fetterolf DE. A prospective randomized comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. Int Wound J. 2013 Oct;10(5):502-7.

MiMedx

Multi-Site RCT For Venous Leg Ulcer Wound

Study completed across 8 centers indicated that both one application and two applications are more effective than standard of care.



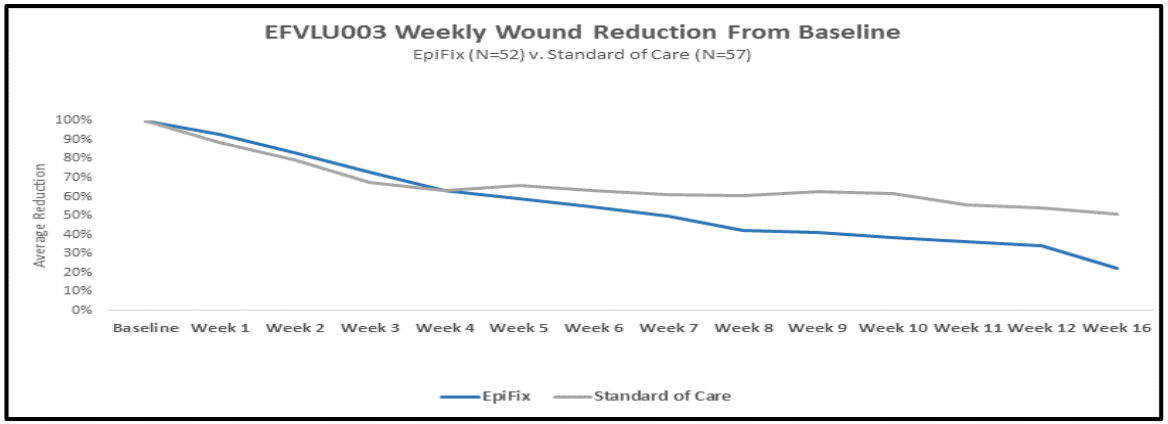
	Baseline Healing	Week 1	Week 2	Week 3	Week 4
EpiFix 1	0%	21%	34%	43%	52%
EpiFix 2	0%	28%	37%	50%	48%
MLCT only	0%	11%	19%	21%	21%

Mean percent reduction in wound size during the 4-week study period

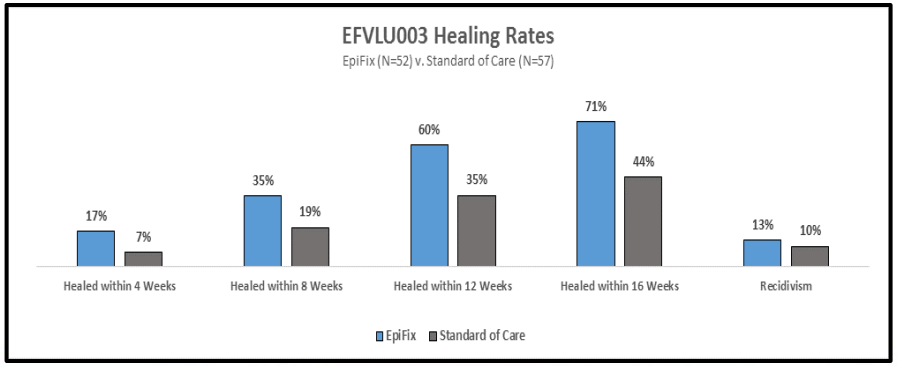
Serena TE, Carter MJ, Le LT, Sabo MJ, DiMarco DT, and the EpiFix Study group. "A Multi-center Randomized Controlled Clinical Trial Evaluating the Use of Dehydrated Human Amnion/Chorion Membrane Allografts and Multi-layer Compression Therapy vs. Multi-layer Compression Therapy Alone in the Treatment of Venous Leg Ulcers." Wound Repair Regen. (22)6. November-December 2014. pp 688-693.

Venous Leg Ulcer Randomized Clinical Trial (RCT) Outcomes

- **EpiFix® with Standard of Care vs. Standard of Care (SOC) alone**
- **EpiFix healed 60% vs. SOC 35% at 12 weeks**
- **EpiFix healed 71% vs 44 % at 16 weeks**



Ulcers healed	SOC (n=57)	EpiFix® (n=52)	P value
12 Weeks	20 (35%)	31 (60%)	0.0128
16 Weeks	25 (44%)	37 (71%)	0.00625



"A Multicenter Randomized Controlled Trial Evaluating the Efficacy of Dehydrated Human Amnion/Chorion Membrane (EpiFix) Allograft for the Treatment of Venous Leg Ulcers," was authored by Christian Bianchi, MD, FACS; Shawn Cazzell, DPM, FACFAS; Dean Vayser, DPM, FACFAS; Alexander M. Reyzelman, DPM, FACFAS; Hasan Doslouglu, MD, FACS; Gregory Tovmassian, DPM; and the EpiFix VLU Study Group of Delores Farrer, DPM, MBA, CWS; Elisa Taffe, MD; Lacey Loveland, DPM; David O'Connor, MD; Marc D. Baer, DPM, FACFAS; and Sara Dahle, DPM, MPH

We believe using EpiFix in combination with existing Standard of Care treatments, can enhance the treatment and safe healing of chronic, non-healing lower extremity wounds.

Safety and Testing

Major Process Step	Criteria that Ensures Tissue Safety
Donor Screening	Performed per 21 CFR 1271 domestically.
Infectious Disease Testing	Negative results for all FDA approved and **CLIA Certified** tests that includes HIV, Hepatitis B and C, Syphilis, and Human T-cell lymphotropic virus (HTLV)
PURION® Process	A validated process with proven Bacterial/Spore reduction capabilities that range from 1.4 –5.6 Logs
Terminal Sterilization of all grafts	A validated process per **ISO 11137** standards providing at least a 10^{-6}SAL with irradiation dose monitoring linked to the release of every tissue distributed
Double sterile barrier product packaging	A validated process per FDA recognized **ASTM D4169** standards that ensures sterility is maintained post distribution

Completed Level I Studies

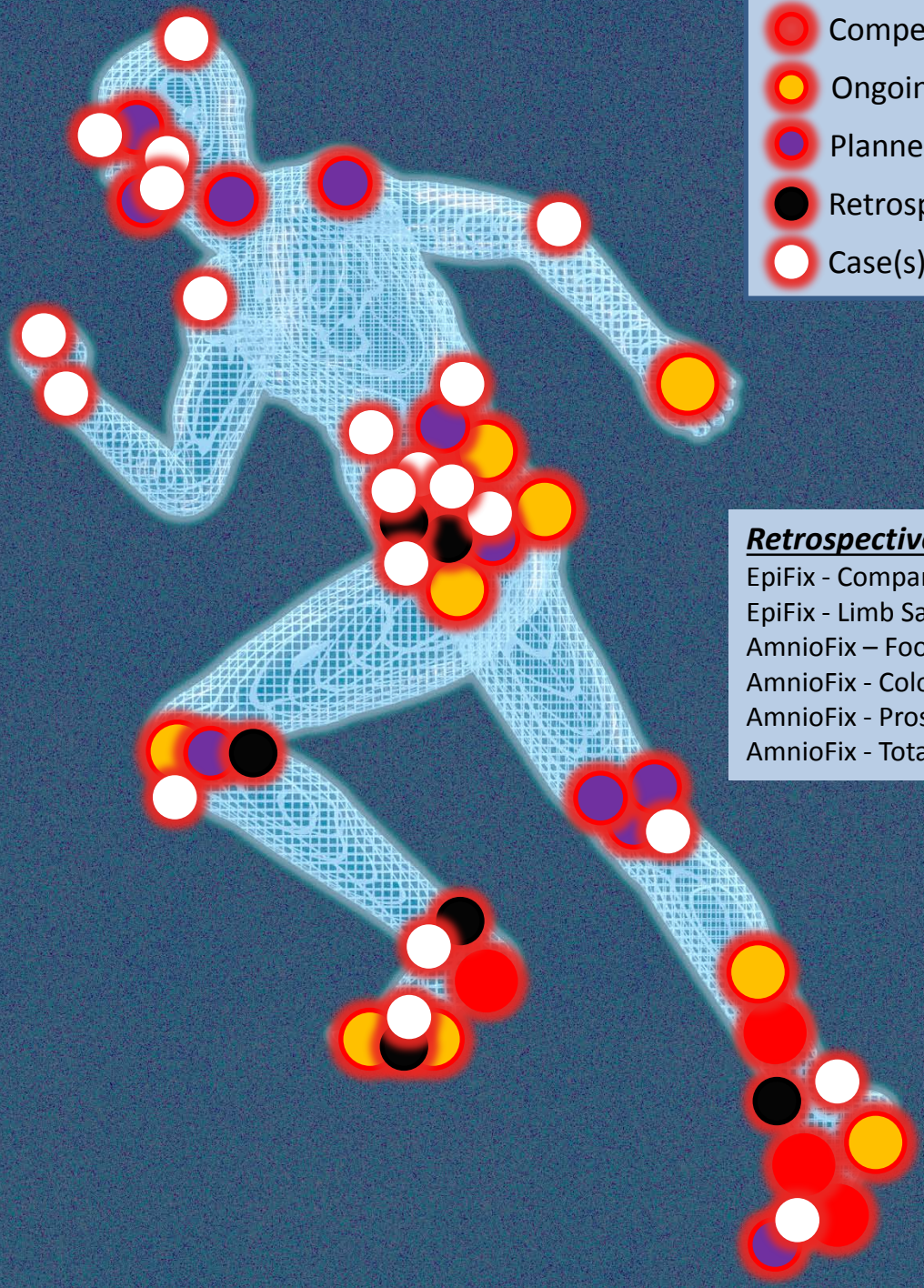
EpiFix® - Diabetic Foot Ulcer
EpiFix - Comparative DFU Study
EpiFix - Venous Leg Ulcer
AmnioFix® - Plantar Fasciitis

Ongoing Level I Studies

EpiFix - Diabetic Foot Ulcer
EpiFix - Pressure Ulcers
EpiFix - Venous Leg Ulcer
AmnioFix - Spine
AmnioFix - Prostatectomy
AmnioFix - Plantar Fasciitis
AmnioFix - Achilles tendonitis
EpiCord® - Diabetic Foot Ulcer
OrthoFlo® - Ortho Knee
EpiBurn® - Burns

Planned Level I Studies

EpiFix - Adult Facial Burns
EpiFix - Pediatric Facial Burns
AmnioFix - ACL Repair
AmnioFix - Head and Neck
AmnioFix - Partial Nephrectomy
AmnioFix - Knee OA
AmnioCord® - Hallux Rigidus
AmnioCord - Supraspinatus Repair
OrthoFlo - Early OA
OrthoFlo - Gluteal Tendinopathies
OthroFlo - Knee (1)
OrthoFlo - Knee (2)



Competed Level I Studies
Ongoing Level I Studies
Planned Level I Studies
Retrospective Studies
Case(s)/ Series

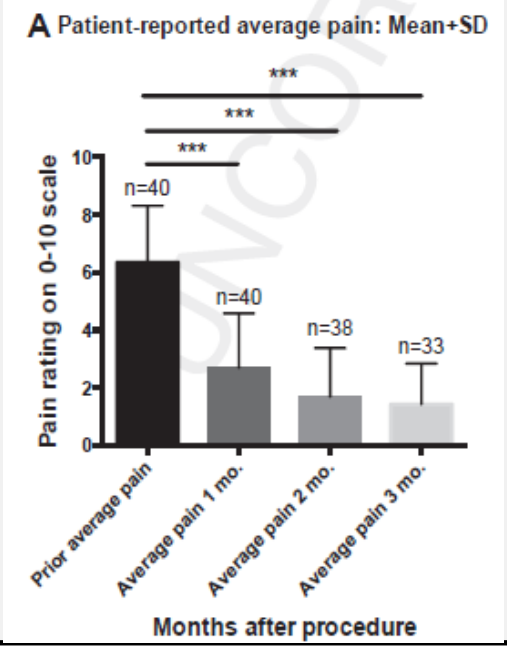
Retrospective Studies

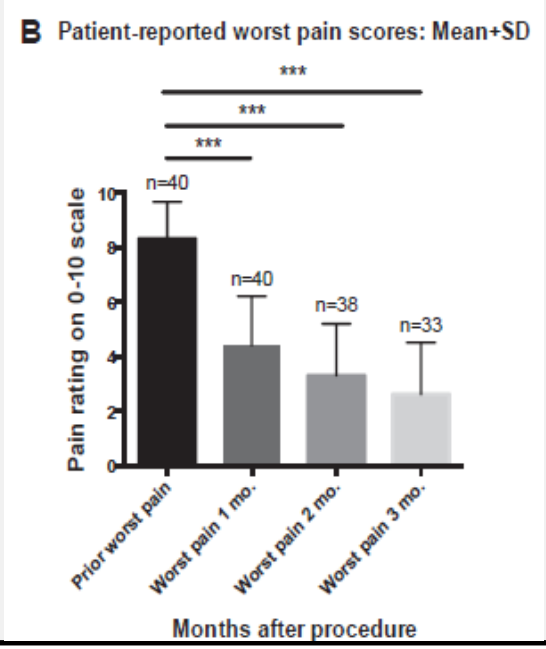
EpiFix - Comparative Effectiveness
EpiFix - Limb Salvage
AmnioFix – Foot and Ankle
AmnioFix - Colon Resection
AmnioFix - Prostatectomy
AmnioFix - Total Knee Arthroplasty

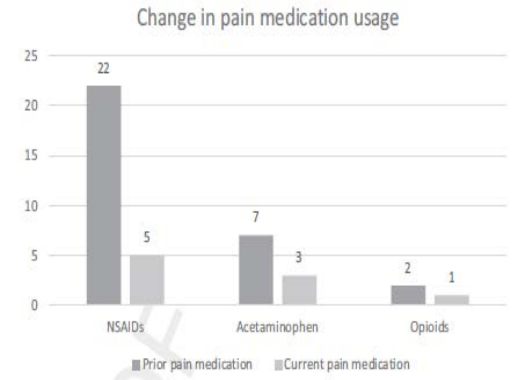
AmnioFix Injectable Data

Multiple cases/studies completed or underway

Gellhorn and Han: ***The Use of Dehydrated Human Amnion/Chorion Membrane Allograft Injection for the Treatment of Tendinopathy or Arthritis: A case Series Involving 40 Patients****







*Physical Medicine and Rehabilitation. 2017 doi10.1016/j.pmrj.2017.04.011

MiMedx

SUMMARY

MiMedx Value Proposition

- ✓ **Promotes Healing**- Scientific data shows dHACM ability to draw stem cells toward the site to modulate inflammation, reduce pain and accelerate healing
- ✓ **Superior Published Clinical Data** - 11 Randomized Control Trials (RCTs) showing statistical significance
- ✓ **Proprietary PURION Process** preserves 226+ different growth factors
- ✓ **Patient Safety -** Terminal Sterilization
- ✓ **USP Monograph** - Rigor in processes ensure consistent product quality
- ✓ **Storage and Ease of use** - Ambient conditions with 5 year shelf life

MiMedx®

THANK YOU