DataBiologics

An overview of

Regenerative Treatments for Orthopedic Conditions

2021 Outcomes Report

Contents

DataBiologics

OUR MISSION is to empower an
international network of physicians,
researchers and patients with an outcomes
data registry in order to pioneer innovative
and effective treatments for patients with
orthopedics conditions.

OUR VISION is to help reshape the
landscape of orthopedics by using real-
world data to allow physicians, patients
and industry leaders to determine the
safety, efficacy and cost effectiveness of
orthobiologic therapies.

Foreword

At DataBiologics, our ambitious goals start with physicians and patients. Since our inception in 2018, we've worked closely with our colleagues in the field to build an organization that meets the need for data in regenerative medicine. This document was formulated with the intent of sharing our progress thus far and to be used as a quick overview for patients, physicians and researchers.

Regenerative medicine within orthopedics is an innovative field and we are hopeful that current and prospective patients find this information useful in better understanding alternative treatment options for both acute and chronic orthopedic conditions.

DataBiologics aims to collect patient-centered data from participating providers in order to obtain valuable information about the potential of different forms of regenerative therapies. Our mission is for the analysis of this data to assist in the selection of appropriate treatment procedures from the perspectives of both patients and physicians.

As you read this report, we hope you will gain an understanding of the progress regenerative medicine has achieved, as well as recognize the dire need for more real-world evidence in order to shape a better orthopedic landscape. Most importantly, we hope this resource will demonstrate our efforts to provide a tool for physicians that improves the quality of patient care and outcomes.

About DataBiologics

DataBiologics provides physicians a complete patient data collection service to determine the safety and efficacy of orthobiologic procedures. We provide a simple, user friendly, and practical product to assist doctors in collecting real-world evidence using validated Patient Reported Outcomes (PROs). This real-world data will allow for more informed treatment decisions and better patient care.

Founded by leading physicians

DataBiologics was founded by three world-renowned physicians in the field of regenerative medicine. They bring years of expertise as practicing doctors who have published dozens of papers, led clinical trials and lectured on the topics of sports medicine, pain management and regenerative medicine.
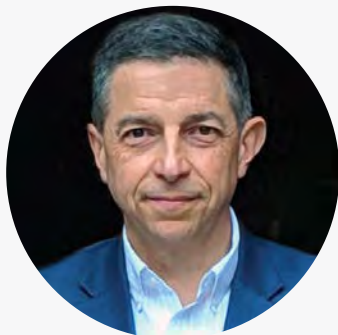
Gerard Malanga, MD
- Board-certified physician specializing in Physical Medicine & Rehabilitation, Sports Medicine, and Pain Medicine
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- Founder of New Jersey Regenerative Institute

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- Medical Director of New Jersey Regenerative Institute
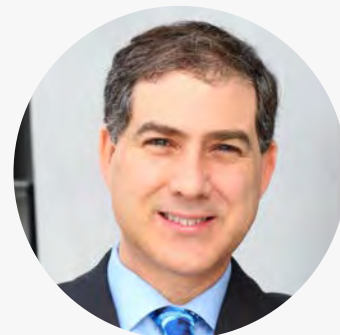
Christopher Rogers, MD
- Board-certified physician specializing in Physical Medicine & Rehabilitation
- Founder of San Diego Orthobiologics Medical Group
- Medical Director of Personalized Stem Cells, Inc.

Scientific Advisory Board

Steve Sampson, DO, founder of Orthohealing Method and The Orthobiologic Insitute (TOBI)
Ken Mautner, MD, Director of Sports Medicine at Emory Healthcare
William Murrell, MD, Chief Medical Officer for Emirates Healthcare in Dubai

The Promising Future of Orthobiologics

Orthobiologic treatments, commonly referred to as "Regenerative Medicine," are innovative treatment options for patients seeking relief from the pain and limitations of common orthopedic conditions. Broadly, Regenerative Medicine refers to the use of a patient's own tissues (blood, bone marrow and adipose) as a source for medical treatments and therapies. These autologous cells release various growth-factors that have been found to assist in the healing of torn tendons, tendinitis/tendinosis, muscle injuries, arthritis-related pain, and joint injuries.[1]

The potential to treat conditions, such as osteoarthritis, provides patients with an alternative to complicated, expensive and invasive surgeries. By 2030, there are expected to be over 1.28 million total knee replacement surgeries in the U.S.[2] While surgery is sometimes necessary, regenerative medicine treatments offer alternatives that help to fill the treatment gap and allow for reduction in pain and improvement in function.
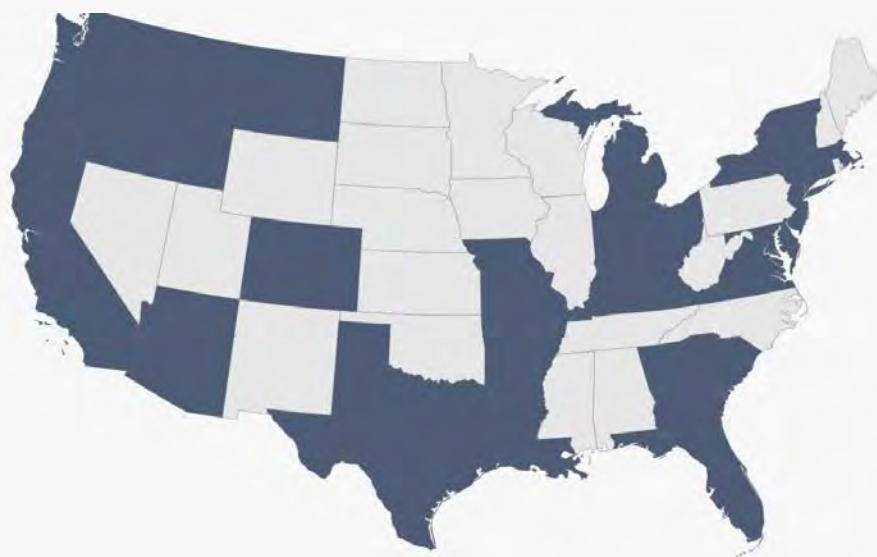
The Need for Real-World Data

This exciting and innovative new field of medicine promises tremendous benefits, but additional data is necessary to understand and validate the true potential. The progression of the field must be rooted in real-world evidence. In recent years, certain regenerative medicine treatments have become widely accepted at some of the most prestigious medical centers in the country. In numerous clinical trials they have been shown to be both safe and effective. Although there is growing research demonstrating safety and efficacy, there continues to be a need for patient-centered data to encourage a high standard of care.

The collection of real-world data directly from patients in a standardized fashion is crucial for maximizing good outcomes. While clinical trials can provide a foundation for the efficacy of a particular treatment, they are performed using very limited patient inclusion and take a great deal of time and money to complete. Real-world evidence can provide a much deeper and broader understanding of the best treatments for specific conditions and patients. This data will empower physicians and their patients to make informed medical decisions based on data produced in their own medical clinic, rather than solely opinion or published research.

Creating the largest orthobiologics outcomes network in the world

65
Physicians

43
Clinics

24
States

Some of our current members

BOSTON SPORTS & BIOLOGICS

ORTHOHEALING CENTER

San Diego Orthobiologics Medical Group

NEW JERSEY REGENERATIVE INSTITUTE

Why Patient Reported Outcomes?

Patient Reported Outcomes (PROs) engage patients directly in the care process. Through PRO collection, patient feedback becomes a crucial part of discovering the success of treatments, which helps dictate future care decisions. Particularly with regenerative procedures, physicians face the challenge of proving efficacy of their procedures using real-world evidence. At their core, PROs reflect the essence of care and why patients seek treatment: to reduce pain and improve their quality of life. That is why patient reported outcomes are becoming increasingly valued in medical research, and why we have established this platform to make the task easier for both physicians and patients. Ultimately, PRO data is a tool for providers to assess the patient's outcomes following a procedure from his or her own perspective.

What we track

Patient Reported Outcomes	Body Parts	Treatments
Adverse Events	Ankle	Adipose (MFAT)
FAAM	Cervical Spine	Bone Marrow
HOOS Jr.	Elbow	Hyaluronic Acid
KOOS Jr.	Foot/Toes	Perinatal Tissue
Neck Disability Index	Hip	Platelet Lysate
Oswestry Disability Index	Knee	Platelet Poor Plasma (A2M, PPC)
Pain Scale (NPRS)	Lumbar Spine	Platelet Rich Plasma (PRP)
PHQ-4	Pelvis	Prolotherapy
QuickDASH	Shoulder	Shock Wave Therapy (ESWT/EPAT)
VISA-A	Thoracic Spine	Sonex
	Wrist/Hand	Tenex

How is this information used?

The data collected by DataBiologics is used to evaluate outcomes of specific procedures individually and cumulatively, to look at trends over time and across different sites, and to track patient performance at large-scale. Patient reported outcomes allow clinicians to:
- Analyze changes in the patient's condition throughout their individual journey
- Engage patients in their care and allow them to gain a better understanding of their improvement
- Demonstrate the quality of care a physician is providing and its effectiveness
- Gain broader insight and compare efficacy of treatments and physician success
- Improve clinical decision-making based on data insights

Privacy

We uphold patient privacy at the highest standard to protect the confidentiality of all patient information collected. All data sent over the network is encrypted, and follows the details listed in our Privacy Policy. DataBiologics adheres strictly to all HIPAA guidelines. Data is never shared without patient consent and when shared patient identifiers are removed.

Regenerative Treatments

Platelet Rich Plasma (PRP) is a procedure that uses concentrated platelets from a patient's own blood to harness the body's ability to heal.[3] Platelets are small cells in the blood that help prevent bleeding, but also contain large reservoirs of growth factors known to accelerate tissue repair and regeneration. By utilizing the increased concentration of growth factors present in PRP, studies show we can stimulate healing in tendons, ligaments and bone as well as promote the growth of new blood vessels essential for health.[4,5,6]

Adipose Cell Therapy, utilizes adipose (fat) tissue that functions to cushion and support the areas of injury and can also help reduce inflammation and scarring to facilitate healing of tissues such as tendon and cartilage.[7] Fat is very rich in regenerative cells, growth factors, and cytokines. The adipose is typically extracted from the abdomen or thighs. Adipose cell based procedures have been shown to be especially effective for areas with soft tissue defects (partial rotator cuff tears, patella tendon tears, labral tears, meniscal tears, and knee arthritis).[8,9,10]

Bone Marrow Aspirate Concentrate (BMAC) is a non-surgical regenerative procedure helping accelerate healing in patients suffering from orthopedic conditions, such as osteoarthritis and cartilage injuries.[11,12] Bone marrow is obtained through aspiration from the back of the pelvis area. Under certain conditions, regenerative cells from the bone marrow are capable of replicating into various types of tissue, allowing for a robust, concentrated mixture of regenerative cells following extraction.[13] This concentrate contains various cells and proteins which modulate pain and inflammation and can facilitate tissue healing such as tendon, cartilage and bone repair.[14]

Non-biologic emerging therapies

Tenex Health TX® utilizes minimally invasive technology to remove damaged or degenerated tissue at the injured site with the assistance of ultrasound imaging.[15] Rather than having a surgical or arthroscopic procedure, Tenex can be performed by the physician in the office using local anesthetic and has shown benefits in improving pain levels and recovery in patients with chronic tendon disease. Patients can expect to return to their normal activities approximately 6-8 weeks following treatment.[16]

The **SX-One Microknife®** from Sonex Health is a minimally invasive procedure used to treat patients with carpal tunnel syndrome. The Microknife® is used to perform a carpal tunnel release, and can be performed by the physician in the office using local anesthetic. Unlike traditional surgery, this procedure is associated with a quicker recovery time, smaller incision scar, and faster pain relief.[17]

Extracorporeal Shockwave Therapy (ESWT) is a non-invasive treatment that utilizes an acoustic wave to promote regenerative processes of bones, tendons, and soft tissues and accelerate tissue repair and cell growth.[18] ESWT is used across the world and has been shown to help patients with chronic pain or chronic tendinopathy.[19] Typically, the treatment is once per week for 3-6 treatments.

Global Outcomes Overview

To compare the efficacy of regenerative procedures, standardized patient reported outcomes measures were used. The data presented below is from medical practices participating in the DataBiologics network.
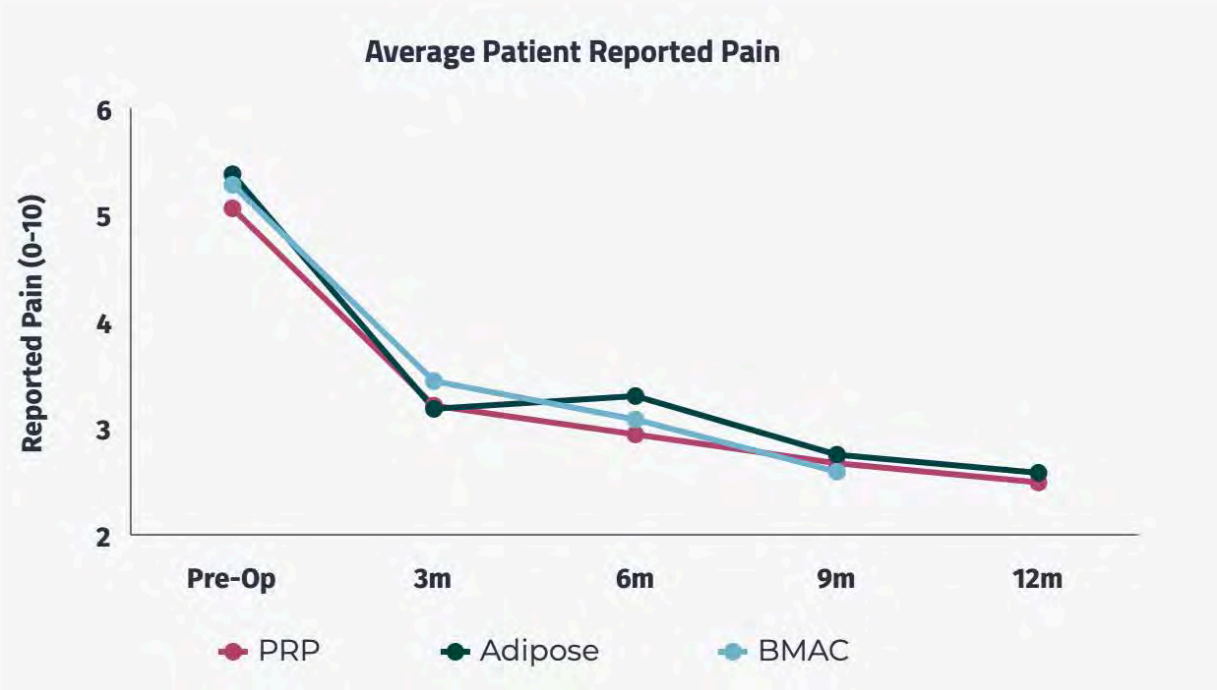
The above line chart represents the mean patient reported pain level (across all body parts) at each time point and does not account for those lost to followup. Only patients who reported pain >2/10 at baseline were included on this graph. Individual patient characteristics such as age, medical condition and disease severity are not represented.

The data presented throughout this report is not meant to affirm or reject any medical treatments. The purpose of this report is to provide a general overview of the outcomes of regenerative treatments solely within the DataBiologics network. All data reported is an average of outcomes data from the approx. 3,200 patients enrolled in DataBiologics across its member clinics. There are many nuances that impact the outcomes of any medical treatment, especially in regenerative medicine. Therefore, more data is needed with deeper analysis for a better understanding of their effectiveness. Each patient and diagnosis is unique. This data is for educational purposes only and to demonstrate some of the ways patient reported outcomes can be used to study orthobiologic treatments. The content of this report is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical condition.
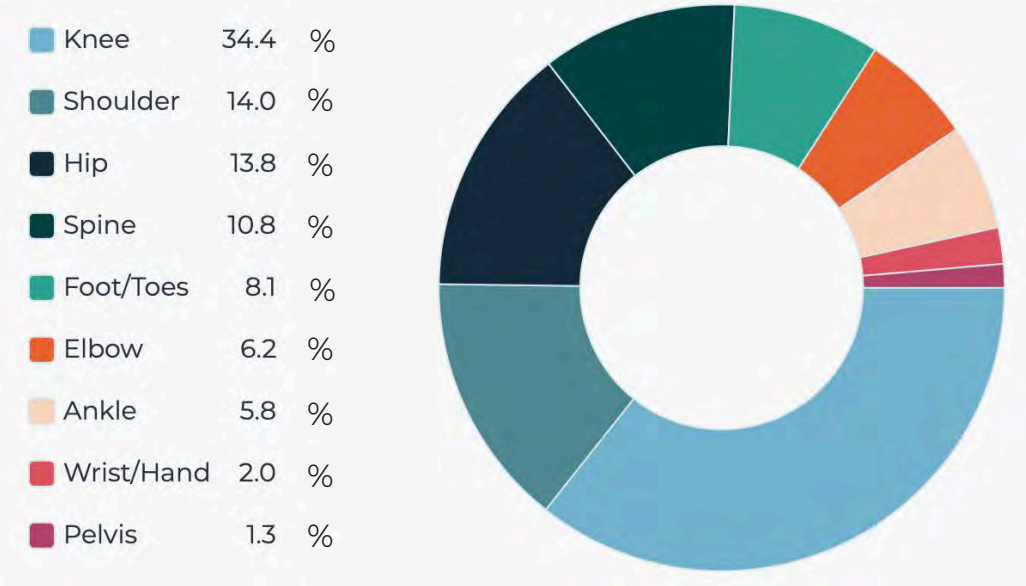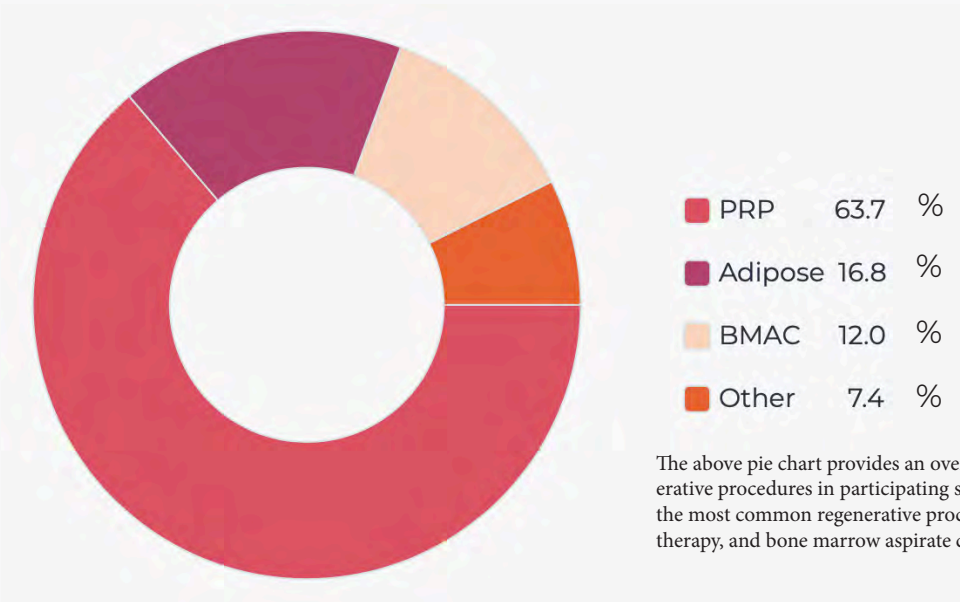
Data Overview

9,450
Assessments Completed

3,275
Patients Enrolled

Average Age: **54**
Average BMI: **26.8**

Knee	34.4	%
Shoulder	14.0	%
Hip	13.8	%
Spine	10.8	%
Foot/Toes	8.1	%
Elbow	6.2	%
Ankle	5.8	%
Wrist/Hand	2.0	%
Pelvis	1.3	%

The above pie chart illustrates the most commonly treated body parts from DataBiologics-participating sites. Data collected reveals that patients who underwent regenerative procedures are most often treated for knee, shoulder, and hip conditions.

PRP	63.7	%
Adipose	16.8	%
BMAC	12.0	%
Other	7.4	%

The above pie chart provides an overview of the types of regenerative procedures in participating sites. Data identifies PRP as the most common regenerative procedure, followed by adipose therapy, and bone marrow aspirate concentrate.

Platelet Rich Plasma (PRP)

The Research

The use of platelet rich plasma (PRP) for treating orthopedic conditions has risen over the past decade. Estimates suggest that approximately 86,000 athletes are treated with PRP annually in the United States.[20] The safety of PRP has been widely supported in published scientific studies, but when it comes to effectiveness, there have been conflicting conclusions.[21] In recent years, more refined PRP methodology combined with a better understanding of the potential uses of the treatment have led to research demonstrating the effectiveness for PRP in treating osteoarthritis and tendon injuries of the elbow (tennis and golfers elbow).[4,5]

High-Quality Evidence

Supports the use of PRP injection for **lateral epicondylitis** and PRP for **knee osteoarthritis**.[22,23]

Strong Evidence

Supports the use of PRP injection for **patellar tendinopathy** and PRP injection for **plantar fasciosis**.[22]

Emerging Evidence

For **rotator cuff tendinopathy**, **osteoarthritis of the hip**, or **high ankle sprains**.[22]

PRP Systems

World-wide, more than 50 companies have manufactured medical devices for the collection, processing and administration of PRP. The various biologic products created with these devices varies widely from one system to another and have not been fully validated in the published medical literature. DataBiologics currently tracks patient outcomes with the following systems:

- EmCyte PurePRP®
- Arthrex ACP®
- Endoret® (BTI)
- Tropocells®
- Xcell®
- Eclipse®

Our Outcomes Data

73%
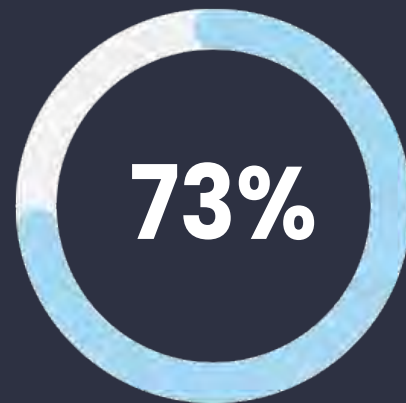
of patients experienced a meaningful reduction in pain within 12-months following treatment

Average patient reported pain (0-10) following PRP treatment across all conditions

Adipose Tissue Therapy

The Research

Autologous adipose tissue has become an increasingly validated source of cells and proteins in the treatment of various orthopedic conditions.[24] In general, adipose treatments are used for patients with more severe conditions. Adipose tissue is a good source of naturally occurring regenerative cells particularly due to its abundance and easy access. In addition, it can provide cushioning and help to fill structural defects.[25] Although clinical trials of adipose tissue based treatments are limited, recent studies have shown great potential to reduce pain and inflammation, as well as support the native cartilage tissue in patients with knee osteoarthritis.[10]

Strong Evidence

Supports the use of adipose injections for **knee osteoarthritis**.[10]

Emerging Evidence

For **rotator cuff and labral tears**, **osteoarthritis of the hip**.[9,26]

Adipose tissue processing methods

There are several different methods for processing adipose tissue. These devices must be FDA compliant and assure that the processing does not exceed "minimal manipulation" of the adipose tissue. DataBiologics currently tracks patient outcomes with the following systems:

- Lipogems®
- Puregraft®
- Tulip Nanofat™
- Intellifat™

Our Outcomes Data

70%

of patients experienced a meaningful reduction in pain at 12-months following treatment

Average patient reported pain (0-10) following adipose tissue based treatment across all conditions

Bone Marrow Aspiration Concentrate

The Research

In clinical studies, bone marrow aspiration concentrate (BMAC) injections have been evaluated as an alternative to knee, hip or spine surgery.[27] Bone marrow cells and platelets along with cytokines and growth factors in the bone marrow, may help in tissue healing.[14] In addition, BMAC has been shown to decrease inflammation, assist with wound healing and repair non healing bone or cartilage injuries.[11,12,14] Although BMAC has shown promising results, much like PRP, more research will be necessary to fully understand the benefits of this emerging treatment.

....

Strong Evidence

Supports the use of bone marrow injection for **knee osteoarthritis** and **low back pain**.[11,28]

....

Emerging Evidence

For **degenerative meniscal tear**, or **hip capsular injury, intervertebral disc repair** and **patellar tendinopathy**.[29,30,31]

BMAC processing methods

There are several different methods for extracting and processing BMAC. Many physicians also have their own proprietary methods. DataBiologics currently tracks patient outcomes with the following systems:

- Arthrex Angel®
- EmCyte PureBMC®
- Celling® ART
- ThermoGenesis PXP®

Our Outcomes Data

61%

of patients experienced a meaningful reduction in pain at 12-months following treatment
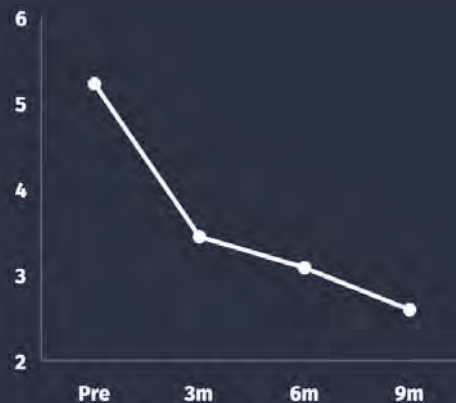
Average patient reported pain (0-10) following BMAC treatment across all conditions

Report for Knee Pain

Knee osteoarthritis is one of the most commonly treated orthopedic conditions. This report demonstrates the potential effectiveness of PRP and adipose tissue based treatments for this indication by aggregating patient-reported outcomes data from the clinics across the DataBiologics platform.

Average Knee Pain (NPRS)

Average Knee Function (KOOS Jr.)
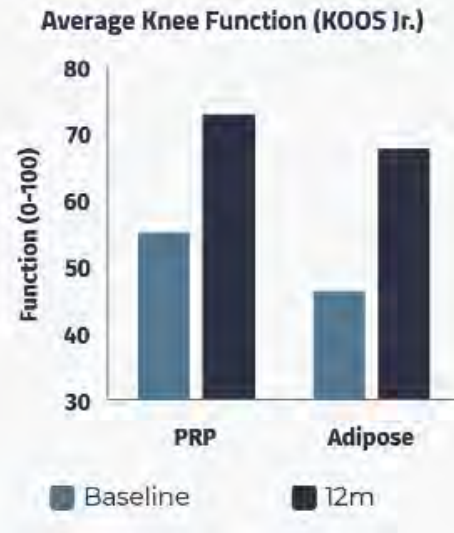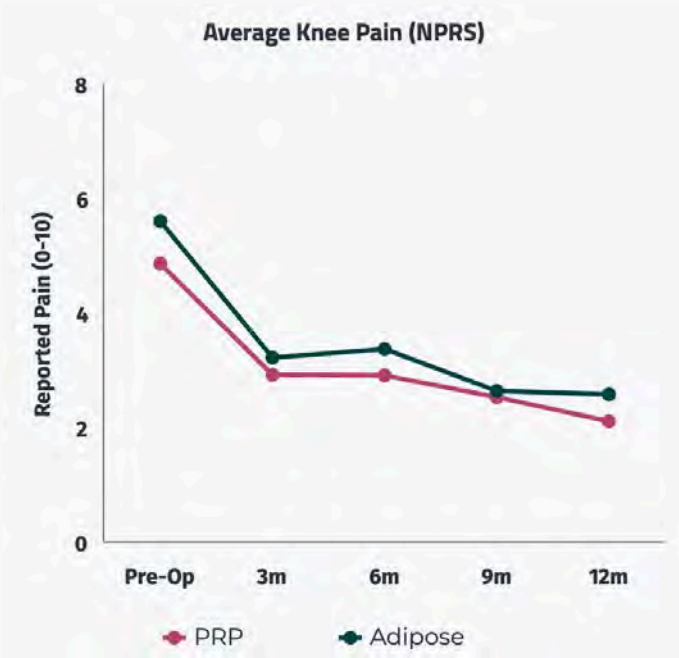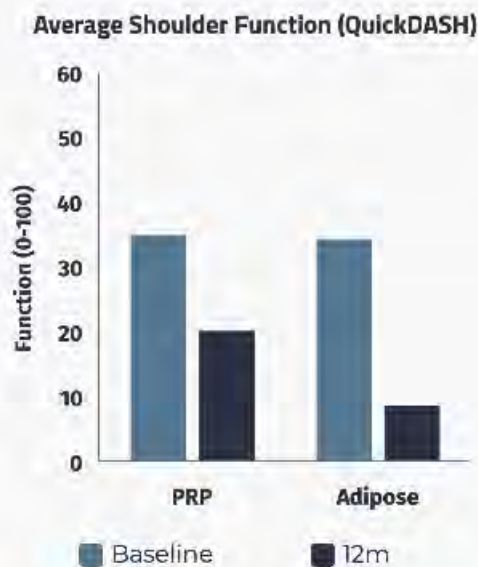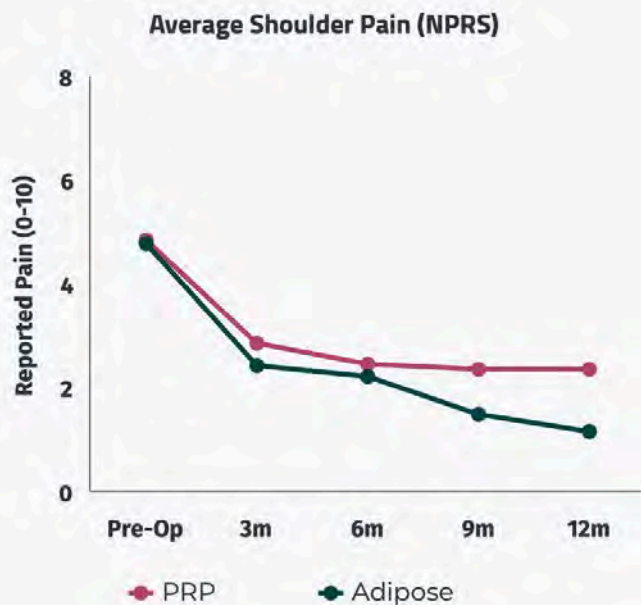
Note: Higher score=better function

Our Analysis

The above outcomes data seems to show that good outcomes can be obtained from both PRP and adipose tissue based treatments for the treatment of knee conditions such as knee osteoarthritis. This information should be used with caution as there are several differences among the treatment groups. For example, the use of PRP or adipose tissue based treatments depends upon the unique characteristics of a patient's condition. Therefore, while this data is useful for demonstrating the general efficacy of a given treatment option, meaningful inferences will require the collection of specific data for unique patient populations.

Report for Shoulder Pain

Shoulder pain is also a common orthopedic condition which has several different potential causes such as rotator cuff tendon tears and osteoarthritis. This report demonstrates the potential effectiveness of PRP and adipose tissue based treatments for this indication by aggregating patient-reported outcomes data from the clinics across the DataBiologics platform.

Average Shoulder Pain (NPRS)

Average Shoulder Function (QuickDASH)

Note: Lower score=better function

Our Analysis

The data shown above demonstrates long-term outcomes with adipose tissue based treatments that are superior to that obtained with PRP. These results are consistent with previously published clinical trials. However, this information should be used with caution as the limited sample size makes it difficult to form any detailed observations about efficacy. The collection of a large number of patient reported outcomes in the future will assist with such analysis.

Laying the ground work for precision medicine

The Future of DataBiologics

The DataBiologics platform was launched in 2019 in an effort to allow early-adopters an opportunity to begin patient reported outcome data collection. With the assistance of valuable feedback from our physician network, we are now in the process of developing the next generation of the DataBiologics software. These updates will offer greater ease of use for physicians and a better overall experience for their patients. Our mission continues to focus on simplifying the collection of meaningful data to allow physicians and their patients make informed medical decisions.

Here's where we're headed:
- New data collection methods that are even more simple to use
- Enhanced features to encourage high patient response rates
- Increased collaboration and data sharing through a growing network of physicians
- Expanded treatment details to improve the analysis of patient selection and specific treatment protocols
- **The creation of the largest database of patient outcomes in Orthobiologics**

Our Software Developers

DataBiologics is excited to announce their partnership with Perk Health. Based in Minneapolis, Minnesota, Perk Health is focused on the pursuit of answering some of the most pressing questions in healthcare. They have collaborated with prominent institutions including Medstar Health, Mayo Clinic and the Fairview HealthEast Kidney Stone Institute. Perk Health has an 8-year track record of creating award-winning digital health solutions that drive long-term behavioral change and meaningfully bend patient outcomes towards better ones.

Our Partners

Sources

1. https://pubmed.ncbi.nlm.nih.gov/24182709/
2. https://aaos-annualmeeting-presskit.org/2018/research-news/sloan_tjr/
3. https://www.hss.edu/condition-list_prp-injections.asp
4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3565396/
5. https://pubmed.ncbi.nlm.nih.gov/26561282/
6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4611136/
7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6073159/
8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7459379/
9. https://clinicaltrials.gov/ct2/show/NCT03714659
10. https://pubmed.ncbi.nlm.nih.gov/30762487/
11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6197942/
12. https://pubmed.ncbi.nlm.nih.gov/31095402/
13. https://stemcells.nih.gov/info/Regenerative_Medicine/2006Chapter2.htm
14. https://my.clevelandclinic.org/health/articles/21077-bone-marrow-concentrate-bmc
15. https://pubmed.ncbi.nlm.nih.gov/26602153/
16. https://www.tenexhealth.com/clinical-efficacy/
17. https://sonexhealth.com/educational-institute/clinical-research/
18. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3666498/
19. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6029898/
20. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5632954/
21. https://pubmed.ncbi.nlm.nih.gov/31628542/
22. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220007/
23. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220006/
24. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4972861/
25. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5626678/
26. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6503401/
27. https://doi.org/10.1007/s00264-020-04703-w
28. https://pubmed.ncbi.nlm.nih.gov/26156727/
29. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6429139/
30. https://pubmed.ncbi.nlm.nih.gov/28748380/
31. https://pubmed.ncbi.nlm.nih.gov/28990575/

Acknowledgements

No Medical Use

DataBiologics

> **"Without data you're just another person with an opinion."**
>
> -W. Edwards Deming

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to learn more