

**CLIENT REPORTED OUTCOMES** 

# INFLAMMATORY ARTHRITIS

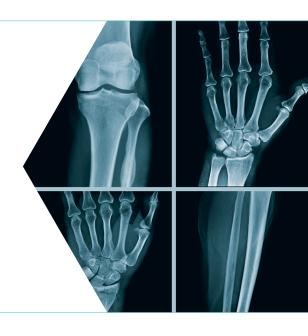
This study overview illustrates the benefits seen using one's own MSCs, cultured by Celltex, to help alleviate symptoms of inflammatory arthritis.

DISCLAIMER: The Celltex study on inflammatory arthritis is being shared with you at your request. It reflects actual outcomes from individuals who received therapy using Celltex-produced mesenchymal stem cells. The study shows positive results for these individuals. It is important to note that the study is not scientific. No representation is being made that you or any other individual would get similar positive results. You should consult with your physician on what is best for you. Please call us if you wish to find out more about Celltex and the positive results individuals are having as reflected in this study.





# STEM CELLS AND INFLAMMATORY ARTHRITIS: HOW IT WORKS



#### Inflammatory Arthritis (IA)

Inflammatory arthritis describes a group of autoimmune diseases affecting one or more joints.

Conventional IA treatments work to limit the damage done by autoimmune attacks on the joints by blocking parts of an individual's immune system.

While these medications work to reduce joint damage, their effect on the immune system subjects individuals to risks like severe infections or even tumors

Only one-third of individuals taking these medications reach clinical remission, highlighting the need for a safer, more effective approach.<sup>[1]</sup>

#### Why Mesenchymal Stem Cells?

Mesenchymal Stem Cells (MSCs) are a unique, naturally occurring type of stem cell shown to potentially help reduce inflammation seen in IA.

MSCs have the ability to regulate certain immune cells and inflammatory proteins associated with IA without impairing an individual's immune system overall. [2]

Studies have shown MSCs to be safe and well-tolerated in the body, offering a promising new avenue for alleviating the symptoms of IA.<sup>[3]</sup>

This study overview illustrates the benefits seen using one's own MSCs, cultured by Celltex, to help alleviate symptoms of IA.

Data is based on reported outcomes of Celltex clients with IA.

Overview based on study conducted by the Celltex Research & Development Team: Patient Reported Outcomes: Surveys of Patients with Inflammatory Arthritis Treated with Autologous Mesenchymal Stem Cells, 2021 Update.



# CLIENT REPORTED OUTCOMES FOR IA

#### Study Overview

Celltex conducted a registry study based on the reported results of our clients with IA.

The study utilized a number of survey methods to assess the reported results of clients with IA who received MSC therapy between October 2011 and December 2018.

#### Types of Inflammatory Arthritis

Inflammatory arthritis is an umbrella term for a group of inflammatory autoimmune conditions, like rheumatoid arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, and more.

#### OF ALL CELLTEX CLIENTS WITH IA WHO PARTICIPATED IN THE STUDY:

48% had rheumatoid arthritis (RA)

had dysautonomia with arthritis

11% had psoriatic arthritis (PsA)

had juvenile rheumatoid arthritis

14% had some other form of IA



OF CLIENTS WITH IA INDICATED
IMPROVEMENT IN ONE OR
MORE SYMPTOMS

# Every respondent reported improvement in at least one of their symptoms.

While these results are very promising, the specifics of how each client's IA improved, and to what extent, still varied from client to client.



## **A CLOSER LOOK**

#### Validated Assessment Tools

Clients were given four surveys, each meant to measure the impact of MSC therapy in a different way.

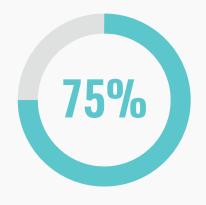


#### **4 HEALTH SURVEYS WERE USED TO COLLECT DATA:**

surveys were completed by clients themselves

survey was completed by clients' physicians

The most compelling data came from this physiciansubmitted survey



OF CLIENTS SHOWED

MEASURED IMPROVEMENT

THROUGH PHYSICIAN

EVALUATION.

#### Physician-Validated Results

The ACR20 is an assessment tool developed by the American College of Rheumatology to help measure how different treatments impact the severity of an individual's IA.

Based on their physician's objective evaluation, the majority of surveyed clients met the ACR20's criteria for improvement following MSC Therapy.

#### **Client Reported Impact**

In addition to the physician-submitted results, clients were also asked to characterize whether they thought MSC therapy had helped them.

#### WHEN CLIENTS WERE ASKED THEIR OPINIONS REGARDING MSC THERAPY:



would recommend MSC therapy to others.



felt their need for medication had decreased.



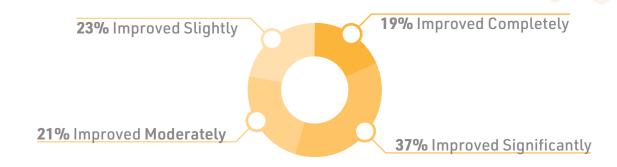
# IMPACTING THE SYMPTOMS OF IA

#### **Degrees of Improvements**

While every client experienced improvement for at least one symptom, which symptoms improved and to what extent varied from client to client.



#### OF THE SYMPTOMS THAT SHOWED IMPROVEMENTS:



#### Frequency of Symptom Improvements for IA Clients

The chart below represents the percentage of respondents that reported seeing improvement for their indicated symptom. Not every individual had every symptom.

Emotional State	90%	Eye Issues	64%
Fatigue	90%	Need for Assistive Device	<b>100%</b>
Need for Splints	91%	Performing Household Tasks	86%
Performing Tasks With Hands	88%	Pulmonary Issues	63%
Skin Issues		Sleep Difficulty	
Stiffness	70%	Walking for 30+ Minutes	81%
	89%	g a via	96%



## ADMINISTERING STEM CELL THERAPY

While the type of administration and frequency of therapies often varies based on a clients' specific circumstances, each respondent received at least one, if not more, IV infusions during this study.

#### **Routes of Administration**

How MSCs are administered into the body varies based on physician recommendation and the individual client's needs.



The MSCs are infused into the body through an IV. This is the most common route of administration.

#### Intraarticular (IA)

The MSCs are injected directly into the affected joint(s).

#### Intranasal (IN)

The MSCs are infused through the nasal passage.

#### Frequency of Administration

Within a single round of MSC therapy, the average client received three IV infusions accompanied by another type of infusion or injection. Other types of infusions/injections included, but weren't limited to, the routes of administration listed above.

In some cases, clients received more or less than three IV infusions in a single round of MSC therapy. This was dependent upon an individual's circumstances and physician recommendations.

**Physicians often recommend IV infusions**, regardless of condition, because they allow MSCs to travel via the circulatory system and regulate inflammation systemically.



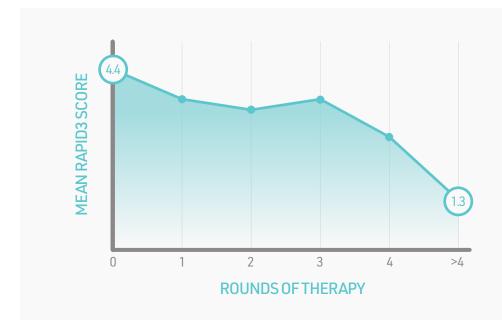
### **REPEAT THERAPIES**

#### The ACR RAPID3 Assessment

The American College of Rheumatology's RAPID3 Assessment is another widely-used survey tool that was utilized in this registry study to measure the severity of a client's IA.

The study compared average RAPID3 scores among clients and how many rounds of MSC therapy they had received. There was a trend of lower (better) RAPID3 scores among those who received additional rounds of MSC therapy.





# Repeat therapies appear to have further effects.

Based on the RAPID3, surveyed clients appeared to see further benefits with additional rounds of MSC therapy.

#### **Client Reported Impact**

In addition to the RAPID3 Assessment, clients were asked to share whether they thought receiving multiple rounds of therapy would be beneficial or necessary.

#### WHEN CLIENTS WERE ASKED THEIR OPINIONS ON REPEAT THERAPY:



felt additional rounds of therapy would result in further benefits.



felt additional rounds of therapy were needed to maintain benefits.



## **MOVING FORWARD**

#### Safety of MSC Therapy

There were no severe adverse events to MSC therapy in this registry study of Celltex clients with IA.

In fact, Celltex-produced MSCs have been used in over 10,000 therapies across various disease categories with no severe adverse events.

#### More Research is Crucial

Using MSCs to help alleviate the symptoms of IA certainly has potential, but more research is still a priority.

MSC therapy may already be an option for some. Learn more at CelltexBank.com/Therapy.

#### The Celltex Difference

Stem cell banking is the critical first step in the MSC therapy process that separates Celltex from other stem cell companies. Stem cell banking with Celltex involves (1) extracting a one-time sample of an individual's fat tissue, (2) isolating MSCs from that sample, (3) expanding the pure MSCs in quantity, and (4) cryopreserving a lifetime supply for future therapeutic uses.

Celltex's technology enables an individual's stored MSCs to be expanded into quantities exponentially greater than that of current same-day stem cell clinic offerings, greatly increasing the potential for positive results when therapeutic application is necessary.

This difference in cell quantity, along with the compatibility from using one's own cells, contributes to the superior quality of Celltex-produced MSCs. Celltex-produced MSCs have the potential to succeed where same-day stem cell therapies have failed before.

## YOUR NEXT STEPS

## Take Our Virtual Consultation

Visit <u>CelltexBank.com/IA-Eval</u> to see if stem cell banking or therapy is right for you.

#### Talk to Your Celltex Representative

Here for you every step of the way, we can answer any question you might have about our process.



# SUPPORTING INFORMATION

#### References

Overview based on study conducted by the Celltex Research & Development Team: Patient Reported Outcomes: AdMSC in Inflammatory Arthritis, 2021 Update.

#### Additional References:

[1] Curtis, J. R., & Singh, J. A. (2011). Use of biologics in rheumatoid arthritis: current and emerging paradigms of care. Clinical therapeutics, 33(6), 679–707. https://doi.org/10.1016/j.clinthera.2011.05.044

[2] Wang, L. T., C. H. Ting, M. L. Yen, K. J. Liu, H. K. Sytwu, K. K. Wu and B. L. Yen (2016). "Human mesenchymal stem cells (MSCs) for treatment towards immune- and inflammation-mediated diseases: review of current clinical trials." J Biomed Sci 23(1): 76

[3] Álvaro-Gracia, J. M., Jover, J. A., García-Vicuña, R., Carreño, L., Alonso, A., Marsal, S., Blanco, F., Martínez-Taboada, V. M., Taylor, P., Martín-Martín, C., DelaRosa, O., Tagarro, I., & Díaz-González, F. (2017). Intravenous administration of expanded allogeneic adipose-derived mesenchymal stem cells in refractory rheumatoid arthritis (Cx611): results of a multicentre, dose escalation, randomised, single-blind, placebo-controlled phase Ib/IIa clinical trial. Annals of the rheumatic diseases, 76(1), 196-202. https://doi.org/10.1136/annrheumdis-2015-208918

#### Acknowledgments

We would like to acknowledge the generous contribution of those who received their own MSCs under the registry study in which this overview is based on. Their willingness to perform and submit surveys throughout repeated data collection cycles made these analyses possible.

We give our deepest thanks to these people for their contribution to help advance understanding in stem cell research.

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