

## FACT SHEET

# Adipose-Derived Mesenchymal Stem Cell Therapy



Cell based therapies offer exciting potential in treating conditions such as discogenic back pain (pain due to a damaged disc). Adipose (body fat) tissue is a rich source of mesenchymal (adult) stem cells. These stem cells may improve symptomatic discogenic back pain by:

- reducing inflammation
- assisting the healing mechanism
- regenerating the damaged disc

It's important to understand that not all patients are suitable for stem cell therapy, nor are all stem cell therapies the same.

### WHY USE MESENCHYMAL STEM CELLS?

The function of mesenchymal stem cells (MSC) is to begin the healing process when the human body is injured. These adult stem cells 'wake up,' move through the body to the site of injury, express proteins to suppress inflammation, express other proteins to stimulate new cellular growth, recruit new growth factor proteins and then, begin to change into the very cells that have been damaged.

Throughout this process, these cells are giving and receiving signals

with the surrounding environment. This is an extremely important aspect and one of the central discoveries regarding stem cells and the point that differentiates them from any other cell.

The most common therapeutic use of stem cells is to harvest them from one part of the body where they exist in greater amounts and then re-implant them at the site of injury.

For adults with diminishing stores of stem cells, this is an effective way to stimulate healing at sites of injury. One problem with using adult stem cells is that the quantity of cells is only as good as the patient's supply. However, in those cases, one strategy is to put the patient's small number of stem cells into a culture media and allow them to expand.

### WHAT IS THE PROCESS?

The process of treating your discogenic back pain will require multiple steps.

1. Pre-assessment
2. Stem Cell harvesting
3. Stem cell injection and repeat treatment if required.
4. Follow-up

## PRE-ASSESSMENT

Pre-assessment will determine if stem cell treatment is suitable for your condition, or whether more appropriate, or less invasive measures may be used. Any risks to your health while undergoing this procedure will also be assessed.

Pre-assessment will involve

- Full history and physical examination
- Possible MRI (if clinically applicable)
- A discography procedure to see if stimulation of the disc reproduces your back pain.

You will also be asked to fill in a number of functional and pain scales as a baseline of your symptoms. Pre-assessment provides baseline staging of your condition and allows us to follow any clinical improvement or regeneration that may occur.

## WHAT HAPPENS DURING THE CELL HARVEST?

Adipose-derived stem cell therapy involves a mini-liposuction of about 100ml of abdominal fat, to harvest stem cells. It is performed under sterile conditions with a local anaesthetic and light sedation.

The procedure is done at the Melbourne Stem Cell Centre. You will require a referral from your doctor.

This very common procedure used extensively by cosmetic surgeons is very safe.

The stem cell component will be extracted from the adipose tissue, with stem cells undergoing expansion to produce increased cell numbers and improve efficacy.

## WHAT ARE MY CELLS PROCESSED IN?

Bovine culture media will be used to culture your cells. Bovine deprived culture media is used commercially in the development of many clinical products including vaccines. All procedures will be performed in a sterile environment where air quality of room is constantly monitored to inhibit any environmental contamination and to limit any risk of infection. All the laboratory staff handling the cells will be well trained and experienced in sterile techniques. The isolated mesenchymal stem cells will be suitably stored meeting TGA biological product/treatment requirements.

## WHAT HAPPENS AT MY STEM CELL INJECTION PROCEDURE?

This procedure will take place at the hospital approximately a week or two following your liposuction.

You will receive an injection of your stem cells into your symptomatic spinal disc. This procedure will be performed under sterile conditions, in an operating theatre, via live fluoroscopy (x-ray) guidance.

You will also have a follow-up appointment with your treating physician.

\*Note: It's normal for pain to flare up after the procedure, which should subside in a few days. However, please tell your doctor about any discomfort you may experience following the treatment.

## WHAT ARE THE FORESEEABLE RISKS OR DISCOMFORTS THAT I MAY EXPERIENCE?

### Harvesting Liposuction Procedure

1. Discomfort — You may experience discomfort during the liposuction procedure. All liposuction will be performed using a local anaesthetic which is an internationally accepted practice.
2. Infection — The risk of this occurring is low, as you will receive a single dose of intravenous antibiotics prior to the liposuction procedure. However, you will be monitored for signs of infection
3. Bruising — You may notice minor bruising at the liposuction site.

### Intra-disc Injections

1. Discomfort — Pain during intradiscal injections is common, but can be alleviated by the use of anaesthetist assisted sedation. The skin area and disc entry sites will also be anaesthetised.
2. Infection — This is low and antibiotics are not required for disc injection. However, you will be monitored for infection, and will be referred to your doctor if necessary.
3. Bruising — You may experience minor bruising at the injection site.

\*Note: Medical doctors perform all the procedures. They all have an equivalent of a Bachelor of Surgery and Bachelor of Medicine (MBBS) degree, current medical registration, medical indemnity, and are

all very experienced in performing disc injection procedures. Doctors performing lipo-harvesting have appropriate qualifications within this area.

## WHAT TREATMENT OUTCOME SHOULD I EXPECT?

MSC therapy is an emerging treatment. Initial studies suggest patients may experience reduced pain and improved mobility.

It is anticipated that MSC therapy will have disease modifying properties and may improve, or prevent further disc degeneration. However, given the current limited understanding of this therapy, these results cannot be guaranteed.

## WHAT ALTERNATIVE TREATMENT OPTIONS ARE THERE?

Alternative treatments are available to treat your lower back pain. In order to be considered for MSC therapy, you need to have tried and failed to get an outcome, using these options.

## ARE STEM CELLS SAFE?

Systematic review of articles on the use of MSC in treating various conditions has shown them to be safe. A review of over 1000 patients who had received intra-vascular injections of mesenchymal stem cells did not identify any significant adverse events other than transient fever (Lalu, et al. 2012). Further review of patients who had received intra-articular (within the joint) injections showed similar levels of safety. There has been no association between MSC therapy and adverse events such as infection, death or malignancy. Importantly adipose-derived stem cells are an autologous medium, meaning that they are taken from your own body.

## WHAT IS THE EVIDENCE?

To date, most research has focused on 'off the shelf' allogeneic mesenchymal stem cell transplants, and although promising, donor derived allogeneic mesenchymal stem cell therapy is not currently approved by the regulatory authorities for use in standard care. The alternative 'point-of-care' minimally manipulated, autologous mesenchymal stem cell preparations performed under the supervision of the treating physician, represents an

assumed safer approach by using the patient's own stem cells.

A study of 10 patients with confirmed intervertebral disc disease injected with autologous mesenchymal stem cells, described rapid improvement in pain and disability at three months, followed by a modest improvement within six and 12 months after injection. Whilst there appeared to be no improvement in disc height, the water content of the disc was significantly elevated at 12 months, suggesting a significant increase in nucleus pulposus cell content.

## HOW IS MY THERAPY AT METRO PAIN GROUP AND MELBOURNE STEM CELL CENTRE DIFFERENT?

Metro Pain Group and the Melbourne Stem Cell Centre (MSCC) are research driven organisations with a clear focus on using evidence based techniques in stem cell therapies. These stem cell therapies use 'pure' high dose (MSC) preparations that have been shown to not only improve pain and function but also to stimulate tissue regeneration.

Other 'stem cell' clinics commonly use techniques that result in therapies that have less than 10% stem cells. These techniques/therapies are thought to be less effective.

### DISCLAIMER

Please note the contents contained in this Patient Fact Sheet are not intended as a substitute for your own independent health professional's advice, diagnosis or treatment. At Metro Pain Group, we assess every patient's condition individually. As leaders in pain intervention, we aim to provide advanced, innovative, and evidence-based treatments tailored to suit each patient. As such, recommended treatments and their outcomes will vary from patient to patient. If you would like to find out whether our treatments are suitable for your specific condition, please speak to one of our doctors at the time of your consultation.

## REFERENCES

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