Not only Fat Grafting, It is a real SVF isolation, **A real regenerative therapy**



Microlyzer. SVF Kit Non-Enzymatic SVF Isolation

PROF. DR. Michele L. Zocchi

A long time has passed since I isolated the very first Adipose Derived SVF ever described in Medical Literature using a special manual centrifuge system I had developed and patented back in 1988.

Over the years I have developed, tested and mastered a wide range of techniques using different devices based both on enzymatic and mechanical approach.

Easiness of use, speed, efficiency and cost have always been the most crucial aspects I consider when evaluating a new device for the isolation, preparation and concentration of SVF.



In my experience very few devices however can satisfy those very important criteria. One in particular, more than the others, is the Microlyzer, the features of which I have extensively outlined in a long Masterclass published in 2019 in the European Journal of Plastic Surgery (EJPS).



About PROF. DR. MICHELE L. ZOCCHI

Graduated at Medical University in Turin - Italy in 1978 he moved to the United States first and afterwards to France for more than ten years where he completed his Board in maxillofacial surgery and in Plastic, Reconstructive and Aesthetic Surgery, working as Resident and Researcher in the most prestigious Plastic Surgery Departments and Institutes worldwide.

- Adjoint Professor at the University of Science at the H.C.M. Vietnam National University.
- Chairman of the International Academy of Regenerative Medicine (IARM).
- Founder Member and International Advisor of the Chinese Society of Adipose Medicine (CSAM).
- Scientific Director of the Continuous Educational Program (PFP) of SICPRE Italian Society of Plastic, Reconstructive and Aesthetic Surgery.
- National Coordinator for the Chapter of Aesthetic Surgery of the Italian Society of Plastic, Reconstructive and Aesthetic Surgery (SICPRE).
- National Delegate for Italy for the European Society of Plastic Reconstructive and Aesthetic Surgery (ESPRAS).
- Member of the Editorial Board of the European Journal of Plastic Surgery (EJPS).

Regenerative Effect

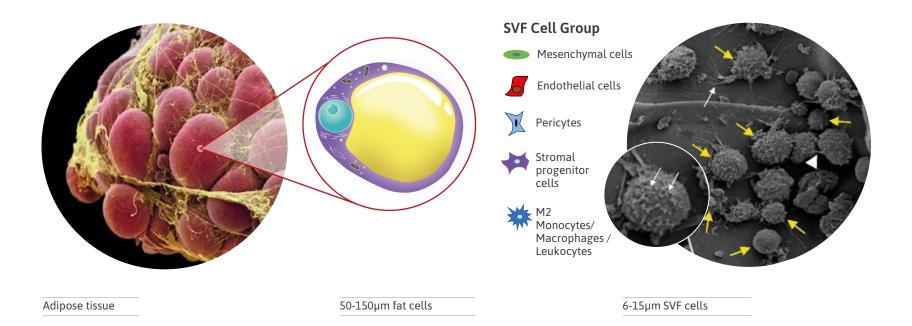
- Real SVF isolation
- Proven Protocol
- High nucleated cell count
- High stem cell rate
- High viability

Fast and Cost Effective

- No enzyme cost
- No high investment cost
- No additional component needed
- Preparation in 40 minutes
- Centrifuge only 2 times

Safe

- No enzyme risk
- No regulation risk
- All sterile components
- Single use lipoaspiration cannula
- Sterile Bucket
- Safe injection with 41 Micron Filter



Cell Isolation, NOT FAT GRAFTING

The process of making injectable adipose tissue is not called Stem Cells. Our method however completely isolates SVF cells from the adipose tissue.

While our final product is rich in highly viable nucleated cells, it completely excludes fibrotic tissue, fat cell and Triglyceride since additionally to the Microlyzer Blade filter the final product is also processed through a 41 Micron filter in order to offer you a **pure and safe injection**.

Regenerative Effect, NOT ONLY MECHANICAL

Fat grafting is a key technique in soft tissue reconstruction, the effect it provides however are mainly mechanical, that is the crucial difference between Fat Grafting and SVF which is a high concentrate of Stem Cells.

Stem cells that are separated from the adipose tissue and concentrated can multiply rapidly in the human body and differentiate into several lineages . It offers you a real regenerative treatment, unlike fat grafting.

Countable Cells, NOT TISSUE

Micronized fat tissues also contain stem cells, this does not mean however that the SVF cells isolated within these tissues have been concentrated.

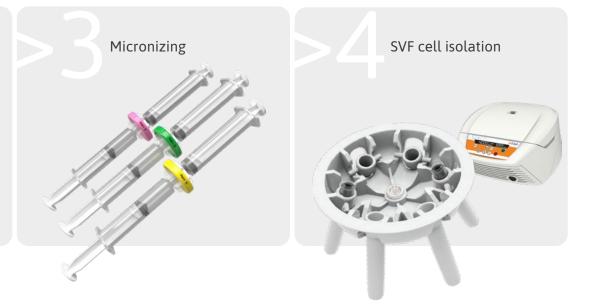
After processing the adipose tissue through the Microlyzer, **you will be able to see the SVF pellet with your own eyes on any microscope**, even detect, count and easily measure the viability of nucleated / non-nucleated cells with a fluorescent microscope.

STEP BY STEP PURITY AND CONCENTRATION





The Microlyzer SVF Kit offers you all the stages in a single sterile package. The need to search for additional components disappears, saving you a lot of time.



Microlyzer. CELL-LEVEL PROCESSING BLADE STRUCTURE

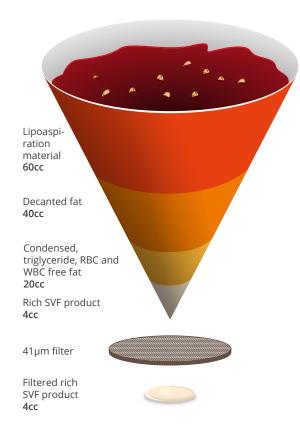
2400µm, 1200µm, 600µm, 41µm

Unlike many filtration technologies, it is a revolutionary product that can mechanically tear off the cells by gradually shrinking fat tissue using a superior blade technology.



WHY NON-ENZYMATIC SVF?

Microlyzer SVF Kit offers you an enzyme-free SVF cell isolation method as opposed to Fat Grafting systems.



The most commonly used method for SVF isolation in the world is to incubate the adipose tissue with enzyme collagenase to separate the cells from the tissues, then concentrate and collect the decomposing SVF cells by centrifugation. This is the method that the world decisively finds most successful in publications. Despite all this success, there are important reasons why this method is not preferred today; it is very risky to inject highly toxic collagenase enzyme back into the patient, which can break down collagen. If the enzyme cannot be completely removed before it is administered to the patient, it will cause serious damage to the tissue in which it is injected. In practice, it is almost impossible to completely stop enzyme activity. For this reason, both the FDA and the EU Commission do not consider this application reliable and its use is not allowed in Clinical Practice Other than scientific research. In the "no significant manipulation" criteria that do not require licensing under the regulation of the European parliament and of the council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, applications such as mechanics and filtration, centrifuges are allowed, while enzyme application is not.

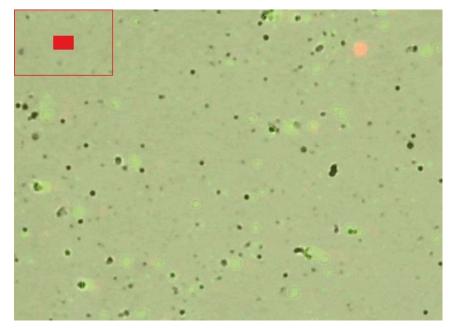
Aside from the risks involved in enzymatic SVF decomposition methods, this method requires large investment costs, high costs per application, and two-to three-times longer preparation time compared to a Non-Enzymatic technique with the Microlyzer.

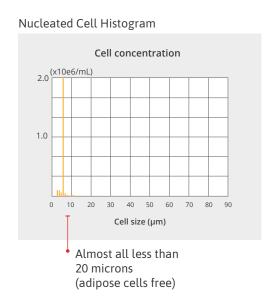
Microlyzer SVF offers a fast, rich, regulation risk-free, cost-effective solution that can mechanically isolate real SVF with a high regenerative effect.

Counting and analysis results with fluorescent microscope immediately after SVF cell isolation

| [Total cell] | : 4.24 x 10 ⁷ cells/mL |
|----------------------|-----------------------------------|
| [Nucleated cell] | : 2.36 x 10 ⁷ cells/mL |
| [Non-nucleated cell] | : 1.89 x 10 ⁷ cells/mL |
| | |

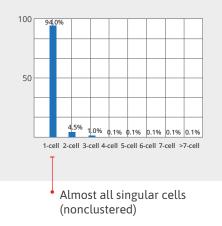
Viability of nucleated cell: 92.8%Average nucleated cell size: 5.6µm

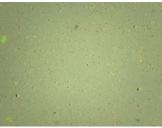




Nucleated Cell Clusters

Cell cluster (%)



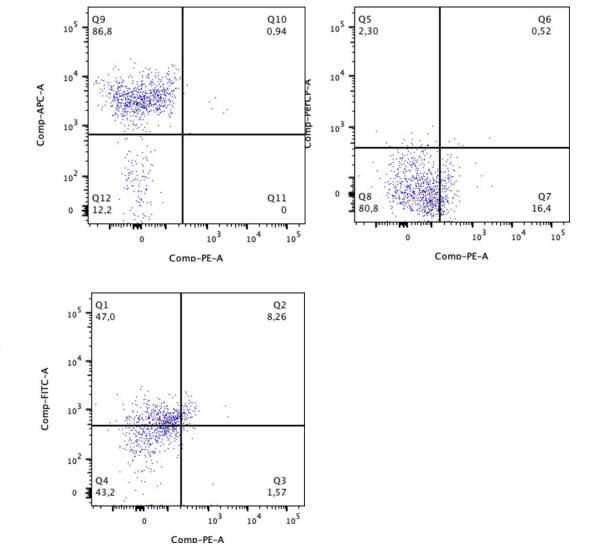


The sample cell count dating from the 28th of December 2020 were obtained with a Luna Stem device and extracted from the report written by Dr Seher Üstün Yaylacı.

Isolated SVF cell (without culturing) Flow Cytometry data

| FITC:CD73 | :%61,6 |
|-------------|---------|
| APC:CD90 | : %81,2 |
| PerCP:CD105 | : %2,3 |

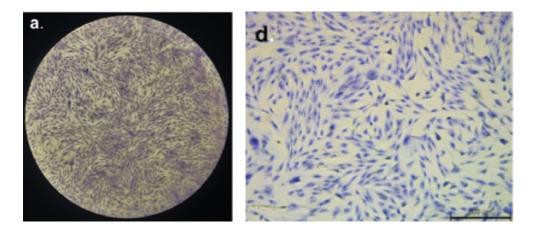
In an effort to differentiate hematopoeitic and endothelial cell populations, a cell surface antigen marker analysis was performed (CD45, CD34, CD29, CD14, CD11b and HLA-DR) with Flow Cytometry technique which plays a crucial role in classifying the end product by producing an accurate measurement of mesenchymal, endothelial, pericyte, leukocyte, stromal/progenitor cells in terms of percentage.



^{*}The cell count results are an extract derived from a report written by Associate Dr. Seher Üstün Yaylacı on sample analysis dated 28.12.2020. The characterization was carried out in joint cooperation with Hacettepe University Teknokent Maia Sağlık consultancy using BD FACSCanto II device and BDFACS Diva software.

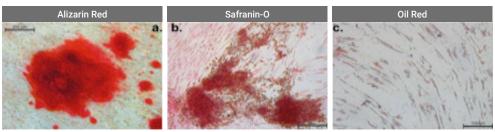
CFU-F Assay (Colony Forming Units)

Images of Colony Formed by Mesenchymal Stem Cells isolated with the Microlyzer Device.



For Osteogenic, Chondrogenic and Adipogenic Differentiation

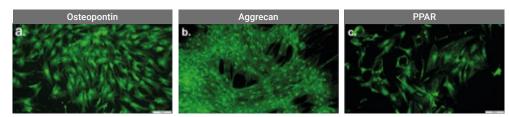
Adipose Tissue-Derived Mesenchymal Stem Cells Isolated with the Microlyzer SVF kit were differentiated using the following methodologies: Adipogenesis is shown with the deposition of lipid vacuoles stained with Oil Red O. Chondrogenesis displayed as stained with Safranin-O sulfated Proteoglycan-rich matrix that indicates the accumulation. Osteogenesis is indicated by staining extracellular matrix calcification with Alizarin Red.



The Adipose Derived Mesenchymal Stem Cells were cultured for 13 days in Adipogenic, Chondrogenic and Osteogenic Milieu

Immunofluorescence Staining of Specific Markers for Differentiation

Immunofluorescence staining of proteins specific to adipose-derived mesenchymal stem cells obtained from Microlyzer devices:



At the end of the 14th day, using Anti-Osteopontin, Anti-Aggrecan and Anti-PPAR gamma dyes for Osteocyte, Chondrocyte and Adipocyte cells; the cell differentiation was proved by immunofluorescence staining.



A E S T H E T I C S O R T H O B I O L O G I C S T H E R A P E U T I C S

T-LAB has been developing products in the field of regenerative medicine since 2012. More than 1 Million+ treatments have been performed with our PRP products, We are Türkiye's leading PRP kit manufacturer. In the scope of regenerative medicine, T-LAB has made significant R&D investments on enzymatic and non-enzymatic SVF protocols in the past five years, and has developed its own mechanical SVF isolation method. This intensive R&D gave birth to the Microlyzer SVF Kit which consists of all single-use components. 10 different medical devices were separately manufactured to create a complete CE certified system.

In addition to the Microlyzer SVF, T-LAB also offers the Microlyzer Fat Grafting kit as an advanced solution for augmentation and Fat transfer. T-LAB aims to go further in the field of regenerative medicine with PRP, PRF, hydrogel wound cover and ozone-based liposomal cocktails products and many more that it develops and continues to develop.



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