Adimend Biosciences' Dual Syringe Stem Cell Device

Opportunity

The prevalence of degenerative cartilage disorders in the United States is striking. The CDC estimates that 33 million people live with osteoarthritis. Over 27 percent of adults have been diagnosed with degenerative disk disease. Not surprisingly, non-inflammatory arthritis is a major cause of suffering and disability.

Despite the frequency of such disorders, options for treatment remain limited. Typical treatments include corticosteroid injections, viscosupplementation for knee arthritis, pain medications, supplements, and surgical interventions. These interventions are palliative at best and potentially harmful at worst.

Expenditures for treatments including both surgical interventions and medications/supplements are in the hundreds of billions annually in the United States.

Regenerative medicine for musculoskeletal disorders has the potential to change the management of degenerative processes like osteoarthritis and disk disease. Stem cell therapy in particular, though, has been both expensive and difficult to access.

Solution

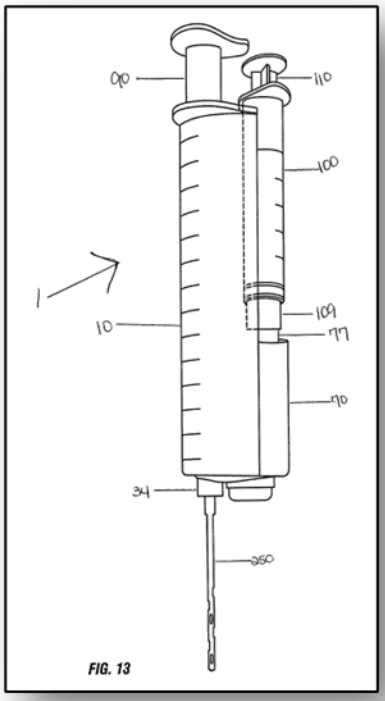
Adimend Biosciences, LLC, has developed a dual syringe device to allow mesenchymal stem cell harvesting, processing, and purification in the office setting. A patient's own stem cells can then be administered to treat osteoarthritis, degenerative disk disease, and many other ailments.

The advantages of Adimend's device are many:

- Utilization of adipose tissue, which is the best source of mesenchymal stem cells for use in cartilage repair;
- Closed system design to prevent contamination and infection;
- Simple procedure which can be performed in under thirty minutes;
- Low cost device to allow mass adoption; and
- Simple FDA regulatory pathway as the dual syringe can claim similarity to predicate devices.

In addition, Adimend has invented an aspiration cannula to allow ease of use by non-surgeons such as primary care doctors.

Design details



The above figure is excerpted from the dual syringe's patent application.

The following steps describe the use of the dual syringe:

1. After administration of local anesthesia to the abdominal pannus, 45-60ml of adipose tissue is aspirated using the aspiration cannula. The cannula has a needle in the bore allowing skin puncture. After puncture the internal needle is removed and the blunt-tipped catheter is used to obtain adipose without the risk of peritoneal puncture. The catheter side ports have sharpened edges facilitating easy harvesting of adipose tissue.
2. After adipose tissue is obtained, the cannula is removed and the port capped. The entire device is placed in a centrifuge for processing. Of note is that the large plunger (labeled 90 in the figure) has a detachable component to reduce the size of the device.
3. Centrifugation is then performed without enzymatic processing.
4. The device is removed from the centrifuge and the smaller plunger is used to obtain both the mesenchymal stem cell pellet and the stromal vascular fraction (if desired).
5. The small syringe is then disconnected and the harvested tissue is ready for administration.

Development pathway and potential

The patent protection for the dual syringe device allows confident investment in further development including FDA approval and development of a procedure kit for sale in offices. Of import is that while the most obvious use of this device is in musculoskeletal medicine, myriad other potential markets exist including cardiovascular applications (myocardial and vascular repair), neurologic applications (central and peripheral nervous system regeneration), ophthalmic applications (macular degeneration and use in other degnerative eye diseases), and others.

Design and optimization of the dual syringe has been completed (including 3D printed prototypes) and the device has been patented in the United States. Further development steps would include mass production and application for FDA approval via the 510K pathway for human use. Development in the veterinary setting would be straightforward as no FDA approval would be required.

Selected References

1. Molnar V, Pavelić E, Vrdoljak K, Čemerin M, Klarić E, Matišić V, Bjelica R, Brlek P, Kovačić I, Tremolada C, Primorac D. Mesenchymal Stem Cell Mechanisms of Action and Clinical Effects in Osteoarthritis: A Narrative Review. Genes (Basel). 2022 May 26;13(6):949. doi: 10.3390/genes13060949. PMID: 35741711; PMCID: PMC9222975.

This is a review article describing the use of mesenchymal stem cells in osteoarthritis.

2. Margiana R, Markov A, Zekiy AO, Hamza MU, Al-Dabbagh KA, Al-Zubaidi SH, Hameed NM, Ahmad I, Sivaraman R, Kzar HH, Al-Gazally ME, Mustafa YF, Siahmansouri H. Clinical application of mesenchymal stem cell in regenerative medicine: a narrative review. Stem Cell Res Ther. 2022 Jul 28;13(1):366. doi: 10.1186/s13287-022-03054-0. PMID: 35902958; PMCID: PMC9330677.

This is a review article describing broader regenerative medicine uses of mesenchymal stem cells.

3. Gentile P, Calabrese C, De Angelis B, Pizzicannella J, Kothari A, Garcovich S. Impact of the Different Preparation Methods to Obtain Human Adipose-Derived Stromal Vascular Fraction Cells (AD-SVFs) and Human Adipose-Derived Mesenchymal Stem Cells (AD-MSCs): Enzymatic Digestion Versus Mechanical Centrifugation. Int J Mol Sci. 2019 Nov 2;20(21):5471. doi: 10.3390/ijms20215471. PMID: 31684107; PMCID: PMC6862236.

This is a review article comparing various methods of mesenchymal stem cell isolation and preparation. Centrifugation without enzymatic processing (such as the use of collagenase) appears to produce superior results.