A new technology for standardized separation and concentration of SVF cells during liposuction

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Introduction

The stromal vascular fraction (SVF) from adipose tissue contains mesenchymal stem cells (adMSC). SVF and adMSC are currently being used in various clinical indications (see www.clinicaltrials.gov).

Due to their potential capability of regenerating cartilage, bone, and tendons, autologous SVF and adMSC are being used in treating patients with osteoarthritis, chondromalacia, meniscus tear, osteonecrosis of the femoral head, and tendon injuries in many clinical studies.

The newly developed system presented here may be applied in these indications.

Objective

We are aiming for a new technique for a standardized separation and concentration of the SVF from adipose tissue. This technique should enable the sterile separation and concentration of SVF in a closed system in a standardized process, immediately following the liposuction. Furthermore, the concentrated SVF should be directly sampled from the sterile system for immediate re-injection, at the point of care.

Under this objective, the Q-graft system was developed.

Results

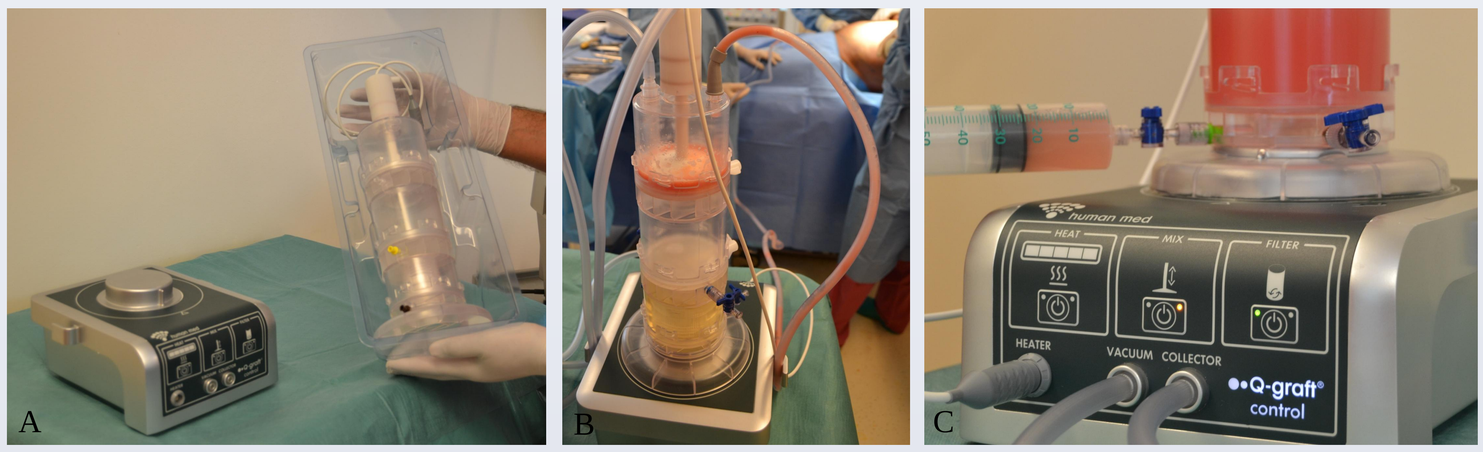

Figure 1: The Q-graft System in the OR. A: preparation of the single-use Q-graft collector and Q-graft control, B: fat harvesting directly into the Q-graft collector during liposuction, C: Q-graft control function keys for warming (37°C), mixing and filtration on the Q-graft control.

The Q-graft system consists of two elements:

- The sterile single-use medical device **Q-graft collector.** It includes three compartments: in the top compartment (incubation chamber) the adipose tissue is effectively mixed and warmed to 37°C during enzymatic digestion, in the middle compartment mechanical tissue dissociation takes place with consecutive filtration steps separating the SVF cells from adipose tissue, oil and connective tissue, and in the bottom compartment the SVF cell suspension is being concentrated.
- The medical device **Q-graft control** regulates the mixing and warming (37°C) of the adipose tissue in the incubation chamber and the cross-flow-filtration and concentration of the SVF cells in the bottom chamber of the single-use Q-graft collector.

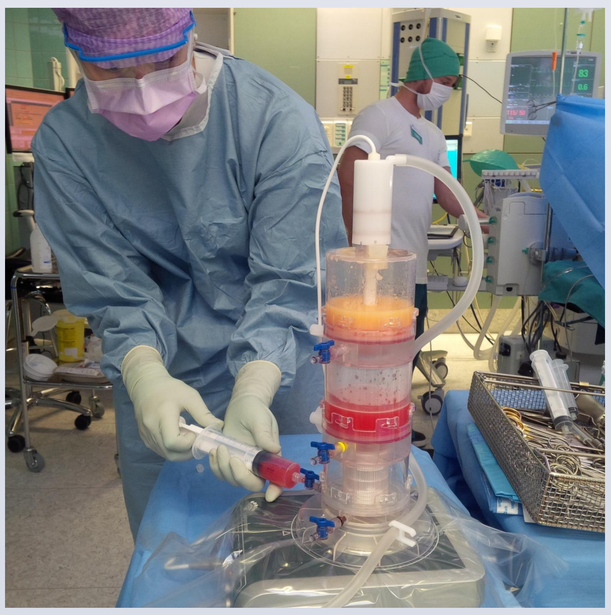

Figure 2: Sterile sampling of the concentrated SVF cell suspension via the CELLS port of the Q-graft collector at the point-of-care

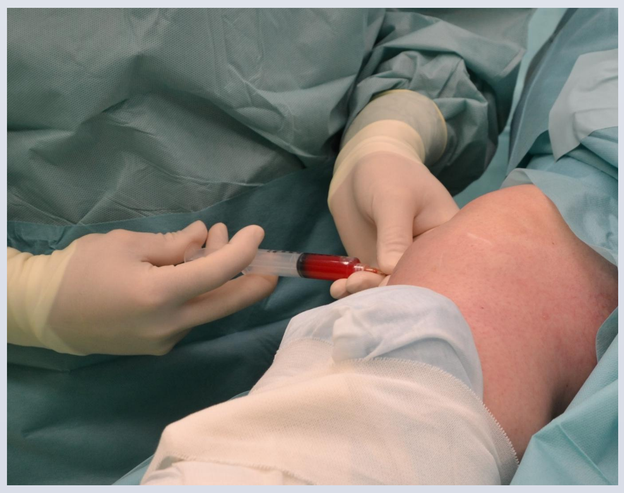

Figure 3: Injection of the concentrated SVF cell suspension into the knee joint, immediately after harvesting with Q-graft

The process of SVF separation can be carried out with or without centrifugation, and with or without enzyme digestion. The addition of only one centrifugation step will yield a higher count of SVF cells. A special Q-graft centrifugation set enables sterile transfer between patient and centrifuge and back.

The SVF is separated in an essentially mechanical process. The entire process is completed in the sterile area of the operating room, right on the instrument table. The process time including fat harvesting is less than 60 minutes. The fat is aspirated directly into the Q-graft collector, right on the sterile instrument table in the OR.

Conclusions

The Q-graft system provides

- Sterile and reproducible SVF separation and concentration in the OR (directly on the sterile instrument table) or in the laboratory
- Harvesting of viable fat tissue and SVF separation in one sterile closed system (in combination with body-jet liposuction device)
- SVF separation with or without collagenase (“Humanase” enzyme mixture)
- SVF separation with or without centrifugation.

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Q-graft is a Class IIa medical device according to MDD 42/93 EEC, Annex IX, section I. - 1.4 and 1.5

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