

# MSC Retention on ConCelltrate® 100 by CellRight Technologies®

Jesus Hernandez, B.S., Dean Troyer, M.D., Duke Kasprisin, M.D.

## BACKGROUND

CellRight Technologies® has developed ConCelltrate® 100, a dehydrated osteoinductive bone graft matrix. ConCelltrate® 100 becomes a moldable osteoregenerative matrix when hydrated with a patient's mesenchymal stem cells (MSC's). ConCelltrate® 100 may be hydrated with saline, blood, Bone Marrow Aspirate (BMA), Platelet Rich Plasma (PRP), or other cellular components in accordance with a physician's well-informed medical judgment. The clinician may add autograft or allograft to ConCelltrate® 100 and hydrate the matrix to the desired consistency. ConCelltrate® 100 does not contain any extrinsic carriers and is entirely derived from 100% human allograft bone. ConCelltrate® 100 resists irrigation and has a shelf-life of 5 years from the date of packaging. CellRight Technologies® uses a proprietary process that preserves native BMP's and growth factors. Every lot of ConCelltrate® 100 is verified for osteoinductivity post sterilization as a condition for distribution. In-vivo test results demonstrate all 5 bone-forming elements present (Chondrocytes, Osteocytes, Bone Marrow Cells, Cartilage, and New Bone). ConCelltrate® 100 is also in-vitro lot tested for the endogenous BMP-2 test marker for osteoinductivity. Test results demonstrate up to 40x BMP level as measured against the BMP-2 control. BMP's irreversibly induce differentiation of perivascular mesenchymal-type cells into osteoprogenitor cells.

It is well documented that not all DBM's are created equal. How a DBM is processed and formulated have the biggest effects on its potential efficacy (1). There is a positive association between greater % DBM-base (bone powder) in the DBM-base product and higher fusion rate (2). Moreover, it doesn't matter how great your cell is, if you don't deliver it with the right carrier with appropriate cell-friendly characteristics, cells will not likely survive after implantation (3).

A 5cc sample of ConCelltrate® 100 was provided to a well known U.S. cell-concentration device manufacturer for the purpose of rehydrating ConCelltrate® 100 with a fluid rich in growth factors (GFC) and mesenchymal stem cells (MSC's). The study was designed to measure percent cell viability over one (1) hour as a worse case scenario. Current clinical practice is to implant the patient's concentrated stem cells back into the patient as quickly as possible in an effort to maintain cell viability.

## 1.0 METHODS

- Mix 0.5 cc of ConCelltrate® 100 with 0.5 cc of fluid containing 250,000 MSC's /GFC with a spatula, standard equipment available in the OR
- Incubate material at room temperature for 60 minutes
- At designated time points of 15, 30, and 60 minutes, gently rinse ConCelltrate® 100 with 1 cc of PBS (without Ca or Mg) so as to not disturb the material
- Using a nucleocounter, determine the number of unbound, living cells in the sample
- The percentage of bound cells was determined

## 2.0 RESULTS

TIME	GFC %
15 Minutes	96.5%
30 Minutes	96%
60 Minutes	90%

Table 1: Data represents the % of bound cells calculated as described above.

## 3.0 CONCLUSION

This investigation corroborates a previous independent study performed by a U.S. platelet rich plasma (PRP) concentration device manufacturer confirming that ConCelltrate® 100 maintained greater than 98% cell viability after two hours.

Furthermore, this study further validates that ConCelltrate® 100 is a superior verified osteoinductive bone graft matrix with appropriate cell-friendly characteristics that is able to deliver and maintain 90% cell viability for a minimum of one (1) hour at room temperature.



ConCelltrate® 100 with Bone Marrow Aspirate (BMA)

### References:

- 1) Douglas W. Jackson, *Using DBMs in Clinical Orthopedics: Orthopedics Today*, October 2005
- 2) Kanim LEA; Homan J; Zhao L; Safai Y; Bae HW; Kropf MA; Delamarter RB: *Spine Center, Cedars-Sinai Medical Center, Los Angeles, CA, Composition of Demineralized Bone Matrix-Based Products on Spinal Fusion Rate*, Orthopaedic Research Society (ORS) 2012 Annual Meeting
- 3) Dr. Wellington K. Hsu, *Interest in Using Stem Cells in Spinal Surgery Increasing: AAOS Now*, September 2014