

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