MSC Retention on PentOS OI™ Max

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BACKGROUND

PentOS OI™ Max, a dehydrated osteoinductive bone graft matrix, becomes a moldable osteoregenerative matrix when hydrated with a patient's mesenchymal stem cells (MSC's). PentOS OI™ Max 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 PentOS OI™ Max and hydrate the matrix to the desired consistency. PentOS OI™ Max does not contain any extrinsic carriers and is entirely derived from 100% human allograft bone. PentOS OI™ Max resists irrigation and has a shelf-life of 5 years from the date of packaging. A proprietary process is used to preserve native BMP's and growth factors. Every lot of PentOS OI™ Max 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). PentOS OI™ Max 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 PentOS OI™ Max was provided to a well known U.S. cell-concentration device manufacturer for the purpose of rehydrating PentOS OI™ Max 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.

METHODS

- Mix 0.5 cc of PentOS OI™ Max 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 PentOS OI™ Max 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

RESULTS

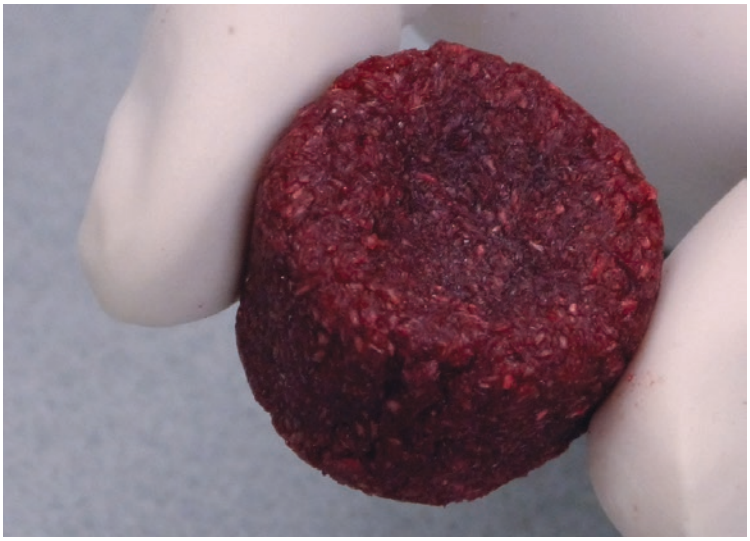
TIME	GFC %
15 Minutes	96.5%
30 Minutes	96%
60 Minutes	90%

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

CONCLUSION

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

Furthermore, this study further validates that PentOS OI™ Max 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.



PentOS OI™ Max with Bone Marrow Aspirate (BMA)

References:

1) Douglas W. Jackson, Using DBMs in Clinical Orthopedics: Orthopedics Today, October 2005

2) Kanim LEA; Houman 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

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