Mesenchymal Stem Cell Retention on AlloSync™ Pure

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Background

AlloSync Pure, a dehydrated osteoinductive bone graft matrix, becomes a moldable osteoregenerative matrix when hydrated with a patient's mesenchymal stem cells (MSCs). AlloSync Pure 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 AlloSync Pure and hydrate the matrix to the desired consistency. AlloSync Pure does not contain any extrinsic carriers and is entirely derived from 100% human allograft bone. AlloSync Pure resists irrigation and has a shelf life of 5 years from the date of packaging. AlloSync Pure uses a proprietary process that preserves native bone morphogenetic proteins (BMPs) and growth factors (GFCs). Every lot of AlloSync Pure is verified for osteoinductivity post-sterilization as a condition for distribution. In-vivo test results demonstrate that all 5 bone-forming elements are present (chondrocytes, osteocytes, bone marrow cells, cartilage, and new bone). Each lot of AlloSync Pure is also tested in vitro for the endogenous BMP-2 test marker for osteoinductivity. Test results demonstrate up to 40x BMP levels as measured against the BMP-2 control. BMPs irreversibly induce differentiation of perivascular mesenchymal-type cells into osteoprogenitor cells.

It is well documented that not all demineralized bone matrices (DBMs) are created equal. How a DBM is processed and formulated has the biggest effect on its potential efficacy.[1] There is a positive association between a greater percentage DBM-base (bone powder) in the DBM-base product and higher fusion rate.[2] Moreover, cell quality is unimportant if the cells are not delivered using the right carrier with appropriate cell-friendly characteristics otherwise, cells will not likely survive after implantation.[3]

A 5 cc sample of AlloSync Pure was provided to a well-known US. cell-concentration device manufacturer for the purpose of rehydrating AlloSync Pure with a fluid rich in GFCs and MSCs. The study was designed to measure percent cell viability over 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 AlloSync Pure with 0.5 cc of fluid containing 250,000 MSCs/GFCs using a spatula or 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 AlloSync Pure 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
- From here, determine the percentage of bound cells

Results

Table 1 shows the percentage of bound cells calculated as described above.

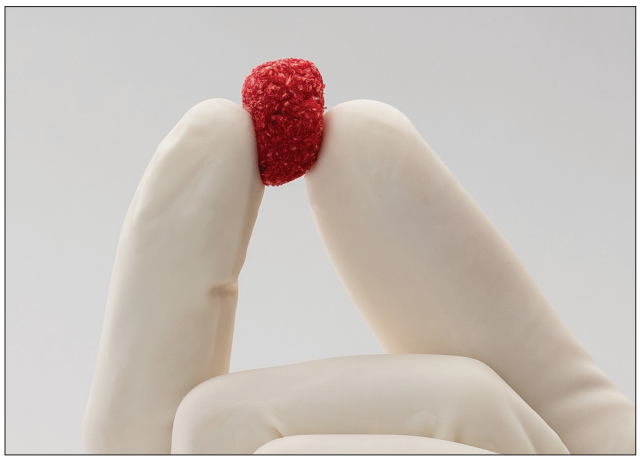
Table 1

Time	GFCs %
15 Minutes	96.5%
30 Minutes	96%
60 Minutes	90%

Conclusion

This investigation corroborates a previous independent study performed by a PRP concentration device manufacturer in the US which confirmed that AlloSync Pure maintained greater than 98% cell viability after 2 hours.

Furthermore, this study provides supports that AlloSync Pure is a verified osteoinductive bone graft matrix with appropriate cell-friendly characteristics that is able to deliver and maintain 90% cell viability for a minimum of 1 hour at room temperature.



AlloSync Pure with BMA

References

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3. Hsu WK. Interest in using stem cells in spinal surgery increasing. *AAOS Now*. September 2014.

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