

# Polymerizable Reverse Emulsions as a Mechanically Tunable Biomaterials Platform

Nazareth, G; Cohen, C; Arora, P; + Devore, D; \*Ducheyne, P

Gentis Inc Wayne, PA, 19087;

+Department of Chemistry and Chemical Biology, Rutgers University, Piscataway, NJ 08854 and

\*Center for Bioactive Materials and Tissue Engineering -

Departments of Bioengineering and Orthopaedic Surgery, University of Pennsylvania, Philadelphia, PA 19104

nazareth@gentisinc.com

## STATEMENT OF PURPOSE

Polymerizable reverse (water in oil) emulsion composites as biomaterials are a novel concept. They offer a highly versatile platform for developing biomaterials and can be easily tuned to meet the material properties useful over a wide range of applications. Through the appropriate selection of monomers, ingredients and phases, reverse emulsion technology can yield biocompatible, radio-opaque and injectable materials that can be implanted using minimally invasive delivery techniques. These emulsions are designed to polymerize *in-situ* with low exotherm and possess mechanical properties which can be "tuned" to cover a wide range.

Initially developed and studied for augmentation and replacement of the nucleus pulposus of the intervertebral disc, polymerized reverse emulsion materials have been shown to possess excellent fatigue properties<sup>1</sup>. Presented below is the overall materials platform and a report on the variation in mechanical properties that can be achieved,

## METHODS AND MATERIALS

Several samples of reverse emulsions were prepared by varying individual concentrations of Lauryl Acrylate monomer, Bis-Phenol-A-Dimethacrylate (BisGMA), Silanized Barium Glass Powder, Hydroxypropyl Methyl Cellulose (HPMC) and purified distilled water. Sample compositions are shown in Table 1. The emulsions were poured into dual cylinder cartridges with Benzoyl Peroxide added to one cylinder and Di-Methyl-P-Toluidine added to the other for free radical initiation. Each formulation formed a stable two part emulsion<sup>2</sup>. The liquid emulsions were dispensed through a static mixing tip fitted with an 18G needle into stainless steel molds to produce the cured solid samples used for mechanical testing.

Sample	Lauryl Acrylate(LA)	Bis-GMA	Silanized Glass Powder	Aqueous Content**
A	74.86	0.14	20	5.00
B*	54.90	0.10	40	5.00
C	53.00	2.00	40	5.00
D	36.50	1.00	60	2.50
E	33.34	3.33	60	3.33
F	27.5	10.00	60	2.50

Table 1. Composition of components in % weight by weight of the emulsion

\* DiscCell; \*\*2.50% wt/wt solution of HPMC prepared in Distilled Water

Samples A, B and C were molded into discs of height 7 mm and diameter 17.5mm and samples D, E and F into cylinders of height 14mm and diameter 6.9mm. The molds were incubated for 1 hour at 37°C after which the polymerized samples were removed from the molds and conditioned at 23°C ± 2°C and 50% ± 10% relative humidity for at least 8 hours<sup>3</sup>.

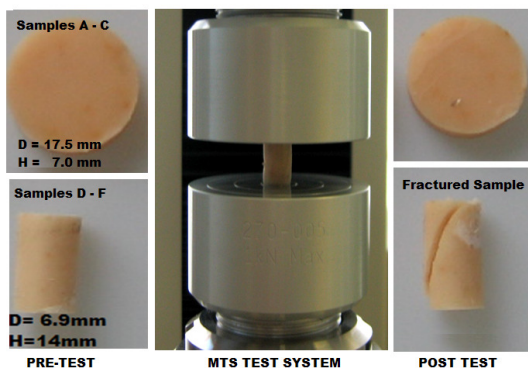


Figure 1

Five specimens per sample type were used to determine the material's elastic modulus. The specimens were compressed between stainless steel plates attached to an MTS mechanical testing system. Samples A-C were compressed to ~10% and D-F compressed until fracture.

## RESULTS AND DISCUSSION

Calculations of the elastic modulus for the samples were made from the stress-strain curve using the tangent modulus<sup>3</sup>. The reported modulus of elasticity indicates the maximum slope of the tangent in the initial linear portion of the curve. Figure 2 shows the mean modulus of the specimens on a log scale. The modulus ratio for Sample A: F was 1:3737.

Samples A - C were observed to be relatively soft, tacky and rubber-like. As a consequence, they flattened without fracture under compressive loading. Samples D-F exhibited modulus values that were orders of magnitude higher than samples A-C; they eventually fractured under compression (Fig 1). The percentage compression at fracture for D, E and F was 1.3%, 0.8% and 0.7% respectively. The ultimate compressive strengths for D, E and F were 3.8, 5.3 and 16.7 MPa respectively.

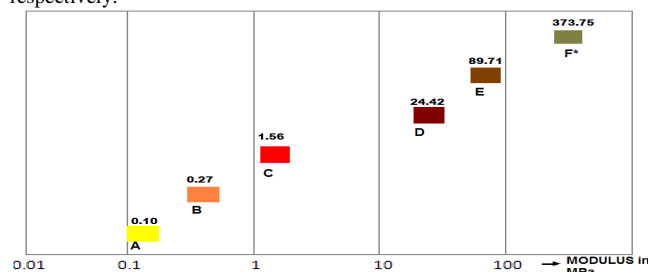


Figure 2 – Elastic Modulus of Samples A – F (\*n=4)

Due to their relatively softer nature, samples A-C were molded into disc specimens rather than cylinders to prevent buckling and shear effects under loading.

As seen in Fig 2, an increase in the glass content from 20% in A to 40% in B while maintaining the LA: BisGMA ratio constant resulted in an increase in modulus by a factor of 2. The exponential increase in C can be attributed to the strong cross linking provided by increased BisGMA content. A similar trend for 60% glass can be seen in samples D-F. It is clear that a wide range of moduli can be achieved with these reverse emulsions that correspond to the properties of diverse human tissues. Viscoelastic studies including creep and stress relaxation tests are currently underway.

## CONCLUSION

The data of this study substantiates that polymerizable reverse emulsions can be tuned to have a wide range of mechanical and elastic properties.

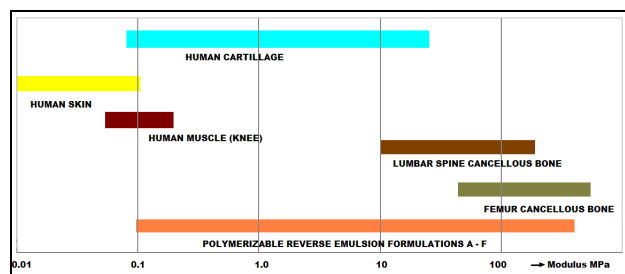


Figure 3: Comparison of elastic modulus of various human tissues<sup>4</sup> in the range of Samples A-F

## REFERENCES:

- 1) Cohen C. et al, "Constrained Compression and Torsion Fatigue Testing of Polymer Emulsion Composites for Nucleus Pulposus Augmentation", Transactions of the 54th Annual Meeting of the Orthopedic Research Society, 2008, #1450. 2) Devore D., Ducheyne P., Cohen C., "Polymerizable Emulsions for Tissue Engineering", US Patent# 7,537,754 2009. 3) Standard Test Method for Compressive Properties of Rigid Plastics, ASTM D695-08. 4) Black J., Hastings G. W. "Handbook of biomaterial properties", 1998.