# *In vitro* Evaluation of Mesh-reinforced Absorbable Self-setting Composite Adhesive Bone Cement

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**Statement of Purpose:** Preliminary results demonstrating the feasibility of producing new self-setting adhesive bone cements based on methoxypropyl cyanoacrylate and inorganic phosphates prompted the exploration of fiber-reinforced absorbable self-setting composite bone fillers for treating different forms of bone defects.[1-3] This led to conducting an exploratory study on fiber-reinforced absorbable self-setting composite bone filler based on methoxypropyl cyanoacrylate reinforced with warp-knitted mesh made of multifilament yarn of a high-lactide copolymer.[4-6] Preliminary results of the exploratory study demonstrated the feasibility of producing a self-setting composite adhesive bone filler with promising properties for repairing bone defects, including those in the maxillofacial and cranial regions.[6] A logical extension of these activities was to conduct a focused study on the preparation and *in vitro* evaluation of representative forms of these composites as discussed in the present communication.

**Methods:** Self-setting, absorbable bone cements were prepared from methoxypropyl cyanoacrylate and either (1) calcium phosphate with potassium phosphate (SCC-P type composites) or (2) calcium phosphate in combination with calcium silicate (SCC-PS type composites). All composites were reinforced with warp-knitted mesh made of multifilament yarn of a high-lactide copolymer. Using molds constructed from stainless steel and Teflon, mesh-reinforced samples of 3 in. x 3 in. x 2 mm were prepared for SCC-P type and SCC-PS type bone cements. Samples of approximately 1 cm x 5 cm x 2 mm were cut from original molded samples and evaluated by mechanical three-point bending. *In vitro* mass loss testing was evaluated after samples were incubated in deionized water at 50 ºC for 28 days.

**Results:** Compositions of each sample are described in Table I. As expected, *in vitro* mass loss for mesh-reinforced composites over a 28 day period were similar to those of unreinforced samples of the same composition (Table II). Overall, SCC-PS3 had a greater mass loss than SCC-PS12 at all time periods tested. Results from three-point bending tests revealed that the $CaSiO_3$-containing SCC-PS3 composites possessed better mechanical properties than the $K_2HPO_4$-containing SCC-P12 (Table III). However, the mechanical properties of both mesh reinforced samples for SCC-PS3 and SCC-PS12 were similar.

**Table I. Compositions of SCC-P and SCC-PS-type Composites Used to Prepare Mesh-reinforced Samples**

| Sample SCC- | Solid / MPC, g/mL | Composition of Solid Component; weight ratio |
|---|---|---|
| PS3 | 50/50 | 50 / 50, $CaHPO_4$ / $CaSiO_3$ |
| P12 | 60/40 | 95 / 5, $CaHPO_4$/ $K_2HPO_4$ |

**Table II. *In Vitro* Mass Loss Data at 50 ºC**

| Sample SCC- | Percent Mass Loss | | | |
|---|---|---|---|---|
| | 7 Days | 14 Days | 21 Days | 28 Days |
| PS3 | 34.8% | 38.2% | 41.0% | 43.1% |
| PS3 Reinforced | 35.9% | 38.5% | 37.7% | 40.9% |
| P12 | 2.4% | 4.2% | 6.2% | 8.8% |
| P12 Reinforced | 9.4% | 4.7% | 6.3% | 11.1% |

**Table III. Three-point bending Data for Mesh-reinforced SCC-P12 and SCC-PS3**

| Sample SCC- | Peak Load (N) | Peak Stress (psi) | Modulus ($N/mm^2$) | Energy Under Curve ($N/cm^3$) |
|---|---|---|---|---|
| PS3 | 51 | 356 | 76 | 39 |
| PS3 Reinforced | 33 | 245 | 64 | 34 |
| P12 | 29 | 217 | 32 | 131 |
| P12 Reinforced | 34 | 242 | 41 | 70 |

**Conclusions:** Similar mass loss for mesh-reinforced composites and unreinforced composites of the same composition indicate that the inclusion of a high-lactide copolymer into our self-setting adhesive bone cements does not significantly alter the absorption profile.
However, mesh-reinforcement appears to have improved the mechanical profile of the SCC-P12 composite while diminishing the mechanical profile of the SCC-PS3 composite. These results suggest that mesh reinforcement is more suitable for the SCC-P type composites than the SCC-PS type. Future studies will verify the effect of mesh-reinforcement on the mechanical profile of different composites.

**References:**

1. Shalaby, S.W. et al., U.S. Patent app. 11/601,994 (2006).
2. Shalaby, S.W. et al., U.S. Patent app. 12/080,649 (2008).
3. Shalaby, S.W. et al., *Trans Soc Biomater*, 31, 519 (2009).
4. Shalaby, S.W. U.S. Patent 7,048,753 (2006).
5. Anneaux, B.L. et al., *Trans Soc Biomater*, 25, 659 (2002).
6. Vaughn, M.A. et al., *Trans Soc Biomater*, 31, 522 (2009).

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