Oriented composites meet tough orthopedic demands

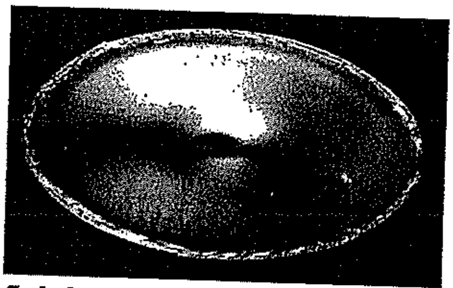
BY R.L. REIS*, A.M. CUNHA* AND M.J. BEVIS**

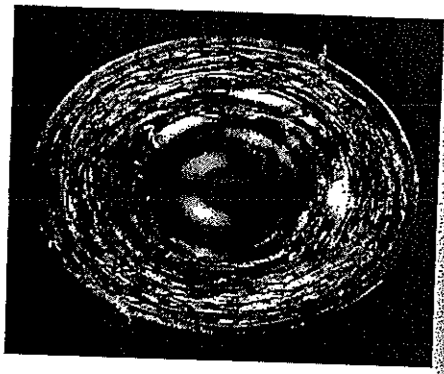
Innovative processing technology offers greater stiffness and ductility for manufacture of human implants.

Biomaterials are a growing applications field for polymeric materials and composites. The severest problem facing them is that when molded, the parts are subjected to highly demanding service conditions. In the specific case of orthopedic devices – prostheses, bone fillers, or fixation plates – one major challenge is the development of products with mechanical properties that match those of human bone as closely as possible. It is essential for the materials to combine adequate biocompatible and bioactive (i.e., bone-bonding) behavior.

All of these demands have been met by using shear controlled orientation in injection molding (Scorim) to induce an improved morphology or microstructure into moldings that result in a substantial enhancement of the essential material properties. It has been able to match bone mechanical behavior by achieving a modulus greater than 7 GPa.

Materials intended for use as implants for bone fixation must avoid the stress-shielding phenomena that are caused by being too stiff. For example, metallic materials such as titanium or stainless steel have a modulus of 100 to 200 GPa in comparison to the 7 to 20 GPa range found in human cortical bone. Consequently, almost all the stress will be supported by the implant and not by the healing bone. Since new bone needs to be under stress to be induced to grow, the problem of using too strong and stiff a material becomes readily apparent. The ideal bone replacement/fixation should have mechanical properties that fall in the 7 to 20 GPa range.





Typical morphology of conventionally molded (above) and Scorim processed HMWPE (right).

Work to date by the authors in relation to biomedical applications has been conducted with two types of polymeric systems; a bioinert material for permanent applications that is based on high-molecular weight polyethylene (HMWPE); and biodegradable starch-based blends aimed at temporary applications. In both cases,

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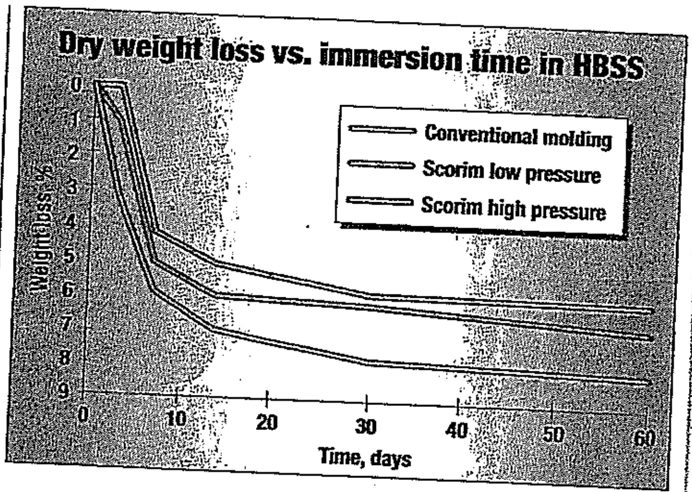
Comparison of mechanical properties, conventional molding vs. Scorim

Material	Weight, % of HA[a]	Conventional injection molding: Modulus at 1% strain, GPa	Conventional injection molding: Tensile strength, MPa	Conventional injection molding: Strain at break, ε_r, %	Scorim: Modulus at 1% strain, GPa	Scorim: Tensile strength, MPa	Scorim: Strain at break, ε_r, %
HMWPE	0	1.20 ± 0.08	25.0 ± 0.5	13.0 ± 0.2	4.54 ± 0.61	83.6 ± 5.5	20.8 ± 4.2
HMWPE + HA	50/30	4.03 ± 0.12	39.2 ± 0.7	5.9 ± 0.4	7.45 ± 0.21	73.5 ± 4.1	18.7 ± 3.1
SEVA-C	0	1.81 ± 0.16	35.6 ± 3.2	5.3 ± 0.5	2.97 ± 0.23	41.8 ± 0.8	7.1 ± 2.0
SEVA-C + HA	30/30	5.24 ± 0.34	35.7 ± 5.6	1.8 ± 0.3	7.19 ± 0.21	42.8 ± 3.1	0.5 ± 0.1
S/CA	0	3.24 ± 0.31	70.2 ± 4.8	5.5 ± 1.2	5.81 ± 0.16	98.7 ± 6.8	8.6 ± 2.0
S/CA + HA	30/30	4.94 ± 0.36	60.4 ± 0.4	4.1 ± 0.3	8.63 ± 0.12	65.4 ± 5.8	3.1 ± 0.2

a HA percentage for achieving maximum stiffness in conventional/Scorim processing.



bioactive reinforcements are used to promote osteoinductive behavior, and simultaneously to boost stiffness.

The layered and highly oriented microstructure that can be obtained through the control of the thermomechanical fields imposed by the Scorim process, maximizes the stiffness of the polymeric matrix. It also enhances the alignment of the reinforcement phase, and leads to the improvement of other important properties, such as reducing the water-uptake in the case of starch-based materials.

The Scorim technology is based on the action of two or more oscillating, hydraulically actuated pistons, that induce a dynamic shear field to the melt during the solidification stages of injection molding. These pistons are assembled on a special injection head that is fitted in the front of the machine barrel. They can be driven to operate in or out of phase, and under different levels of pressure and shearing cycle time. Through the adequate adjustment of these operational processing variables, it is possible to assure a high shear level in the solidifying melt and consequently a very oriented microstructure. The optimum selection of Scorim process variables leads to substantial and simultaneous increases in stiffness and toughness.

Different types of polymeric systems were used in the study, namely, Hostalen GM 9255F, a HMWPE from Ticona; and Mater-Bi, starch-based blends from Novamont, Novara, Italy, obtained from native maize starch (70% amylopectin and 30% amylose) and a synthetic copolymer. Two types of starch-based blends that were studied included starch/poly(ethylene vinyl alcohol) (SEVA-C) and starch/cellulose acetate (S/CA). Hydroxylapatite (HA) was obtained from Plasma Biotal Limited, North Derbyshire, U.K., for use as reinforcement. It is a calcium phosphate salt, the natural bone mineral, but it can also be synthesized for commercial use.

The experimental plan included the preparation of a series of compounds containing the HA reinforcement at weight-percentages of 0, 10, 20, 30, and 50. Both conventional injection molding and Scorim technology were used to produce 5-mm dia cross-section dumbbell specimens for testing.

The molded specimens were conditioned and tensile tested, using an Instron 4505 fitted with a resistive extensometer, in a controlled environment of 23°C (73°F) and 55% relative humidity.

The mechanical test results (table, p. 73) show the enhancing effect of Scorim on the compounds studied. The major increase occurred for HMWPE and is associated with the change in micromorphology induced by the macroscopic shearing action of the Scorim process. The effect of this can be seen in transmission light micrographs (photos, p. 73). The elliptical cross sections result from the sample preparation procedure, where the cuts of the 10-μm-thick slices were made obliquely to the molding cross-section. The characteristic skin-core morphology produced by conventional molding can be contrasted to the oriented layers of the Scorim samples that feature a shish kebab-like semicrystalline structure.

The mechanical properties of both starch-based polymers were also increased by the structure developed under Scorim processing. However, the improvement of properties was not as impressive as for HMWPE because the thermal sensitivity of the materials imposed constraints on the allowable processing conditions, and also because of their intrinsically lower crystallinity. Nevertheless, the SEVA-C and S/CA specimens molded with Scorim showed an increase in tensile strength of 20 to 40%, and gains of 65 to 80% in stiffness and 35 to 55% for strain at break, when compared to conventionally molded samples.

In the reinforced compounds – HMWPE or starch-based – both the matrix and the filler are oriented. Through the Scorim process it was possible to increase significantly the mechanical performance of these grades. For HMWPE, this increase is about 90% for strength and stiffness and more than 300% for ductility.

The mechanical property evaluation showed that there is an optimum level for the HA concentration in order to achieve maximum stiffness, which is determined by the viscosity required for the effective structure development during Scorim processing. Except for HMWPE plus HA, the optimum amount of HA was the same for both conventional and Scorim technologies. For HMWPE plus HA, the ideal weight-percentage of HA was 50% in conventional, 30% for Scorim.

The influence of processing conditions on degradation of the implant materials in Hank's Balanced Salt Solution is shown for conventional molding and moldings produced by Scorim at two different pressures. All samples followed the same trend, and the higher-pressure Scorim moldings exhibited significantly reduced weight loss. This was attributed to the essential microstructural differences imparted by Scorim processing.

Overall, the application of Scorim to the biomaterials systems studied has proved effective in modifying the microstructure of moldings. The process maximizes the mechanical performance of polymers and composites with consequent substantial and simultaneous enhancement of both stiffness and ductility. The more compact and oriented structure also reduces the rates of polymer degradation when subjected to exposure to aqueous environments. This latter feature provides for the retention of mechanical properties for longer periods.

This developmental process shows promising results that we expect will allow it to be used in the future for manufacturing of implants. The process is also being used in a major European Union research project involving Portugal, the U.K., Italy, and the Netherlands. The project's $8 million budget is targeted for the development of Isobone, a starch-based tissue-engineered living bone equivalent intended for the clinical market. Both these promises hinge on the fact that this technology produces a composite product that, like in the Goldilocks fable, is not too stiff, not too flexible, but may be just right. *–Edited by William A. Kaplan* ❑

A PUBLICATION OF THE McGRAW-HILL COMPANIES MAY 1999

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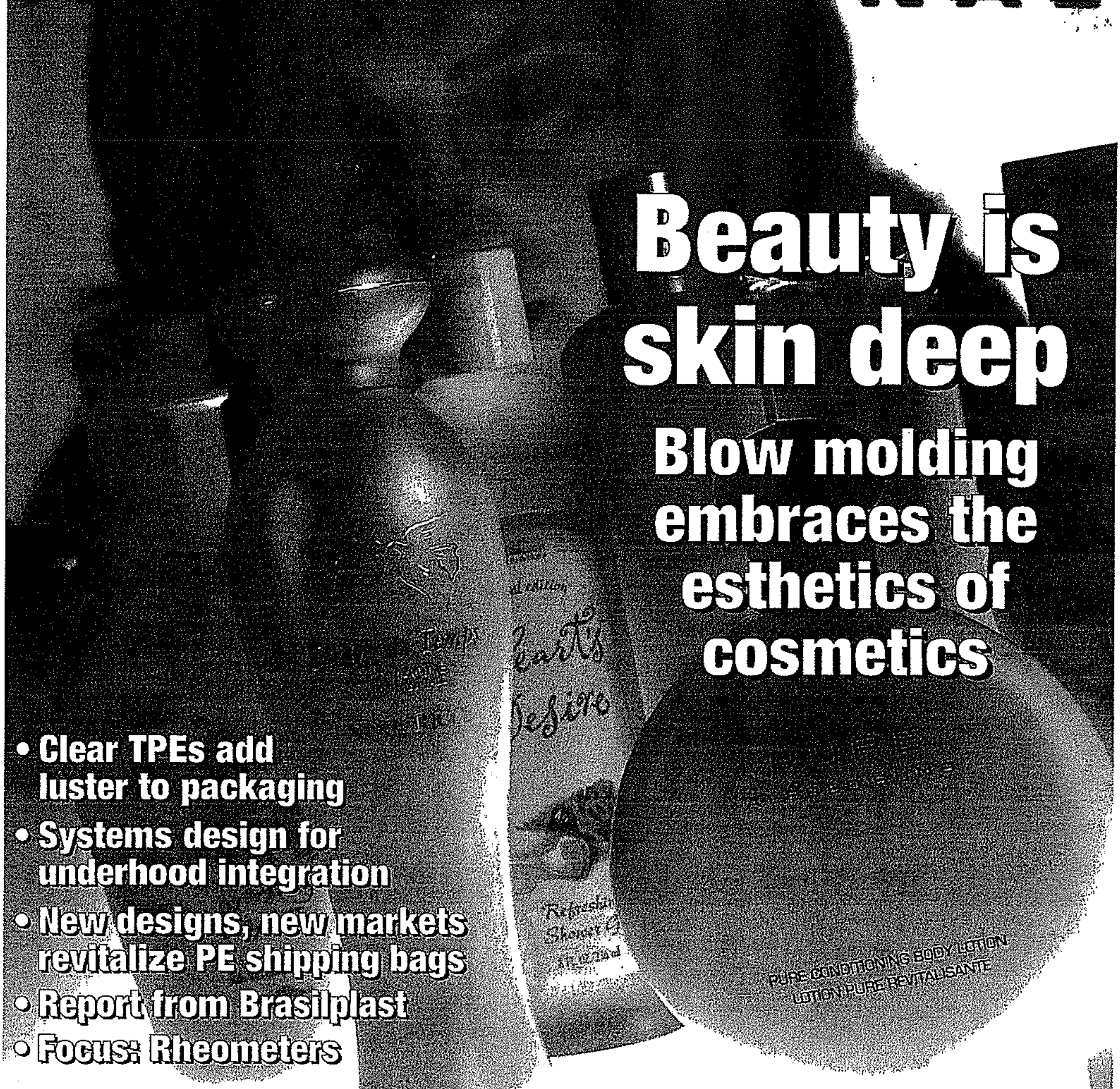

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