Analysis of Contemporary Resins and Conversion Methods
ASTM Working Group for Medical Grade UHMWPE
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The purpose of this study was to survey the mechanical behavior of contemporary Type 1 and Type 2 UHMWPE resins after ram extrusion and compression molding. This information may be used to evaluate the suitability of current requirements for UHMWPE fabricated forms.

Three commercial suppliers provided physical and mechanical property data collected during certification of 680 individual lots of medical grade UHMWPE. Data were provided for GUR 1020 (Type 1) and GUR 1050 (Type 2) resins, all produced by Ticona. The reported data included density, yield and ultimate tensile strength, elongation to failure, as well as IZOD impact resistance. The breakdown of the individual lots in the total data set, according to resin and conversion method, is summarized in Table 1.

Table 1. Number of Individual UHMWPE Lots Evaluated for the Present Study

	GUR 1020 (Type 1)	GUR 1050 (Type 2)	*Total*
Ram Extruded	113	218	*331*
Compression Molded	186	163	*349*
Total	*299*	*381*	*680*

Analytical Methods

Based on the distribution of the density and tensile mechanical properties, parametric statistical methods were judged to be appropriate. Consequently, the reported physical and tensile mechanical properties were statistically evaluated using analysis of variance (ANOVA) and Fisher's PLSD tests to assess the significance of resin (Type 1 vs. Type 2) and conversion methods (Ram Extruded vs. Compression Molded).

The distribution of the Izod impact data, however, did not appear normally distributed. Histograms of impact resistance for four material groups (Extruded 1020, Molded 1020, Extruded 1050, and Molded 1050) are shown in Figure 1. Impact data for 92 of the reported lots were omitted due to missing values. A nonparametric (Kruskal-Wallis) statistical test was used to assess the significance of differences in impact resistance between the four material groups. For all statistical tests, a p-value of 0.05 was used as the basis for statistical significance.

Results and Discussion

Not surprisingly, the data reported by the converters for contemporary UHMWPE was found to exceed the requirements for Type 1 and 2 resins, as set forth in ASTM F648. For density, resin but not conversion method was found to be a significant factor ($p < 0.0001$, Table 2). For the tensile mechanical properties, resin as well as conversion method were both found to be significant factors (Table 2). Although statistically significant, differences in the density and tensile properties of UHMWPE were in general not substantial (less than 21% difference in means between the Extruded GUR 1020 and Molded GUR 1050, Table 2).

Based on the Kruskal-Wallis test, differences in impact strength between the four groups of UHMWPE materials were found to be statistically significant ($p < 0.0001$, Table 3). Resin was expected to substantially influence the impact resistance, based on the standard material specification for medical grade UHMWPE in ASTM F648. However, an unexpected finding of this study was the observation of a substantial difference (34%) between the median impact strengths of the extruded and molded GUR 1050 (Table 3, Figures 1C&D). The median impact strengths of the extruded and molded GUR 1020, on the other hand, were comparable (Table 3, Figures 1A&B).

Table 2. Summary of Mean (± Standard Deviation) physical and tensile mechanical properties of extruded and molded UHMWPE.

Material	Density (kg/m^3)	Tensile Yield (MPa)	Ultimate Tensile Strength (MPa)	Elongation to Failure (%)
Extruded GUR 1020	935 ± 1	22.3 ± 0.5	53.7 ± 4.4	452 ± 19
Molded GUR 1020	935 ± 1	21.9 ± 0.7	51.1 ± 7.7	440 ± 32
Extruded GUR 1050	931 ± 1	21.5 ± 0.5	50.7 ± 4.2	395 ± 23
Molded GUR 1050	930 ± 2	21.0 ± 0.7	46.8 ± 6.4	373 ± 29

Table 3. Summary of IZOD impact strength data for extruded and molded UHMWPE, compared with the minimum specification set forth in ASTM F648. Legend: IQR = Interquartile Range.

Material	Median (IQR) Impact Strength (kJ/m^2)	Minimum Specification (ASTM F648)	Minimum Impact Strength (kJ/m^2)	Maximum Impact Strength (kJ/m^2)
Extruded GUR 1020	157 (18)	140	141	205
Molded GUR 1020	158 (18)	140	140	213
Extruded GUR 1050	117 (8)	73	79	134
Molded GUR 1050	87 (26)	73	73	130

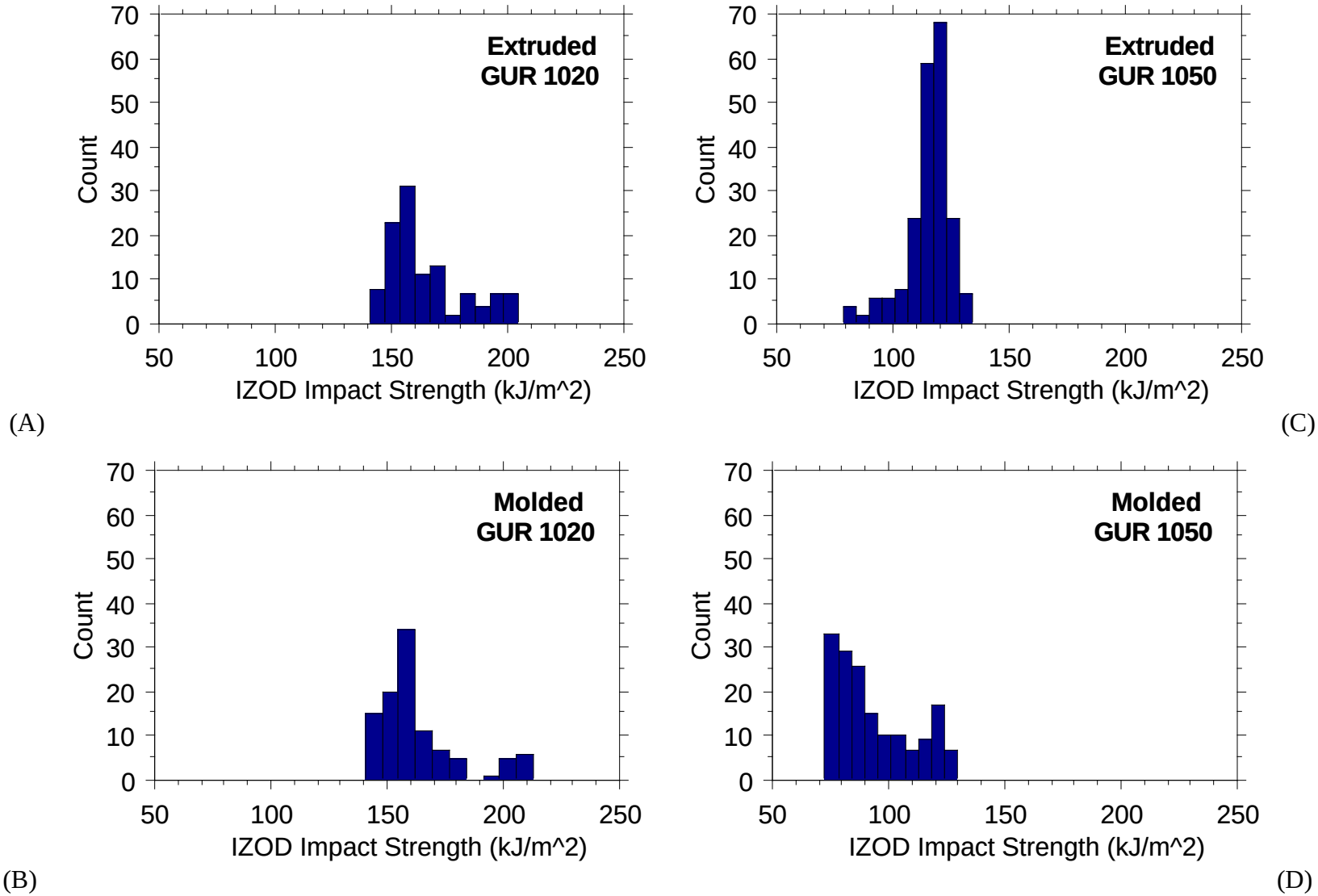

Figure 1. Histograms of Izod Impact Strength for (A) 113 Lots of Extruded GUR 1020; (B) 104 Lots of Compression Molded GUR 1020; (C) 208 Lots of Extruded GUR 1050; and (D) 163 Lots of Compression Molded GUR 1050.