RESEARCH PAPER

Validation of Mechanical Property Variability in Medical-Grade Polymeric Biomaterials Used for Orthopedic Implants

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Abstract

Medical-grade polymeric biomaterials, including polyether ether ketone (PEEK), polymethyl methacrylate (PMMA), and ultra-high molecular weight polyethylene (UHMWPE), are extensively employed in orthopedic implant systems due to their favorable mechanical performance, biocompatibility, and established clinical reliability. Nevertheless, manufacturer datasheets frequently report mechanical properties across broad ranges, which may introduce variability and uncertainty in implant design, computational modelling, and performance prediction.

In the present study, Shore D hardness and compressive strength of medical-grade PEEK, PMMA, and UHMWPE were experimentally determined to establish precise mechanical property values directly relevant to load-bearing orthopedic applications. All testing was performed in accredited laboratories under standardized conditions, with specimen preparation conforming to established testing protocols. The experimentally obtained values were systematically compared with datasheet-reported ranges and previously published literature.

The results revealed notable deviations from nominal datasheet values, particularly in compressive strength, underscoring the necessity of experimental validation prior to tribological evaluation or biomechanical modelling. The validated mechanical property dataset generated herein provides robust input parameters for implant design, finite element analysis, and subsequent wear characterization of medical-grade polymeric biomaterials employed in hip and knee joint prostheses.

Keywords: Medical-grade Polymers, Biomaterials, PEEK, UHMWPE, PMMA, mechanical properties, compressive strength, Shore D hardness, orthopedic implants

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1. Introduction

Medical-grade polymeric biomaterials constitute a cornerstone of contemporary orthopedic implant technology, particularly in hip and knee joint arthroplasty, owing to their low density, resistance to corrosion, favorable biocompatibility, and advantageous mechanical performance [1], [2], [3], [4]. Among these, ultra-high molecular weight polyethylene (UHMWPE) has long been established as the bearing material of choice in acetabular liners and tibial inserts due to its exceptional wear resistance [5], [6], [7].

Polymethyl methacrylate (PMMA) is routinely employed as bone cement, providing reliable fixation of prosthetic components [5], [6], [7]. More recently, polyether ether ketone (PEEK) has emerged as a promising structural biomaterial, distinguished by its high strength, elastic modulus closely approximating that of cortical bone, and radiolucency, which facilitates postoperative imaging and clinical monitoring [8], [9].

Mechanical properties, particularly hardness and compressive strength, represent fundamental parameters that govern the functional performance and long-term durability of orthopedic implants. determinant of surface integrity, influencing resistance to plastic deformation and wear, whereas compressive strength defines the capacity of a biomaterial to sustain physiological loading without mechanical failure [10], [11]. The biomechanical environment of hip and knee joints is characterized by

complex cyclic loading patterns encountered during routine daily activities, with peak forces frequently exceeding several times the individual's body weight. Under such demanding conditions, precise and validated mechanical property data are indispensable for implant design, structural evaluation, and predictive modelling of clinical performance [12].

Despite their critical importance, the mechanical properties of medical-grade polymeric biomaterials are frequently reported in manufacturer datasheets as broad ranges rather than precise values. Such variability may arise from differences in processing techniques, molecular weight distribution, and testing methodologies [13], [14]. Exclusive reliance on these nominal datasheet values can introduce significant uncertainty in implant design, finite element modelling, and tribological investigations [15]. Prior research has consistently highlighted the heterogeneity of polymer properties and underscored the necessity of rigorous experimental validation under application-specific conditions to ensure reliability in orthopedic implant performance [16], [17], [18]. However, the available literature provides limited systematic reporting of experimentally validated hardness and compressive strength values for commonly utilized medical-grade orthopedic polymers prior to tribological or biomechanical evaluation. This gap is clinically significant, as precise mechanical property data are essential for ensuring reliability in implant performance and predictive modelling. Accordingly, the objective of the present investigation was to experimentally determine the Shore D hardness and compressive strength of polyether ether ketone (PEEK), polymethyl methacrylate (PMMA), and ultra-high molecular weight polyethylene (UHMWPE) using

Hardness is a critical standardized testing protocols. The experimentally derived values were subsequently compared with datasheet-reported ranges and previously published literature, with the aim of establishing robust and clinically relevant mechanical property data to support orthopedic implant design and application [13], [14], [15], [16], [17], [18].

2. Materials and Methods

2.1 Materials Selection

The polymeric materials selected for this study include polyether ether ketone (PEEK), polymethyl methacrylate (PMMA), and ultra-high molecular weight polyethylene (UHMWPE). These materials were chosen based on their widespread use in orthopedic implants and distinct mechanical characteristics [1], [8], [19]. PEEK is increasingly used in load-bearing orthopedic components, UHMWPE is predominantly used in articulating surfaces, and PMMA is employed as bone cement for implant fixation.

2.2 Specimen Preparation

Cylindrical specimens were prepared from each material by turning on lathe in accordance with standard testing requirements. Care was taken to ensure uniform geometry, smooth surface finish, and dimensional accuracy to minimize experimental variability as shown in figure1 and as specified in table1.

Figure 1: Specimen of size 15 mm by 30 mm size for Shore hardness test and Compression test for peak stress.

Material	Form Supplied	Specimen Geometry	Dimensions of test sample (mm)	Test Performed	Standard Followed	Testing Facility

PEEK	Rod of Diameter:20 mm, Length: 300 mm	Cylindrical	Diameter: 15mm, Length: 30mm	Shore D Hardness	ASTM D2240	Nashik Engineering Cluster, Nashik
PEEK	Rod of Diameter:20 mm, Length: 300 mm	Cylindrical	Diameter: 15mm, Length: 30mm	Compressive Strength	ASTM D695, ISO 604	Research lab of SSVPS College of Engineering, Dhule
PMMA	Rod of Diameter:20 mm, Length: 300 mm	Cylindrical	Diameter: 15mm, Length: 30mm	Shore D Hardness	ASTM D2240	Nashik Engineering Cluster, Nashik
PMMA	Rod of Diameter:20 mm, Length: 300 mm	Cylindrical	Diameter: 15mm, Length: 30mm	Compressive Strength	ASTM D695, ISO 604	Research lab of SSVPS College of Engineering, Dhule
UHMWPE	Rod of Diameter:20 mm, Length: 300 mm	Cylindrical	Diameter: 15mm, Length: 30mm	Shore D Hardness	ASTM D2240	Nashik Engineering Cluster, Nashik
UHMWPE	Rod of Diameter:20 mm, Length: 300 mm	Cylindrical	Diameter: 15mm, Length: 30mm	Compressive Strength	ASTM D695, ISO 604	Research lab of SSVPS College of Engineering, Dhule

Table 1: Specimen dimensions and preparation details

2.3 Shore D Hardness Testing

Shore D hardness testing was carried out at the Nashik Engineering Cluster, Nashik, in accordance with **ASTM D2240** standards [20]. Multiple indentations were performed on each specimen at different locations to account for surface heterogeneity, and the average value was reported as the representative hardness for each material as shown in table 2, figure 2 shows photograph of Shore D hardness testing setup.

Sr. No.	Specimen	Readings			Average Hardness Value
1	Polyetheretherketone (PEEK)	87.5	87.5	86	87
2	Ultra-High-Molecular-Weight Polyethylene (UHMWPE)	63	62	63.5	63
3	Polymethyl methacrylate (PMMA)	75.5	78	75.5	76

Table 2: Shore D hardness test results

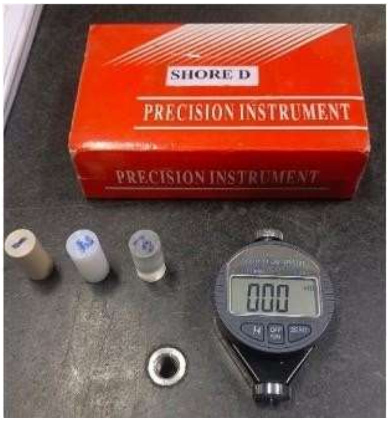

Figure 2: Photograph of Shore D hardness testing setup

2.4 Compressive Strength Testing

Compressive strength testing was conducted at the university-approved research laboratory of SSVPS College of Engineering, Dhule, Photograph of Automatic Compression Testing Machine at SSVPS BSD COE, Dhule's approved research Lab is shown in Figure 3 following **ASTM D695** standards [21]. Specimens were subjected to uniaxial compressive loading at a controlled strain rate until failure or significant deformation occurred. The peak stress sustained by each specimen was recorded as compressive strength as shown table 3, figure 4 shows representative compression test results and Specimen after compression test can be seen in figure 5.

Figure 3: Photograph of Automatic Compression Testing Machine at SSVPS BSD COE, Dhule's approved research Lab.

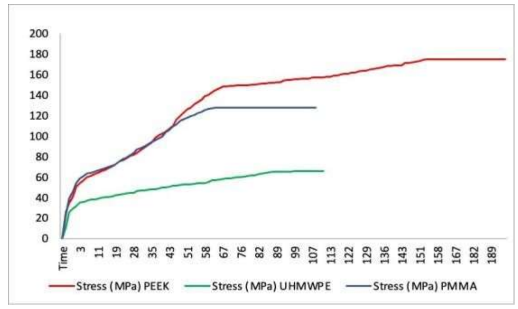

Figure 4: Representative Compression Test Results

Figure 5: Specimen after compression test

2.5 Data Analysis

The experimentally obtained mechanical property values were statistically analyzed and compared with manufacturer datasheet ranges and previously published literature values. Percentage deviations were calculated to assess variability and reliability as shown in table 4 and table 5.

Sr. No.	Sample No.	Sample Name	Weight(kg)	Length (in mm)	Dia (in mm)	Cross Section Area (mm2)	Peak Load (in kN)	Peak Stress (in MPa)
1	1	PEEK	0.006	30.00	15.00	176.72	30.90	174.853
2	1	UHMWPE	0.004	30.00	15.00	176.72	11.60	65.641
3	1	PMMA	0.006	30.00	15.00	176.72	22.60	127.886

Table 3: Compressive strength results of PEEK, PMMA, and UHMWPE

3. Results

3.1 Shore D Hardness

The Shore D hardness values obtained for PEEK, PMMA, and UHMWPE are presented in Table 2. PEEK exhibited the highest hardness, followed by PMMA, while UHMWPE showed the lowest hardness among the tested materials, the graphical representation of the same is shown in figure 6.

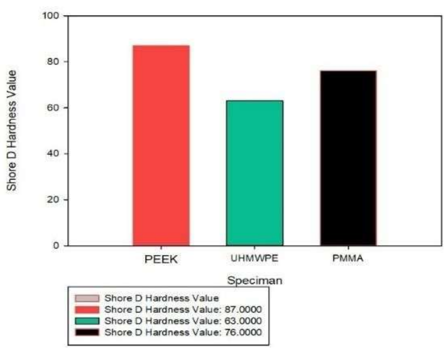

Figure 6: Comparative bar chart of Shore D hardness values

3.2 Compressive Strength

The compressive strength results are summarized in Table 3. PEEK demonstrated the highest compressive strength, indicating superior load-bearing capability. PMMA exhibited moderate compressive strength, whereas UHMWPE showed comparatively lower strength under compressive loading, the graphical representation of the same is shown in figure 7.

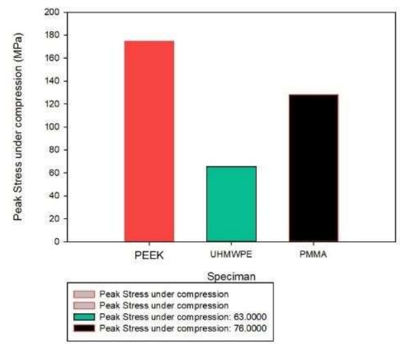

Figure 7: Comparative bar chart of peak stress under compression

3.3 Comparison with Datasheet Values

A comparison between experimentally obtained values and datasheet-reported ranges revealed noticeable deviations, particularly for compressive strength. In several cases, experimentally measured values did not align with mid-range datasheet values as shown in table 4 and table 5, highlighting the importance of experimental validation. Percentage deviation between experimentally measured values and datasheet midrange values was calculated to quantify material property variability and assess the reliability of datasheet-based assumptions.

Material	Property	Experimental Value	Datasheet Range	Mid-range	% Deviation
PEEK	Shore Hardness D Scale	87	85-95	90	-3.333333333
PMMA	Shore Hardness D Scale	76	80-90	85	-10.58823529
UHMWPE	Shore Hardness D Scale	63	60-70	65	-3.076923077

Table 4: Comparison of experimental values with datasheet ranges for Shore D hardness

As shown in table 4 the experimentally measured Shore D hardness values for PEEK, PMMA, and UHMWPE were slightly lower than the corresponding datasheet values, showing percentage deviations of −3.333%, −10.588%, and −3.076% respectively, indicating minor variability attributable to material processing conditions and surface characteristics during testing.

Material	Property	Experimental Value	Datasheet Range	Mid-range	% Deviation
PEEK	Compressive strength (MPa)	174.853	120-150	135	29.52074074
PMMA	Compressive strength (MPa)	127.886	100-140	120	6.571666667
UHMWPE	Compressive strength (MPa)	65.641	30-40	35	87.54571429

Table 5: Comparison of experimental values with datasheet ranges for compressive strength

As shown in table 5 The experimentally obtained compressive strength values for PEEK, PMMA, and UHMWPE were higher than the corresponding datasheet values with percentage deviations of 29%, 6%, and 87%, respectively. One possible reason for this variation is the difference in material grade and molecular characteristics of the supplied polymers. Datasheet values are typically reported as generalized ranges covering multiple processing grades and manufacturing conditions, whereas the specific batch or medical/engineering grade used in the present study may possess higher molecular weight, improved crystallinity, or better processing quality, resulting in enhanced compressive strength under controlled testing conditions. Similar variability in mechanical properties due to material grade and processing history has been reported in polymeric biomaterials used for orthopedic applications [8].

4. Discussion

The Shore D hardness results reflect the inherent molecular structure and stiffness of the tested polymers. The higher hardness of PEEK can be attributed to its aromatic backbone and semi-crystalline structure, which provide enhanced resistance to surface deformation [8], [22]. UHMWPE, with its long linear chains and high molecular mobility, exhibits lower hardness, consistent with previous studies [19], [23].

The compressive strength results confirm the superior load-bearing capability of PEEK, supporting its growing use in structural orthopedic applications [9], [24]. Although UHMWPE demonstrates excellent wear resistance, its relatively low compressive strength limits its use to articulating components rather than load-bearing structures [6], [18], [25]. PMMA's intermediate performance aligns with its primary role as a fixation material rather than a structural implant component [7].The observed deviations between experimentally obtained values and datasheet ranges are consistent with previous reports on polymer property variability due to processing conditions and testing methodologies [14], [16], [17], [18]. These findings emphasize the necessity of experimentally validating mechanical properties before employing these materials in implant design, finite element modelling, or tribological investigations.

5. Biomedical Application Perspective

Accurate characterization of mechanical properties is indispensable for predicting the clinical performance of orthopedic implants under physiological loading conditions. Hip and knee joints are subjected to complex cyclic loading during routine activities such as ambulation and stair climbing, with peak forces often reaching several times the body weight. These demanding biomechanical environments necessitate the use of reliable and validated material property inputs for implant design, computational simulation, and performance evaluation [12], [26], [27]. The experimentally validated mechanical property data presented in this study provide a robust foundation for material selection and serve as essential input for subsequent wear characterization and tribological investigations in orthopedic implant research.

6. Conclusions

In this study, we measured and confirmed the Shore D hardness and compressive strength of medical-grade PEEK, PMMA, and UHMWPE used in orthopedic implants. The results showed clear differences between our experimental values and the ranges reported in manufacturer datasheets, especially for compressive strength. PEEK demonstrated the strongest ability to handle load, while UHMWPE had lower compressive strength despite its well-known wear resistance. These findings highlight the need to test and validate mechanical properties before using them in implant design, computer modelling, or wear studies. The data generated here provide a dependable reference for future research on the biomechanics and wear behavior of polymeric materials in orthopedic applications.

7. Future Scope

Future work will integrate the validated mechanical properties with tribological testing, surface modification studies, and finite element simulations to develop predictive models for implant performance and longevity.

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