

Effects of Low Intensity Pulsed-Ultrasound (LIPUS) on the Mechanical and Thermal Properties of Polyether Ether Ketone (PEEK) and Carbon Reinforced PEEK

¹Fitch, D A; ¹Jones, B; ⁺de Ana, F J
¹Smith & Nephew Inc., Memphis, TN
⁺javier.deana@smith-nephew.com

INTRODUCTION:

Low intensity pulsed-ultrasound (LIPUS) is used extensively to increase fracture heal rates of fractures treated conservatively or with internal fixation. Polyether ether ketone (PEEK) and carbon fiber reinforced (CFR) PEEK are two materials increasingly used in fracture fixation instrumentation such as screws, plates, nails and especially spine fusion instrumentation. We investigated the mechanical and thermal effects of LIPUS on PEEK and CFR PEEK since they have not been previously studied.

METHODS:

Fourteen samples of each material were used for mechanical testing. The PEEK samples were obtained by cutting a 6mm diameter PEEK rod (PEEK OPTIMA® LT1R6, Invibio Inc., Lancashire, UK) into 50mm sections. The CFR PEEK (PEEK OPTIMA® Carbon Fiber, Invibio Inc., Lancashire, UK) samples had 30% carbon fibers by mass and were 'dog bone' shaped tensile bars with a cross section of 4mm by 10mm with the parallel length being 60mm before the bar begins to taper. We were able to use different shaped samples for the PEEK and CFR PEEK samples because the purpose of this study was to understand the effect of LIPUS exposure on each material, not to compare the materials.

All samples were submerged in a phosphate buffered saline solution (Fisher Scientific, Fair Lawn, NJ) and placed in a temperature chamber (Thermo Scientific, Fair Lawn, NJ) at 37°C. The 14 samples for each material were divided into seven-sample control and treatment groups. The treatment samples of each material were exposed to 140 hours, equivalent to 14 months of a daily 20-minute treatment of LIPUS generated by the EXOGEN 4000+™ Ultrasound Bone Healing System (Smith & Nephew Inc., Memphis, TN). All samples were then tested under monotonic load in three-point bend testing to determine the following properties: ultimate static bending strength, failure displacement and bending stiffness. A two-sample Student t-test ($p < 0.05$) was performed to determine if there was a significant difference between control and LIPUS-treated samples for the calculated mean of each property.

Six samples of each material were used for thermal testing. The six PEEK samples were identical to those described for the mechanical testing. Six CFR PEEK samples were obtained by cutting PEEK Optima® Carbon Fiber tensile bars described above into 48mm X 10mm X 4mm prisms. A 0.914mm diameter hole was drilled to the geometric center of each sample and a 30 AWG type T thermocouple (Newport Electronics Inc., Santa Ana, CA) was inserted.

All samples were submerged in phosphate buffered saline and placed in a temperature chamber (Gruenberg, Blue M, Tenney, Lunaire, New Columbia, PA) to equilibrate to 37°C. An additional thermocouple was placed in the saline solution away from the transducer to measure its temperature. The samples were exposed to two consecutive 20-minute treatments from the EXOGEN 4000+™. Samples were rearranged within the ultrasound beam and testing repeated so as to expose the samples to different parts of the beam. The absolute temperature was recorded for each sample and the saline solution during each treatment at a sampling frequency of 3 Hz. The mean temperature difference between the samples and saline solution was calculated to provide the temperature change caused by the LIPUS, minimizing the influence of the effect of the fluctuations in the temperature of the saline solution.

RESULTS:

Table 1 shows the results obtained from three-point bend testing of the control and LIPUS-treated samples of both materials. The p values resulting from the Student t-test comparing the controls to the LIPUS-treated PEEK samples were 0.441, 0.097, and 0.340 for the ultimate bending strength, failure displacement, and bending stiffness respectively. The p values comparing the control to the LIPUS-treated CFR PEEK samples were 0.065, 0.833, and 0.589 respectively.

Table 1. Summary of results from monotonic three-point bend testing. (Mean ± standard deviation)

Samples (N=7)	Ultimate Bending Strength (N)	Failure Displacement (mm)	Bending Stiffness (N/mm)
Control PEEK	485.18±6.4	6.34±0.2	140.7±2.9
LIPUS PEEK	487.51±4.3	6.55±0.2	139.0±3.5
Control CFR PEEK	780.45±16.3	2.06±0.2	395.7±6.4
LIPUS CFR PEEK	764.43±12.9	2.08±0.1	409.4±16.2

The maximum temperature difference between the saline solution and the PEEK samples was less than 1°C for all but one sample which reached a difference of 1.19°C. The maximum temperature difference for the CRF PEEK was less than 1°C for all but three samples. The maximum difference was 1.31°C. Figure 1 shows the temperature difference between the saline solution for three PEEK samples during two consecutive treatments. There was an interval of 2-3 minutes between the two 20-minute treatments. The samples were placed in the center of the beam (position 2) or slightly off center (positions 1 and 3).

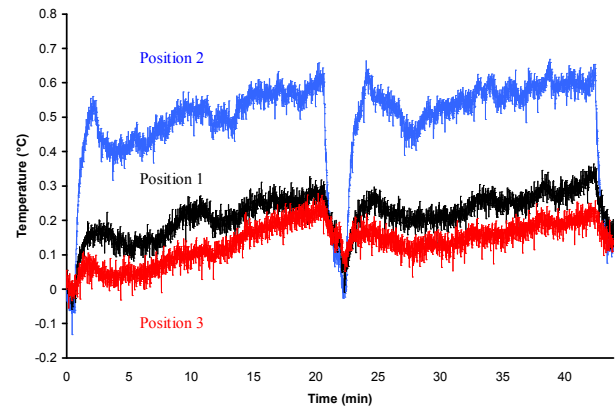


Fig 1. Temperature difference between the saline solution and three PEEK samples for two consecutive treatments.

DISCUSSION:

There were no statistically significant differences in the ultimate bending strength, failure displacement, or bending stiffness between the control and LIPUS-treated samples for each material. There was a small percent difference ($\leq 3.3\%$) between control and LIPUS-treated samples for the average values for all three parameters. These results suggest that the equivalent of 14 months of LIPUS treatment does not affect the mechanical properties of PEEK and CFR PEEK.

The maximum temperature difference between the phosphate buffered saline solution and any of the samples was 1.19°C for PEEK and 1.31°C for CFR PEEK. The samples located at the center of the beam consistently experienced larger temperature increases than those positioned slightly off center as they were exposed to greater ultrasound intensity.

CONCLUSIONS:

LIPUS does not negatively affect the mechanical properties of PEEK or CFR PEEK over the course of 14 months of 20-minute daily LIPUS treatments. LIPUS can cause small temperature increases ($\leq 1.31^\circ\text{C}$) in PEEK and CFR PEEK.