Research Paper

Carbon fiber reinforced PEEK Optima—A composite material biomechanical properties and wear/debris characteristics of CF-PEEK composites for orthopedic trauma implants

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ABSTRACT

Background: The advantageous properties of carbon fiber reinforced polyetheretherketone (CF-PEEK) composites for use as orthopedic implants include similar modulus to bone and ability to withstand prolonged fatigue strain.

Methods: The CF-PEEK tibial nail, dynamic compression plate, proximal humeral plate and distal radius volar plate were compared biomechanically (by four-point bending, static torsion of the nail, and bending fatigue) and for wear/debris (by amount of the debris generated at the connection between the CF-PEEK plate and titanium alloy screws) to commercially available devices.

Results: Four-point bending stress of the tibial nail and dynamic and distal radius plates yielded characteristics similar to other commercially available devices. The distal volar plate bending structural stiffness of the CF-PEEK distal volar plate was 0.542 Nm² versus 0.376 Nm² for the DePuy’s DVR anatomic volar plate. The PHILOS proximal humeral internal locking system stainless steel plate was much stronger (6.48 Nm²) than the CF-PEEK proximal humeral plate (1.1 Nm²). Tibial nail static torsion testing showed similar properties to other tested nails (Fixion, Zimmer and Synthes). All tested CF-PEEK devices underwent one million fatigue cycles without failure. Wear test showed a lower volume of generated particles in comparison to the common implants in use today.

Interpretation: Thus, these tested implants were similar to commercially used devices and can be recommended for use as implants in orthopedic surgery.

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1. Introduction

A composite material consists of two or more constituent materials of different physical or chemical properties in the micro to macro size range ($10^{-4}$–$10^{-2}$). This pattern encompasses one or more discontinuous phases embedded within a continuous phase. The discontinuous phase is usually harder and stronger than the continuous phase and is called the reinforcement material, whereas the continuous phase is termed the matrix (Migliaresi and Alexander, 2004). One of the composites

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Currently available in orthopedic use is the carbon fiber reinforced polyetheretherketone (CF-PEEK). Its mechanical, stiffness, strength, toughness and long-term properties have been characterized elsewhere (Kurtz and Devine, 2008; Rae et al., 2007; Vakiparta et al (2004); Zhao et al., 2009). CF-PEEK composites show a high utilization of the fiber in stiffness and strength, and a similarly high utilization of the matrix ductility in toughness. The effect of temperature on strength was examined by Carlile et al. (1989) for fiber and matrix dominated lay-ups. Those authors demonstrated that a high proportion of those properties were retained at different temperatures up to 143 °C (the glass transition temperature), whereas the crystalline melt transition temperature (Tm) occurred at around 343 °C. CF-PEEK exhibited high levels of toughness in a wide range of assessment techniques, such as fracture mechanics, instrument falling weight impact and post-impact compression. The fatigue test studied lifetimes in excess of one year (10^6 cycles), enabling cyclic loads to be accounted for in structural applications (Carlile et al., 1989). After polymerization, CF-PEEK was shown to be chemically inert and insoluble in all conventional solvents at room temperature, with the exception of 98% sulfuric acid (Ha et al., 1997).

The radiation stability of crystalline and amorphous CF-PEEK has been studied extensively. Total exposure of high doses of gamma irradiation between and above 10–50 MGy showed some degradation and cross-linking of CF-PEEK. This value is far higher than the irradiation needed for repeated sterilization, i.e., up to four times the 25–40 KGy doses of gamma irradiation in air, or 40–70 KGy in cases of treatment for bone metastasis (Kim et al., 2007; Kwarteng and Stark, 1990; Sakurai et al., 2002; Vaughan and Stevens, 1995).

Composite materials started to interest orthopedic surgeons in the late 1980s, who initially used them for joint replacement and for fracture fixation in cases of trauma (Bradley et al., 1980; Brown et al., 1990; Kurtz and Devine, 2008; Pemberton et al., 1992; Skinner, 1988; Tayton et al., 1982). Composite materials were introduced in the form of spinal cages as adjuvants to spinal fusion for degenerative discs (Brantigan et al., 2000; Brantigan and Steffee, 1993). A composite material was found to facilitate radiographic assessment by being radiolucent regardless of the used modality, i.e., X-ray, computerized tomography or magnetic resonance (Schulte et al., 2000). The use of the composites for total joint replacement, however, currently has more drawbacks than advantages due to a high failure rate (Adam et al., 2002; Akhavan et al., 2006; Jakim et al., 1983; Morscher and Dick, 1983). We can assume that the high rate of joint replacement failure can be explained by a fibrous capsule formation around FRC implants that prevents their integration to bone (Ballo et al 2010). The first composite plates were made of thermosetting polymers, such as plastic or epoxy that had the disadvantage of the inability to be contoured according to bony anatomy, a property that was preserved by the use of thermoplastic polymeric plates.

Additional biomechanical studies to verify which design can be best fitted for orthopedic purposes had been performed on different fiber orientations of CF-PEEK bone plates (Fujihara et al., 2003, 2004). Although there are some clinical and animal studies that used carbon fiber plates for trauma, no intramedullary nails or plates were clinically tested or used with the CF-PEEK Optima composite thus far.

2. Materials and methods

2.1. Nail description

The 10 mm composite tibial nail (CTN) was designed according to the specifications of a classic intramedullary interlocking...
nail. It has a slight 10% curve with three screw holes in the proximal part and three screw holes with a 10 mm distance between their centers in the distal part. The proximal screw hole is located 20 mm from the cranial end of the cranial, and the last hole is located 10 mm proximal to the distal end of the nail. The carbon fiber HexTow\textsuperscript{\textregistered} IM7 (Hexcel corporation, Stanford, CT, USA) used in this setting is a continuous, high-performance, intermediate modulus with a filament count tow of 6 K (6000). Each tow’s cross-sectional area is 0.13 mm\textsuperscript{2} and its filament diameter is 5.2 μm. The fiber volume is 60% in the composite matrix. Three samples of each new nail were evaluated according to the American Society of Testing and Materials (ASTM) (ASTM F 1264, 2000). The nail’s characteristics were compared to three other commercially available nails: Fixion 8.5/13.5 mm, Synthes URTN 10 mm and Zimmer 10 mm (Fig. 1).

2.2. Plates description

Three types of plates were studied: dynamic compression (DCP), proximal humeral (PHP) and distal volar radial (DVRP).

2.2.1. Dynamic compression plate (DCP)

Five samples of the Piccolo composite DCP that were 4.5 mm in thickness and 190 mm long, and one sample of a predicate device, the Synthes 4.5 mm locking compression plates (LCP), were evaluated. The Synthes LCP was chosen for the test because its holes are smaller than those of the Piccolo composite DCP, and, as such, the latter plate represents the worst case for the bending test. In addition, the results of preliminary tests on the Piccolo composite LCP (with the different types of holes characteristic) indicated that the failure point following static four-point bending tests (according to ASTM F382 recommendations) occurred at the compression portion of the combination hole, further supporting the decision to test the Piccolo composite DCP. The plate with a thickness of 4.5 mm was evaluated since it was the thinnest of the diaphyseal plates and therefore represented the worst case for testing the bending properties of diaphyseal plates.

2.2.2. Proximal humerus plate (PHP)

Five samples of the Piccolo composite PHP (3.7 mm in thickness and 190 mm long), and one sample of a predicate device, the Synthes 3.5 mm PHP (Philos) were evaluated.

2.2.3. Distal volar radius plate (DVRP)

Five samples of the Piccolo Composite DVRP (2.4 mm in thickness and 90 mm long), and one sample of a predicate device, the DePuy 2.4 mm DVR anatomic volar plate, were evaluated. These samples were chosen in accordance with ASTM F 1264 requirements, although the tests were performed under the requirements listed in ASTM F382, which describe test methods for only three specimens.

2.3. Biomechanical characteristics

2.3.1. Four-point bending test

The bending strength and stiffness of the nails and plates were evaluated by the four-point bending stress test. The tests were performed with the nail and plates being held with bridge span settings at 125 mm in the middle portion for the 2 lower bars and at 25 mm in the middle portion for the 2 upper bars (Fig. 3). Four-point bending bridge distances were set following the requirements of ASTM F382, based on plate design and hole locations. The test was performed using the single axis compression machine (Testometric M350-10K, Rochdale UK).

2.3.2. Static torsion of the nail

According to the ASTM 1264 Annex A2, the test was performed using a custom-made torsion adapter mounted on the single axis tension/compression machine (Testometric M350-10K, Rochdale UK), which allows transformation of axial load into torsion by the pulling of a cable wrapped on a wheel. The tension and cable displacement versus the load, as measured by the testing machine load cell, were recorded. The pull test machine speed is set to a constant speed rate of 5 mm/min, and the maximal torque is the product of the tension load multiplied by the wheel’s radius. In order to simulate the weakest condition, 5 mm pins were placed in the distal and proximal screw holes closest to the nail’s center and connected to the testing machine’s gripping devices. The expandable classic Fixion tibial nail was connected directly to the gripping device using the same gauge length.

2.3.3. Bending fatigue test

At least three implants were used for cyclic loading for each Piccolo composite nail and plate type. Load was determined so that the minimal alternating bending load would be at least 60% of the static yield bending strength as determined in the four-point bending static test. All implants had to sustain the load for at least 1,000,000 cycles, based on ASTM F1264 requirements, which is equivalent to a one-year period of healing. A load value of 60% or more of the bending strength was adapted to titanium, a common material of which predicate devices are made and one that has an endurance limit of $\sim 0.5–0.6 \sigma_u$ (Titanium Information Group). Piccolo composite DCPs and the DVRPs were tested as described above (Sections 2.2.1 and 2.2.2). The tests were performed until failure.
items were transferred to an ultrasonic bath for 5–10 min and then washed with flushing water for one minute. The parts were placed in a bath with a soap solution for 10 min. Cleaning and drying was performed as follows: the cycles following ASTM F1264 Annex A3 at 2 Hz (ASTM F 1264, calculated according to Schneider et al. (2001) under partial static torsion of 2 Nm. The applied load on the plate was nate loads of both axial and bending loads under a constant

Fig. 4 – Implant connection to the broken bone construct model within the testing jig.
bending structural stiffness (EI) was $210.8 \pm 11.01$ K [N/mm] and $4.17 \pm 0.21$ EI [Nm²], respectively, for the Piccolo plates and 172 K [N/mm] and 3.4 EI [Nm²], respectively, for the Synthes plate.

### 3.2.2. DCP fatigue test

Three plates were evaluated for cyclic fatigue under a load corresponding to at least 60% of the bending strength determined in the single cycle bend test. A load value of 60% or more of the bending strength was chosen for the fatigue test based on a comparison to titanium, a common material out of which predicted devices are made. Based on published data by Beardmore (2010), the endurance limit of titanium is about $0.5-0.7 \sigma_u$ (ultimate strength). The tests were completed with no failure following at least one million fatigue cycles.

### 3.2.3. PHP four-point bending test

The average bending strength of the 5 Piccolo PHPs was $15.2 \pm 1.13$ [Nm] in comparison to $15.12$ [Nm] for the Synthes Philos plate. The bending structural stiffness was $1.1 \pm 0.10$ EI [Nm²] for the Piccolo plates and $6.48$ EI [Nm²] for the Synthes Philos plate.

### 3.2.4. DVRP four-point bending test

The average bending strength of the 5 Piccolo DVRPs was $3.88 \pm 0.41$ M [Nm] in comparison to $3.24$ [Nm] for the DePuy DVR anatomic volar plate. The bending structural stiffness was $0.542 \pm 0.082$ EI [Nm²] for the Piccolo composite DVRP and $0.376$ EI [Nm²] for the DePuy DVR anatomic volar plate.

### 3.2.5. DVRP fatigue test

The same protocol was applied as for the diaphyseal plate (Section 2.3.3). Three plates were evaluated for cyclic fatigue under a load corresponding to at least 60% of the bending strength as determined in the single cycle bend test. The tests were completed with no failure following at least one million fatigue cycles.

### 3.3. Wear debris test

The tested plates and screws, particularly the interconnected area and debris, were visually inspected and assessed with the aid of an optical microscope (Figs. 5 and 6). The test jig container contents were collected and weighed after the fatigue test was completed. Each weighing procedure was repeated three times, the average and standard deviation were calculated, and they are presented in Table 3 for 1 \(\mu\)m filters and Table 4 for 0.2 \(\mu\)m filters. In order to derive the net weight (E) of the tested sample debris, the average weight of the empty filter (B) was subtracted from each total filter weight (A) following filtration. The average weight of the PBS residues (D) was also subtracted from the total weight.

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**Table 1 – Static four-point bending test for the carbon fiber reinforced polyetheretherketone (CR-PEEK) Piccolo composite nail in comparison to other commercially available nails.**

<table>
<thead>
<tr>
<th>Nails’ types</th>
<th>Structural stiffness [Nm]</th>
<th>Bending stiffness [Nm²]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite (10 mm)</td>
<td>$80.3 \pm 0.6$</td>
<td>$33.9 \pm 2.8$</td>
</tr>
<tr>
<td>Fixion IL (8.5–13.5 mm)</td>
<td>$64 \pm 2.9$</td>
<td>$41.4 \pm 4.4$</td>
</tr>
<tr>
<td>Synthes (8 mm) (tibia)</td>
<td>$43$</td>
<td>$20.7$</td>
</tr>
<tr>
<td>Synthes (11 mm) (tibia)</td>
<td>$43.8$</td>
<td>$33.1$</td>
</tr>
<tr>
<td>Synthes (10 mm) (femur)</td>
<td>$107.5$</td>
<td>$40.7$</td>
</tr>
<tr>
<td>Zimmer (10 mm) (femur)</td>
<td>$75$</td>
<td>$45$</td>
</tr>
</tbody>
</table>

**Table 2 – Torsion test results of three nails were compared to the tibial carbon fiber reinforced polyetheretherketone (CR-PEEK) nail.**

<table>
<thead>
<tr>
<th>Nails’ types</th>
<th>Structural stiffness [Nm]</th>
<th>Torsional stiffness [Nm/°]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite (10 mm)</td>
<td>$15.3 \pm 2.2$</td>
<td>$1.1$</td>
</tr>
<tr>
<td>Fixion IL (8.5–13.5 mm)</td>
<td>$14.3$</td>
<td>$0.83$</td>
</tr>
<tr>
<td>Zimmer (10 mm) (femur)</td>
<td>$13.6$</td>
<td>$1.2$</td>
</tr>
<tr>
<td>Synthes (10 mm) (femur)</td>
<td>$16$</td>
<td>$1.8$</td>
</tr>
</tbody>
</table>

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**Fig. 5 – Picollo composite carbon fiber reinforced polyetheretherketone (CR-PEEK) debris after filtration through a 0.2 \(\mu\)m filter using an optical magnifying microscope.**

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The results showed a significant difference between both collected debris filters, thus indicating that the CF-PEEK had a lower debris weight than the titanium control.

4. Discussion

The introduction of new technology or devices requires transparent reporting of biochemical, biological and biomechanical properties. In this study, we assessed the biomechanical properties of devices produced from carbon fiber reinforced polyetheretherketone (CF-PEEK). We also conducted tests for wear by evaluating the amount of the debris generated at the connection between the CF-PEEK plate and the titanium alloy screws. The biochemical and biological properties of various composite materials had been extensively investigated and reported earlier (Brown et al., 1990; Carlile et al., 1989; Ha et al., 1997; Kwarteng and Stark, 1990; Kurtz and Devine, 2008; Migliaresi and Alexander, 2004; Rae et al., 2007; Skinner, 1988). The biomechanical properties of the composite materials were evaluated as well (Fujihara et al., 2003, 2004), but for other composite combinations and for other plate designs.

In the present study, we evaluated the biomechanical properties of a tibial 10 mm nail, a 4.5 mm thick and 190 mm long DCP, a proximal humeral 3.7 mm thick and 190 mm long plate, and a volar radial 2.4 mm thick and 90 mm long plate, all made of CF-PEEK Optima. Our results were compared to those of three commercially available similarly designed devices in current use in the clinical orthopedic setting.

The 10 mm tibial nail passed the four-point bending test successfully by yielding similar results to those of the commercially available nails. The same diameter and material composition is the base for the other nails’ line, as humeral or femoral nails. The results of the static torsion test that was performed for the studied and the control nails were found to comply with the acceptance criteria of the ASTM standards. The studied nails passed the fatigue test that included the one million cycles without any visual signs of failure under a 2240 N load at a frequency of 5 Hz. The selected force was derived from the static four-point bending test multiplied by 0.7 as being the highest safety margin.

![Fig. 6 – Titanium debris in Fig. 4 after filtration through a 0.2 μm filter using an optical magnifying microscope.](image)

### Table 3 – Wear/debris weight following filtration by 1 μm filters.

<table>
<thead>
<tr>
<th>Sample</th>
<th>(A) 1 μm filters average weight after test solution filtration [mg]</th>
<th>(B) 1 μm clean filters average weight [mg]</th>
<th>(C) Wear debris weight ( (C = A - B) ) [mg]</th>
<th>(D) PBS residues average weight after 1 μm filtration [mg]</th>
<th>(E) Wear debris weight ( (E = A - B - D) ) [mg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>84</td>
<td>78.4</td>
<td>5.6</td>
<td>2.35</td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td>151.3</td>
<td>148.3</td>
<td>3.0</td>
<td>-0.25a</td>
<td></td>
</tr>
<tr>
<td>#3</td>
<td>128.1</td>
<td>126.1</td>
<td>2.0</td>
<td>-1.25a</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>–</td>
<td>–</td>
<td>3.53</td>
<td>3.25</td>
<td></td>
</tr>
<tr>
<td>Titanium</td>
<td>137.1</td>
<td>128.5</td>
<td>8.6</td>
<td>0.78b</td>
<td></td>
</tr>
</tbody>
</table>

* The negative weight is probably the result of the analytical weight resolution and accuracy. The calibrated analytical weight used in the test is accurate within 0.1 mg, therefore absolute uncertainty in the observed weight is ± 0.1 mg.

b The negative values were calculated as 0 for the calculation of the average result.

### Table 4 – Wear/debris weight following 0.2 μm filters filtration.

<table>
<thead>
<tr>
<th>Sample</th>
<th>(A) 0.2 μm filters average weight after test solution filtration [mg]</th>
<th>(B) 0.2 μm clean filters average weight [mg]</th>
<th>(C) Wear debris weight ( (C = A - B) ) [mg]</th>
<th>(D) PBS residues average weight after 0.2 μm filtration [mg]</th>
<th>(E) Wear debris weight ( (E = A - B - D) ) [mg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>112.7</td>
<td>112.5</td>
<td>0.2</td>
<td>-1.2a</td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td>103.0</td>
<td>101.2</td>
<td>1.8</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>#3</td>
<td>114.7</td>
<td>111.5</td>
<td>3.2</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>–</td>
<td>–</td>
<td>1.73</td>
<td>1.4</td>
<td></td>
</tr>
<tr>
<td>Titanium</td>
<td>115.5</td>
<td>110.5</td>
<td>5.0</td>
<td>0.73b</td>
<td></td>
</tr>
</tbody>
</table>

* The negative weight is probably the result of the analytical weight resolution and accuracy. The calibrated analytical weight used in the test is accurate within 0.1 mg, therefore absolute uncertainty in the observed weight is ± 0.1 mg.

b The negative values were calculated as 0 for the calculation of the average result.
The CF-PEEK composite materials have no plastic deformation but rather only elastic ones, therefore failure is defined when the bending test is terminated by a resultant plate breakage, which is expressed as the yield load value. The four-point bending and bending fatigue tests were evaluated for the DCS, the PHP and the DVRP. The bending test results obtained for the DCP and the DVRP were almost equivalent to those obtained for the controls. Specifically, LCP 4.5 mm stainless steel plate for the DCP, and Titanium 2.4 mm plate for the Volar radial plate. The results of the bending strength for the PHP were inferior to the 3.5 mm Synthes Philos stainless steel plate by 20%, but nevertheless sufficient for the purpose of humeral fracture fixation. Specifically, according to published data, the expected load applied on a humerus bone of an individual who is 170 cm tall and weighs 80 kg is ~52 N, which is substantially smaller than the load that can withstand a bending test with an average value of 667 N (Ullian et al., 2008).

All the tested plates passed the bending fatigue test successfully, completing at least one million cycles at a load as high as 60% or more of the plates’ bending strength. As indicated in the ASTM F 382 Appendix X3 (Rationale for Annex A2), $10^6$ cycles for estimating plate fatigue strength is considered conservative since no bone plate in clinical service would normally be expected to withstand $10^8$ high stress loading cycles. There were no observable signs of failure after careful visual inspection of the plates following the completion of the fatigue test. Therefore, it was concluded that fatigue testing of the weakest (the distal volar radius) and the strongest (the diaphyseal) Piccolo composite plates is sufficient, and that further testing of the PHP is not necessary.

The results of the bending and bending fatigue evaluations demonstrated that the composite material Piccolo CF-PEEK Optima passed these tests successfully, thus complying with the acceptance criteria and behaving similarly to other commercially available nails and plates in these capabilities.

The accumulated debris on the 1 μm filters weighed very little, i.e., an average of 0.78 mg of the CF-PEEK material, in comparison to 5.35 mg of the titanium sample. In order to evaluate a worst case scenario, we assumed that all the particles of debris originated from the CF-PEEK plate and not from the titanium screws (although microscopic examination of the filter revealed titanium particles): the specific gravity of CF-PEEK is smaller than that of titanium, resulting in higher volumetric wear. Taking 1.55 mg/mm³ as the average specific CF-PEEK gravity, the obtained composite debris weight that resulted from the wear test was 0.503 mm³ and the volumetric wear rate was 0.503 mm³/million cycles. In comparison, the weight of the titanium debris particles that originated from the control sample and had been accumulated on the 1 μm filter was 5.35 mg, i.e., about 6 times heavier than the Piccolo composite plate-screw samples. Converting this to volume, it emerges that 1.189 mm³ of titanium debris, and it can be reasonably assumed that its use may potentially provide a lesser likelihood of inducing local inflammation. The wear values we obtained for the composite material are comparable with those reported in the literature, especially by Kinbrum (2009a) who derived them from experiments that used CF-PEEK in orthopedic implants (hip and knee replacement). The wear test for the CF-PEEK acetabular cup recorded an average rate of 1.16 mm³/million cycles compared to reported values of 48.2 mm³/million cycles for conventional metal on ultrahigh-molecular-weight-polyethylene (UHMWPE) joints and 4.5 mm³/million cycles for cross-linked polyethylene. Also, additional testing of CF-PEEK as a knee-bearing material produced medial and lateral wear rates of 1.70 and 1.02 mm³/million cycles, respectively. These results are comparable with the published values of 6.69 and 2.98 mm³/million cycles obtained for a unicondylar knee test manufactured of UHMWPE against CoCrMo (Cobalt–Chrome–Molibden), and 6 mm³/year obtained in a study investigating medial Oxford Partial Knee bearings retrieved from patients (Kinbrum, 2009b).

Attempts to modify implant microbiology were studied because periprosthetic infection related to biofilm formation on implants is of considerable concern. One option was chitlase coating of fiber-reinforced composites that was found to have antimicrobial activity and to be stable for highly concentrated lysozyme or H₂O₂ (Nganga et al., 2012).

Implants exposed to long-term moist conditions can lose some of their biomechanical properties, as demonstrated in a study on fiber-reinforced composites (Vallittu, 2007). The need for flawless trauma implants is limited to the healing period. After fracture healing, the bone no longer needs support and the implant can be removed. Further studies are needed for the implants that carry constant load, such as vertebral cages or joint prosthesis, and those that are exposed to long-term moist conditions.

5. Conclusion

Based on the results of this study, the Piccolo CF-PEEK Optima devices provide the recommended requirements for strength and wear for new devices and are safe and effective for intended use in humans.

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