Long-Term Elastic Durability of Polymer Matrix Composite Materials After Repeated Steam Sterilization

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Abstract

We compared the durability of 3 different selected composite materials that underwent repeated steam sterilization with the durability of traditional metal materials. Composite materials Tepex, CFR-PPS (carbon-fiber–reinforced polyphenylene sulfide), and HTN-53 (Zytel HTN53G50HSLR NC010) were evaluated for durability and water retention after repeated steam sterilization. These composites were compared with stainless steel and aluminum. The structural properties of these materials were measured (short-beam load-to-failure and cyclic compression loading tests) before, during, and after repeated steam sterilization. The relative radiographic density of these materials was also compared.

There was no significant difference in the moisture retention of these composite materials before and after repeated sterilization. The composite materials were significantly more radiolucent than the metals. For all the composite materials, load to failure deteriorated after repeated sterilization. The cyclic compression loading tests showed HTN-53 had the poorest performance, with complete failure after 400 cycles of repeated sterilization. CFR-PPS performed slightly better, with 33% failure at final testing. Tepex had no failures at final testing.

Although HTN-53 has shown promise in other orthopedic applications, its performance after repeated sterilization was relatively poor. Tepex showed the most potential for durability after repeated sterilization. Further study is needed to identify specific applications for these materials in the orthopedic industry.

Polymer matrix composite materials have been widely promoted for orthopedic use in a variety of settings, including surgical instruments, medical devices, implants, and bone models.[1-13] These types of composites are engineered from 2 or more constituent materials with significantly different physical or chemical properties; these materials remain separate and distinct on a macroscopic level within the finished composite structure. As a result of ongoing biomaterial research, polymer matrix composite materials can be engineered with a wide range of physical, mechanical, and surface properties, tailored to their application. Given their advantages (eg, high strength-to-weight ratio, radiolucency), these polymer matrix composite materials have gained popularity over traditional metallic materials.

Sterilization is an essential day-to-day procedure in the health care sector, both for single- and multiple-use devices or instruments, and thus a composite material used in medical components should remain unaffected by the process. The type of sterilization most commonly performed is steam sterilization, which achieves microbiological death by moist heat and pressure. Steam is created in an autoclave at a temperature of 132°C (270°F) in typical hospital settings. Steam sterilization cycles last 5 to 14 minutes based on specific manufacturer recommendations. Most medical-grade plastics used in health care have been designed and formulated to withstand the required sterilization cycles without sacrificing key properties. The structure integrity and overall performance of polymer matrix composites may be strongly influenced by the stability of the fiber/polymer interfacial region in terms of physical, chemical, and mechanical characteristics of the material at different scales.[14] Absorption of moisture causes dilatational expansion and induces stresses, which are associated with the moisture-induced expansion resulting in degradation of structure stability.[15] Thus, steam sterilization could affect the properties of the polymer matrix composite materials by excessive absorption of moisture by the polymer.

To our knowledge, no one has studied whether polymer matrix material properties degrade from long-term, repeated steam sterilization followed by mechanical loading. We conducted a study to evaluate the structural properties (short-beam strength, SBS) of several composite materials exposed to repeated sterilization as compared with traditional metal materials: SS-316L (stainless steel 316L) and Al-7075-T6 (aluminum 7075-T6).

Authors' Disclosure Statement: HiPer Technology Inc. and TenCate Advanced Composites USA Inc. provided the composite materials used in this study.

Materials and Methods

We evaluated 3 types of composite materials: Tepex (Tepex Dynalite 201; HiPer Technology Inc.), CFR-PPS (carbon-fiber–reinforced polyphenylene sulfide, Cetex PPS; TenCate Advanced Composites USA Inc.), and HTN-53 (Zytel HTN53G50HSLR NC010; HiPer Technology Inc.) (**Figure 1**). Tepex is being used for orthopedic applications (knee braces, orthoses, insoles) and sporting goods applications. The performance of this material is superior to that of unreinforced thermoplastics. CFR-PPS represented the state of the art in composite materials for aerospace applications (eg, airframe structures, engine nacelles, fan casings, floorboards, interior parts). This is a high-performance material with exceptional high temperature and aggressive chemical resistance characteristics. CFR-PPS is also used to make filter fabric for coal boilers, papermaking felts, electrical insulation, specialty membranes, gaskets, and packing. It is not solubilized by any known solvents, even in long-term exposure, at temperatures up to 200°C. In addition, it exhibits exceptional resistance to organic and inorganic solutions, acids and alkali solutions, and a wide array of miscellaneous chemicals. HTN-53 is a 50% glass-reinforced, lubricated, high-performance polyamide resin with improved flow, developed for applications requiring excellent surface appearance with water-heated molds. This material has specifically shown survivability in hot, cold, chemically aggressive, and load-bearing environments. In addition, it has shown superior moisture and temperature resistance. These 3 composite materials were compared with SS-316L and Al-7075-T6. SS-316L is commonly used for implants in orthopedics, and Al-7075-T6 is a relatively radiolucent alternative for medical applications. Two different tests were performed to evaluate and validate these composite materials: (1) radiographic density evaluation and (2) structural property tests (short-beam load-to-failure [LTF] test, short-beam cyclic compression loading [CCL] test) before and after sterilization cycling.

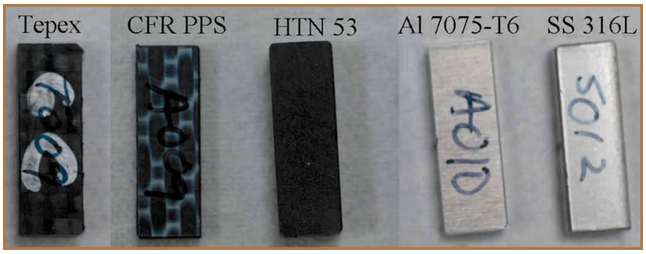

Figure 1. Tested materials: Tepex; CFR-PPS, carbon-fiber–reinforced polyphenylene sulfide; HTN-53, HTN53G50HSLR NC010; Al-7075-T6, aluminum 7075-T6; and SS-316L, stainless steel 316L.

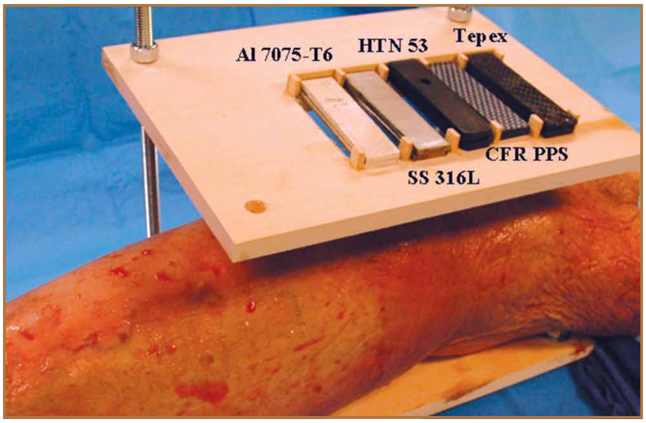

Figure 2. Radiographic density evaluation experimental setup. Abbreviations: Al-7075-T6, aluminum 7075-T6; CFR-PPS, carbon-fiber–reinforced polyphenylene sulfide; HTN-53, HTN53G50HSLR NC010; SS-316L, stainless steel 316L.

Radiographic Density Evaluation

The radiographic density of the 5 materials was evaluated with radiographic images of a cadaveric knee specimen (**Figure 2**). Radiographic image intensification is the gold standard for repeated radiographic imaging in the operating room. Six different radiographic images were obtained for each material superimposed over a cadaveric knee to recreate potential instrument positioning during surgery: posterior to subject (1 piece), posterior to subject (2 pieces), anterior to subject (1 piece), anterior to subject (2 pieces), anterior and posterior to subject in alignment (1 piece), and anterior and posterior to subject in alignment (2 pieces). Image-Pro Plus software (Media Cybernetics) was used to measure the radiographic density of the materials from the grayscale of the images.

Structural Properties Testing Before and After Sterilization Cycling

We used a standard SBS testing method to determine whether any degradation of structural properties resulted from standard repeated sterilization. The material geometries of the test specimens were 18.96×6.50×3.37 mm (length × width × thickness). Standard sterilization procedures were performed with steam sterilization using an autoclave at a temperature of 132°C (270°F) for at least 5 minutes (range, 5-14 minutes). Sample interval testing ran at 0, 200, and 400 sterilization cycles for structural properties in terms of SBS and moisture retention, with the structural properties at the 0th sterilization cycle (material before sterilization was performed) used as a baseline for comparison. Materials were subjected to 400 sterilization cycles, which is representative of the number of sterilization cycles per year an instrument or device would be subjected to.

Three structural tests were performed for each sample interval: moisture retention, LTF, and CCL. Moisture retention was investigated before and after repeated sterilization by measuring the weight of the test materials, as steam sterilization is known to affect the amount of moisture that is absorbed by a material. Twelve specimens of each proposed material were weighed at each sample interval, with the structural weight at the 0th sterilization cycle (material before sterilization is performed) serving as a baseline for comparison.

SBS testing was based on the ASTM (American Society for Testing and Materials) D2344 standard[16] for LTF and CCL tests (**Figure 3**). Six samples of material were used for each test at every sample interval, yielding 180 samples. Seven servohydraulic material testing system instruments (1 MTS 810 and 6 MTS 858 Mini Bionix) were used to test the SBS of each material. For LTF testing, each specimen was loaded in compression from 30 N to complete structural failure at a constant displacement rate of 1.0 mm/min (0.05 in/min). Testing was initiated with 5 preconditioning loading cycles from 30 to 100 N at 1 Hz. The load was then applied continuously until failure occurred; force and displacement data were collected every 0.02 second. This procedure was performed for 6 replicates for each sample interval for each test material.

The calculation for SBS, F_{sbs} (*MPa*), for the constant loading rate until structural failure is:

$$F_{sbs} = 0.75 \times \frac{P_m}{b \times h}$$

where P_m (N) is the maximum applied load observed during the test, b is the measured specimen width (mm), and h is the measured specimen thickness (mm).

CCL testing consisted of each test material axially loaded with 100 to 500 N at a frequency of 1 Hz for 100,000 cycles. The maximum load of 500 N was chosen as a standard based on 80% of the minimum ultimate failure load from previous LTF tests. Displacement and force data were collected every 5 cycles at the maximum compressive load. Degradation of the material was calculated using the difference between the deflection of the initial cycle and the deflection of the final cycle (50th cycle and 100,000th cycle). This procedure was performed for 6 replicates for each sample interval for each test material.

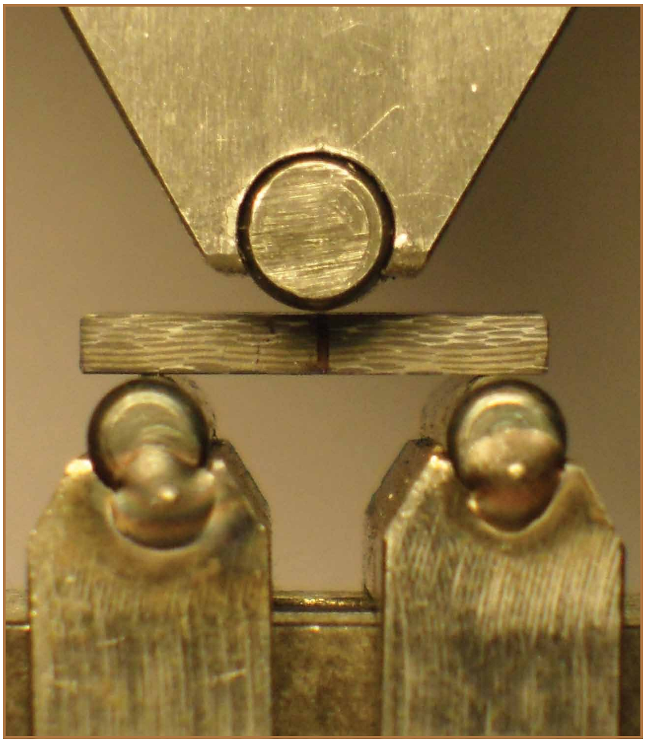

Figure 3. Short-beam strength experimental setup.

Statistical Analysis

LTF and CCL testing data were analyzed for any differences among the test materials using 1-way analysis of variance with the least significant difference multiple comparisons post hoc test method using SPSS Version 16.0, with $P < .05$ denoting significance. These analyses were used to determine the statistical relevance of the difference between the SBS (LTF and CCL) of each test material. Means and standard deviations were calculated for all tests.

Results

Radiographic Density Evaluation

Overall, all the tested composite materials were significantly more radiolucent than either SS-316L or Al-7075-T6. **Figure 4** shows the 6 different radiographic images obtained for each material superimposed over a cadaveric knee to recreate potential instrument positioning during surgery: posterior to subject (1 piece), posterior to subject (2 pieces), anterior to subject (1 piece), anterior to subject (2 pieces), anterior and posterior to subject in alignment (1 piece), and anterior

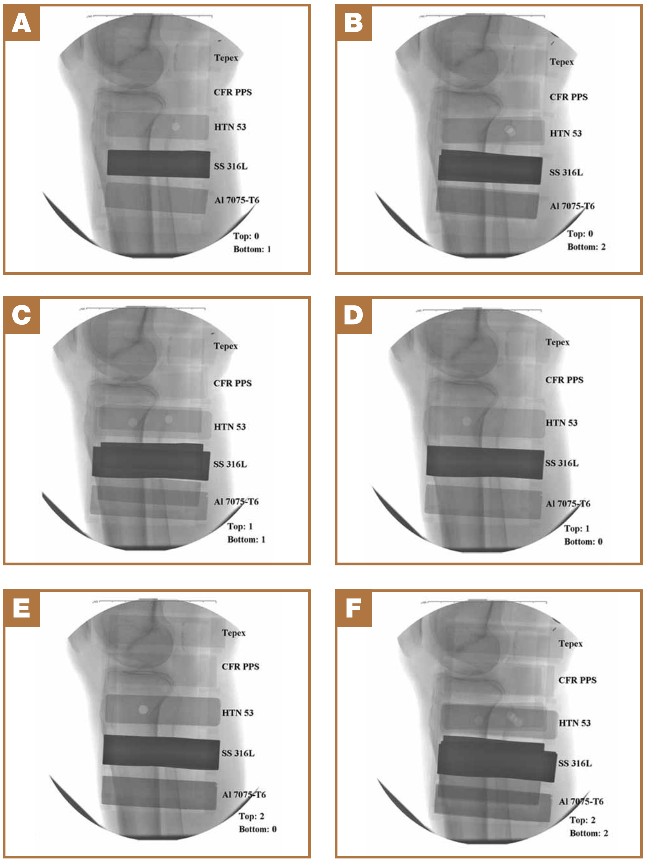

Figure 4. Radiographic density evaluation of 5 tested materials with cadaveric knee specimen: (A) posterior to subject (1 piece), (B) posterior to subject (2 pieces), (C) anterior and posterior to subject in alignment (1 piece), (D) anterior to subject (1 piece), (E) anterior to subject (2 pieces), (F) anterior and posterior to subject in alignment (2 pieces). Abbreviations: Al-7075-T6, aluminum 7075-T6; CFR-PPS, carbon-fiber–reinforced polyphenylene sulfide; HTN-53, HTN53G50HSLR NC010; SS-316L, stainless steel 316L.

and posterior to subject in alignment (2 pieces). SS-316L can be considered radiopaque, and Al-7075-T6 has been used as a relatively radiolucent alternative. Tepex was statistically more radiolucent than the other 2 tested composite materials (**Table 1**). Even with 2 pieces placed anterior to the subject and 2 placed posterior, the radiodensity compared to the cortical bone was still lower than 1 piece of Al-7075-T6 either anterior or posterior to the subject.

Structural Properties Testing

Moisture Retention. Moisture retention was evaluated by weighing the test materials before and after repeated sterilization. There was no significant difference in moisture retention, as weight differences for all the tested materials were less than 0.5 weight percentage compared to the 0th sterilization cycle (**Table 2**). Therefore, the results of this study showed that all the tested materials exhibited good moisture/temperature resistance after 400 sterilization cycles.

Load to Failure. In the LTF test, significant differences were detected in SBS between all 5 tested materials ($P < .05$). **Figure 5** shows the comparison of the structural properties in terms of SBS between the 5 tested materials, and **Figure 6** shows the failure modes for the tested materials. There was no SBS for SS-316L, as the material did not exhibit complete structural failure even after 400 sterilization cycles; however, SS-316L was observed in inelastic deformation failure (Figure 6D). Al-7075-T6 had much higher SBS compared with the other composite materials, and it also resulted in an inelastic deformation failure mode only after 400 sterilization cycles; otherwise, flexure failure modes were observed. Tepex and CFR-PPS exhibited interlaminar shear failure, and HTN-53 exhibited complete structural failure.

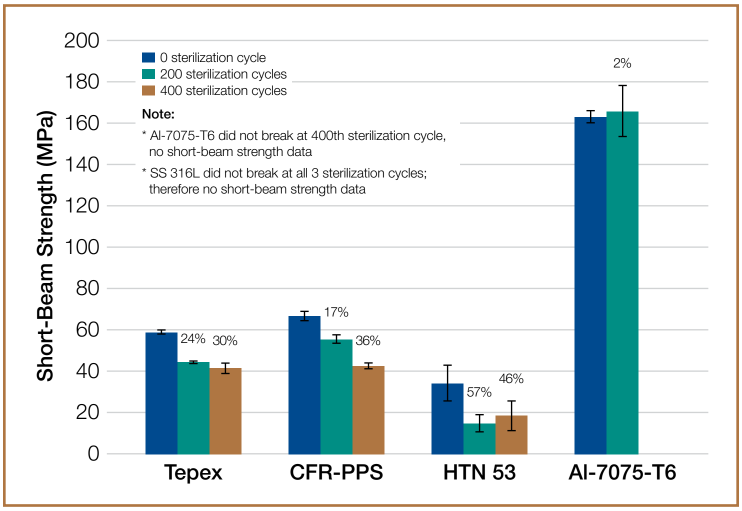

Figure 5. Short-beam strength in terms of load-to-failure testing. Abbreviations: Al-7075-T6, aluminum 7075-T6; CFR-PPS, carbon-fiber–reinforced polyphenylene sulfide; HTN-53, HTN53G50HSLR NC010; SS-316L, stainless steel 316L.

Table 1. **Radiodensity Test Results (% Compared With Cortical Bone)**

	Tested Material				
	Tepex	CFR-PPS	HTN-53	SS-316L	Al-7075-T6
Anterior to subject (1 piece)	6.1	5.1	10.3	25.8	12.6
Anterior to subject (2 pieces)	4.9	7.4	12.7	27.6	16.4
Posterior to subject (1 piece)	5.1	7.8	8.7	26.8	12.1
Posterior to subject (2 pieces)	5.3	9.3	10.9	26.7	15.5
Anterior and posterior to subject in alignment (1 piece)	5.2	8.4	11.9	26.5	16.9
Anterior and posterior to subject in alignment (2 pieces)	11.7	15.4	19.8	30.1	25.8

Abbreviations: Al-7075-T6, aluminum 7075-T6; CFR-PPS, carbon-fiber–reinforced polyphenylene sulfide; HTN-53, HTN53G50HSLR NC010; SS-316L, stainless steel 316L.

Table 2. **Moisture Retention Test Results (Weight % Different Compared With 0th Sterilization Cycle)**

	Tested Material				
Sterilization Cycle	Tepex	CFR-PPS	HTN-53	SS-316L	Al-7075-T6
200	0.38	0.01	0.31	0.02	0.05
400	0.50	0.16	0.29	0.01	0.27

Abbreviations: Al-7075-T6, aluminum 7075-T6; CFR-PPS, carbon-fiber–reinforced polyphenylene sulfide; HTN-53, HTN53G50HSLR NC010; SS-316L, stainless steel 316L.

Every composite material tested using the short-beam test for LTF showed a decrease in SBS with increased sterilization cycles (Figure 5). This decrease ranged from 17% to 57% compared with the 0th sterilization cycle. SBS was higher for CFR-PPS than for the other 2 composites. No statistically significant difference was found between CFR-PPS and Tepex except at the 200th sterilization cycle. HTN-53 was brittle at the 0th sterilization cycle but performed more like a ductile material at the 200th cycle. In addition, HTN-53 had the lowest SBS in terms of LTF testing when compared with the other 2 composites.

During the complete structural failure test, the failure modes for Tepex and CFR-PPS were visually identified as interlaminar shear failure (Figures 6A, 6B), whereas HTN-53 visually exhibited pure flexure failure (Figure 6C). As for the metals, SS-316L exhibited plastic deformation, and Al-7075-T6 exhibited flexure failure (Figures 6D, 6E).

Cyclic Compression Loading. Tepex was the only material to pass the 100,000 loading cycle without failure (**Table 3**). HTN-53 had the poorest performance of all: Its failure rates were 33% (2/6 samples) before sterilization (average cycle, 22,213; range, 21,500-22,925), 83% (5/6 samples) at the 200th sterilization cycle (average cycle, 4,210; range, 0-14,360), and 100% after 400 sterilization cycles (average cycle, 12,725; range, 1,190-21,900). CFR-PPS had no failures before the 400th sterilization cycle, and its failure rate after 400 sterilization cycles (average cycle, 50,735; range, 50,270-51,200) was 33% (2/6 samples).

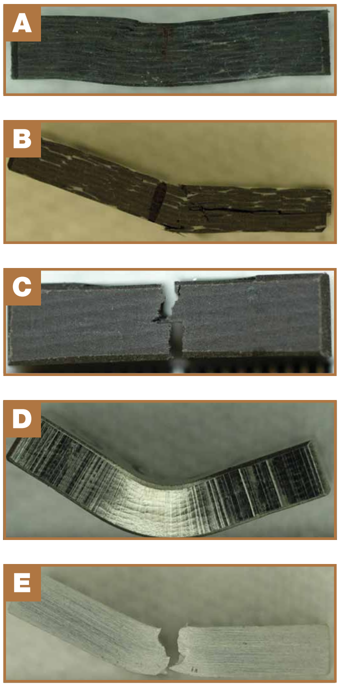

Figure 6. Samples of failure modes for tested materials in short-beam strength testing in terms of load to failure: (A) Tepex, (B) carbon-fiber–reinforced polyphenylene sulfide (CFR-PPS), (C) HTN53G50HSLR NC010 (HTN-53), (D) stainless steel 316L (SS-316L), (E) aluminum 7075-T6 (Al-7075-T6).

Discussion

The success of a reusable composite material for use in orthopedic surgery depends not only on radiographic density, fabrication methods, and design but also on the ability to withstand repeated sterilization. Over the past 3 decades, investigators have explored several high-performance polymer matrix composite materials for use in orthopedics, especially in trauma, hip stems, and spinal implants.[1,3,4,17-34] According to Evans and Gregson,[35] composite materials have been widely promoted as possible orthopedic biomaterials but to date have found few successful commercial applications, because of the many challenging problems encountered in fabrication and testing. One of the most important factors in the mechanical properties of many composite materials is the influence of the cooling and loading rates on fiber-matrix interface adhesion.[36-38] Our results tended to agree with the findings of Evans and Gregson,[35] as some of these composite materials did not withstand repeated sterilizations well.

Guan and colleagues[39] evaluated the influence of sterilization treatment on continuous carbon-fiber–reinforced polyolefin composite. Their 3-point bending test results showed that the levels of maximum load of all the specimens undergoing sterilization by autoclave were lower than those of the control group. For these composites, they concluded that autoclave sterilization and Co-60 gamma ray irradiation sterilization should be avoided and that ethylene oxide is the best method. Our results support their findings with a different set of composites.

Table 3. **Number of Sample Failures During Cyclic Compression Loading Testing**

	Tested Material				
Sterilization Cycle	Tepex	CFR-PPS	HTN-53	SS-316L	Al-7075-T6
0	0	0	2 (33%) Average, 22,213 Range, 21,500-22,925	0	0
200	0	0	5 (83%) Average, 4210 Range, 0-14,360	0	0
400	0	2 (33%) Average, 50,735 Range, 50,270-51,200	6 (100%) Average, 12,725 Range, 1190-21,900	0	0

Abbreviations: Al-7075-T6, aluminum 7075-T6; CFR-PPS, carbon-fiber–reinforced polyphenylene sulfide; HTN-53, HTN53G50HSLR NC010; SS-316L, stainless steel 316L.

Although HTN-53 has shown promise in other orthopedic applications because of its superior moisture and temperature resistance, we found that its performance after repeated sterilization was relatively poor. Tepex showed the greatest potential for durability after repeated sterilization; its mechanical properties were stable after 200 steam sterilization cycles.

Clinical Applications

The composite materials investigated in the present study have potential for use in either instrumentation or long-term implantation applications because of their versatility, mechanical strength, fatigue resistance, and biocompatibility. Akay and Aslan[40] stated that carbon-fiber–filled composite implants can be designed with more appropriate modulus, strength, toughness, or stiffness by the arrangement of reinforcing fiber volume and orientation, and can provide better fatigue resistance. A notable advantage of using a composite plate with metal screws is that the potential for corrosion of metallic components is eliminated. Another major advantage of composite medical implants (eg, DiPhos-RM) is radiolucency, which allows direct visualization of osseous callus formation as well as monitoring of fracture healing, thereby improving clinical assessment and accuracy.

Numerous studies have documented the successful clinical performance of composite materials in orthopedic, trauma, and spinal surgery applications.[41-45] Bagheri and colleagues[41] developed a new carbon fiber–flax–epoxy composite plate and biomechanically compared it with a standard clinical metal plate. Their results confirmed that the carbon fiber–flax–epoxy material represents a potential candidate for bone fracture plate applications, as it can simultaneously provide similar mechanical stiffness and lower stress shielding (higher bone stress) compared with a standard clinical metal bone plate. Tarallo and colleagues[45] evaluated the clinical results of 40 cases at 12-month follow-up using a new plate made of carbon-fiber–reinforced polyetheretherketon (DiPhos-RM, Lima Corporate) for the treatment of distal radius fractures. They reported good clinical results for this device at early follow-up, and its use allowed maintenance of reduction in complex AO (Arbeitsgemeinschaft für Osteosynthesefragen) fractures.

The main advantage in using composites for surgical instruments is their radiolucency. These materials do not obscure images or radiographs during fluoroscopic visualization. Surgery often requires fluoroscopic visualization of internal organs or bones, which may require temporary removal of radiopaque devices (eg, retractors, clamps, forceps, hooks, distractors). Aside from being inconvenient, removal and subsequent reinsertion consume valuable time and interfere with the smooth flow of an operation.

The shortcomings of using composite materials for surgical instruments involve detectability and sterilization. A significant issue in surgery is the accidental leaving behind of instruments in patients, which can cause serious problems ranging from organ perforation and blood infection to death. Although instrument counting and other safety protocols can reduce the risk of overlooking an instrument, mistakes are bound to happen. The other shortcoming is the influence of repeated sterilization on the mechanical properties of the composite materials, as sterilization is mandatory for surgical instruments used in the operation room. The structural integrity and overall performance of the polymer composite materials—especially the stability of the interface and the interphase zones—are strongly influenced by repeated sterilization.

On the other hand, composite materials have potential advantages that may support their introduction into long-term medical implant applications, as sterilization commonly is performed only once, during packaging. The effects of sterilization by radiation or steam are much less pronounced on composite implants than on composite surgical instruments. However, composite implants require careful consideration with respect to the bioactivity of wear particles that may be produced from articulation. Further, carbon-fiber–reinforced polymer implants are still substantially more difficult to manufacture and more costly than their metallic counterparts.[46]

Limitations

This study has some limitations. Most important, studies of this nature do not account for biological factors such as corrosion, biological wear, and the soft-tissue attachment effects on structural properties for potential in vivo use. Another limitation was that the study tested only the mechanical properties in terms of SBS and provided no information about other mechanical properties, such as tensile, compression, and torsion strengths. We think SBS testing adequately evaluates challenging scenarios like thin and narrow instruments/devices that are anticipated in application, and information regarding other modes of failure and mechanical properties (compression, tension, torsion) would be a further area of research. An additional limitation was that our model used a relatively small number of samples. A larger study with more samples and varying layout patterns and layers of the carbon fibers may more clearly demonstrate the effect of steam sterilization on composite materials.

Conclusion

This study provided new information on 3 selected composite materials and their structural properties after repeated steam sterilization. We discovered that these composites were similar in radiographic density and water retention but behaved very differently in terms of mechanical durability after repeated steam sterilization. All selected composites demonstrated deterioration of mechanical properties after repeated steam sterilization. Knowing these results could aid in making decisions about the design and manufacturing of operative instruments and orthopedic biomaterials. Although our preliminary findings are intriguing, further study is warranted to seek specific applications for these composite materials in orthopedic surgery.

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