AC 2009-1725: ENHANCING FUNDAMENTAL MATERIALS ENGINEERING EDUCATION USING BIOMEDICAL DEVICES AND CASE STUDIES

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Enhancing Fundamental Materials Engineering Education Using Biomedical Devices and Case Studies

Abstract

During the past six years several best practices in teaching and learning have been implemented in our Introduction to Materials Engineering course to transform the course from a traditional lecture only course to a course that is centered on conceptual and active learning. In addition, this academic year the content of the course was also reshaped so that this course also serves as the fundamental materials engineering component of a new three course sequence within a new minor in materials science. The minor is interdisciplinary so the student audience now includes engineering technology, chemistry, physics, geology, and manufacturing and supply chain management majors.

Biomedical devices and case studies, nanoengineering, and bioinspired materials have been introduced as focus areas with the intention of improving student learning in fundaments from crystal structure, to materials selection based on mechanical properties/design criteria, and to phase transformations. Also, the course content was changed to build student interest while also finding new and challenging ways to improve the course based upon previously identified course learning objective outcomes that needed improvement. Conceptually, teaching fundamentals in multiple ways, especially in ways which build scaffolds from the students' previous knowledge base, should be effective for a wide range of learners. As it turns out, the materials used in biomedical devices which experience significant loads during service, such as orthopedic replacement devices (knees, shoulders, and hips) and stents, provide another accessible platform to enhance materials engineering education.

Students who enter the course have some conceptual idea of what a hip replacement is or why an arterial stent might be needed. But, they have no idea of what materials are used in these devices or why particular materials are selected for components. To illustrate, it is essential that the elastic constant of the femoral stem in a hip replacement match the elastic constant of bone or bone loss will occur from stress shielding. Conceptually this is very easy for the student to grasp. Since ultra high molecular weight polyethylene is used in orthopedic wear components, it is possible to conceptually link the required mechanical properties of components to the effect of the degree of polymerization, examine the difference between semi-crystalline and amorphous plastics, and probe wear properties. Arterial stents are often made from shape memory materials which are excellent venues for hands-on learning about phase transitions. Device recall case studies provide an opportunity to link manufacturing to materials to in-service failures.

This paper describes the detailed learning objectives for the course that are addressed with this new strategy and specifics on the biomedical devices, including materials, selection criteria and case studies, so that other faculty may use them in their courses. Initial assessment data that examines the effectiveness of the approach, preliminary data on student learning styles, and student perceptions about the effectiveness of this approach are also discussed in the paper. Pre- and post-course concept questionnaires and traditional tests scores were also used to evaluate this approach. The paper concludes with summary of the assessment information and future directions for this course.

Introduction

During the past six years several best practices in teaching and learning have been implemented in our Introduction to Materials Engineering course to transform the course from a traditional lecture only course to a course that is centered on conceptual and active learning. Several papers have been published covering various aspects of these changes with some of the changes resulting in improved student learning and engagement while other approaches were less successful[1-6]. Most of the elements of a student-centered approach are now present in the course: cooperative learning, case-based teaching, active/inquiry learning, concept learning, problem-based learning, and constructive alignment. In addition, more than thirty successful concept questions have been developed and tested during this transformation process. All the changes which have been introduced were based upon studies that researched effective engineering education practices and strategies. The Felder/Silverman/Soloman Index of Learning Styles (ILS) has recently been used to investigate the effect of student learning styles on student outcomes for the course. By understanding how learning styles interact with our various strategies we will be able to more effectively improve and shape our mix and focus of activities, conceptual learning exercises, and mini-lectures.

It is known that if students are more engaged in their own learning, and if students are more interested in the subject, learning is most likely improved[7–25]. Research findings "show that students learn by fitting new information into existing cognitive structures and are unlikely to learn if the information has few connections to what they already know and believe"[7]. The National Research Council (NRC) completed an in-depth study and reported on successful learning strategies[8]. This report and the work of many others [7-25] show that it is important to build upon the "conceptual and cultural knowledge that students bring with them to the classroom"[8]. In general, many of the strategies employed within this course could be characterized as constructivist in nature, where students construct their own understanding based upon specific, guided collaborative activities that build upon the existing knowledge base of the students. Pre- and post-course concept questionnaires have proved invaluable in the course restructuring and refinements[9]. We have identified many cases where we have shown that students do try to create new mental structures based upon their prior knowledge and misconceptions - one of the fundamental guiding principles of constructivism[9]. To illustrate, students come to our basic materials engineering course with a much better understanding of ionic and covalent bonding than they do of metallic bonding (perhaps because their basic chemistry courses focus more on these type of bonds). In the pre-course concept questionnaire we found that the students were trying to construct their own model of how two metal atoms (copper) would be bonded from what they remembered about other types of primary bonds - sharing and filling of shells – rather than any fundamental knowledge base regarding metallic bonding. This misconception was identified as robust and required several specific actions within the course to help the students reconstruct their preexisting misconceptions. Similarly, students held robust misconceptions regarding the words "strong" as in high tensile strength and elastic, as in elastic constant. The strategies that were developed to assist the students in these two conceptual areas were reported elsewhere[1,9].

However, several challenges remained in our basic materials engineering course in that effective strategies and activities had not been found to support all learning outcomes. Researchers in constructivism such as Biggs[10] have offered principles for effective instruction that tells us that "instruction should begin with content and experiences likely to be familiar to the students and that new material should be presented in the context of its intended real world applicatons"[7]. And cognitive research tells us that "all new learning involves transfer of information based upon previous learning"[7,8]. Similarly, motivation to learn affects student outcomes. Learners are motivated "when they can see the usefulness of what they are learning and when they can use it to do something that has an impact on others"[7,8]. So the challenge in a basic materials engineering and science course is to place the content of the course into such contextual areas and develop appropriate learning activities and conceptual questions with effective scaffolding that will guide the students to the desired learning outcomes. The basic premise then is to find these contextual activities, add them to the course, and try to measure improvements in the desired student outcomes.

The activities that are developed should also take into account the various learning styles of the students[16]. As Felder so succinctly states, "the collective evidence favoring the inductive approach over traditional deductive pedagogy is conclusive"[7]. He goes on the point out, however, that merely adopting an inductive approach does not automatically lead to improvements in desired student outcomes and warns that faculty must understand the best practices associated with inductive teaching, such as providing adequate scaffolding, especially as the techniques are introduced in the course[7]. Prince also completed a detailed study of active learning[15]. "Although the results vary in strength, this study has found support for all forms of active learning examined". "For example, students will remember more content if brief activities are introduced to the lecture[15]".

Our experiences in our basic materials engineering course agree very much with this research base[7-26]. It is challenging to find these appropriate contextual applications in materials engineering for several reasons. First, there is not one agreed upon standard set of learning outcomes for basic materials engineering courses as these basic courses are based in different contexts with widely differing purposes and student audiences. Second, since the student audience is diverse, students enter these basic courses with a wide range of experiences and pre-existing conceptual knowledge. Third, much of the course material is new to the students and draws heavily upon the interdisciplinary intersection of chemistry, physics and mathematics for its problems. Fourth, existing text books do not have a similar focus or construct, and, thus, most of the activities and conceptual questions need to be developed, tested, and refined. However, many fundamental courses in materials engineering and science do have a significant segment that is focused upon the broad area of mechanical properties[17,18]. In addition, most courses contain some emphasis which is based upon phases and phase transitions concepts. The overarching goal of structure, function, processing and performance is approached differently in different texts, and is always present in some form within these courses.

Thus, our goal has been to change the contextual construct of the course to build student motivation while also finding new and challenging ways to improve student learning in previously identified problematic course learning outcomes. Conceptually, teaching fundamental mechanical material properties in multiple contexts, especially in ways which could build scaffolds from the students' previous knowledge base, should be effective for a wide range of learners[16]. Based upon the fundamentals premises of inductive teaching, the materials used in biomedical devices which experience significant loads during service, such as orthopedic replacement devices (knees, shoulders, and hips) and stents, may provide another accessible platform to enhance materials engineering education. To illustrate the contextual base for this approach, we considered the following ideas. Students who enter the course have some conceptual idea of what a hip replacement is or why an arterial stent might be needed. But, they have no idea of what materials are used in these devices or why particular materials are selected for replacement components. To illustrate, it is essential that the overall stiffness of the femoral stem in a hip replacement match the elastic constant of bone or bone loss will occur from stress shielding. Conceptually this is very easy for the student to grasp and, thus, provides a contextual base for the students. Another easy concept to grasp is that implant components should last as long as possible. It is easy to begin the activities with a seemingly easy question - which materials should I advise someone to choose who is about to get a hip or knee replacement? What parameters do I need to know to make such decisions?

Orthopedic devices provide multiple contexts for instruction since the materials used in them and their inherent geometric constraints are directly linked to important components of materials engineering education. To illustrate, since ultra high molecular weight polyethylene (UHMWPE) is used in orthopedic bearing wear components, it is possible to conceptually link the required mechanical properties of bearing components to the effect of the degree of polymerization, examine the difference between semi-crystalline and amorphous plastics, and probe wear properties. Arterial stents are often made from shape memory materials which are excellent venues for hands-on learning about phase transitions. Device recall case studies provide an opportunity to link manufacturing processes to materials to in-service failures. It was also true that many important student outcomes also that also needed improvement in our course could be approached within this broad contextual base. Therefore, we decided that biomedical devices might provide many avenues from which we could indeed enhance student outcomes by creating new active exercises and conceptual questions.

We have been especially interested in improving higher order critical thinking in our students so that the students might be able to more effectively distinguish engineering design criteria from material properties. For example, it is often true that a product should be lightweight (an engineering design specification). But the material property to accomplish this specification, is not just density, it is more appropriately specific stiffness or specific strength. The students readily grasp that it is important that joint replacement components be as light as possible at the beginning of the term. By the end of the term, the students should be able to properly connect the mechanical properties needed to accomplish this design constraint and be able to sort out the interplay between materials properties and product geometry. As it turns out, joint replacement component (femoral stems and heads, tibial plateaus and acetabular cups) design seems to be very effective in helping the students build out higher order thinking skills while simultaneously improving their basic understanding of several mechanical properties. Our initial data shows specific improved outcomes based on improvements in traditional exam scores and in pre- and post-course concept gains in the use of the elastic constant, tensile and compressive strength, specific stiffness, specific tensile strengths specific compressive strength, fatigue life, creep, and wear resistance in engineering design applications. Last term, no student who consistently participated in class left the course: believing that lightweight was a material property, confused between anisotropic materials and isotropic materials, or misunderstanding the fundamental differences in mechanical behaviors of elastic and viscoelastic materials. While the outcome data is preliminary, it certainly does seem promising. Perhaps the previous changes in the course, coupled to these new focus areas, has produced more gains than would otherwise be made. We have also had six years to help us understand in practice how to better implement best practices in the research literature. We did not attempt to sort out how the various interacted at this point in our research.

Biomaterials Used in Orthopedic Total Joint Replacements

It took a considerable amount of time (well in excess of 100 hours) to gain the knowledge base necessary in order to add materials engineering activities in our course based upon constructs about orthopedic total joint replacements and stents. While not intended to be a complete resource, the following section contains the basic materials and design information that others will need to implement such activities in a freshman or sophomore level course. Fortunately, research papers and texts available in this broad area are numerous. On the other hand, sorting through it all to find the appropriate contextual base problems and activities for a basic materials science engineering course is a daunting task. Hopefully, the data and references provided here will make that task much less burdensome. Overall, the design and materials selection involved in total joint replacements provides a sound contextual base for the following basic mechanical properties of materials: stiffness (the elastic constant), tensile strength, compressive strength, yield strength, specific stiffness and strength, fatigue, creep, wear (friction), hardness, ductility, and toughness/fracture mechanics. Since UHMWPE is commonly used as a bearing surface in total joint replacements, the relationship between the degree of polymerization and mechanical properties is easily established. Likewise, the use of shape memory materials, such as Nitinol, in stents, establishes the connections between phases/phase transitions and mechanical properties. Recall case studies provide not only additional contextual examples for materials and manufacturing/processing, but they also provide ample opportunities to integrate ethical considerations into the course. Another advantage of using biomedical devices is that the materials must be compatible with the human body and the number of those materials used in these applications is relatively small and controlled by readily available standards. Thus, the information base for these materials is relatively large and open. In addition, the loads upon the devices are related to things familiar to the students – body weight and activity levels. The sizes of the implants are also constrained within familiar boundaries – the human body. A femoral stem of a hip replacement or a tibial component of a knee replacement must fit within the human body and within the appropriate location.

There are several good texts that cover biomedical materials and the mechanical behavior of materials, but Ratner's (and Hoffman, Schoen and Lemons) *Biomaterials Science: An Introduction to Materials in Medicine* and Dowling's *Mechanics of Materials* books were especially useful references [28,29]. Callister's *Fundamentals of Materials Science and Engineering* text also contains a web based supplemental chapter [30] that is helpful as is the University of Cambridge's on-line Teaching and Learning Package (TLP) on the structure of bone and implant materials [31]. In fact, having the students complete this well-developed and interactive TLP as a homework assignment or in-class project (if computers are available) is an excellent way to introduce your students to biomedical materials and design. Dr. Pruitt's Structural Aspects of Biomaterials course (ME C117) is available on the Berkeley Webcasts page from Spring 2006 and 2007 her webcast lectures contain a wealth of information for those faculty who wish to develop their expertise in biomaterials [33]. While there are a number of total joint replacements that are possible (hip, knee, ankle, shoulder, elbow, wrist and finger), we created effective contextual activities that focused on hip and knee replacements which together capture all the components of design and materials needed for a basic course. Stents made from shape memory materials and stainless steels were used to capture several other learning objective outcomes that we had previously identified. The focus of this paper is on the materials and design of knee and hip orthopedic implants.

Based upon current growth rates and increasing application areas, it is also likely that the students will encounter biomedical applications in industry after graduation. Orthopedic biomaterials dominated the worldwide biomaterials market at $14 billion in 2002 and knee replacements alone numbered 700,000 [32]. Today, more than 800,000 hip replacements are done worldwide, with 120,000 performed in the US [34]. Cardiovascular stent sales are $4 billion[40] and the market penetration of peripheral stents is increasing rapidly. Today 1 in 10 Americans have some kind of synthetic body part (pace makers, heart valves, orthopedic implants, lens replacements, surgical screws, etc.) and revenues exceed $78 billion dollars[79]. In 2002, there were more than 13000 manufacturers of medical devices worldwide producing over 80,000 medical devices[79]. Students may also encounter regulation compliance challenges or ethical dilemmas as well after graduation. The Food and Drug Administration's (FDA) Inspector General found that from 1994 to 1999 medical device trials were "twice as likely as trials for drugs to violate FDA regulations and that 78% of the violations were for missing data, poor data collection, and falsification of data"[79].

The number of biocompatible materials that are used in total joint replacements and stents is, relatively, small (from a materials engineering course aspect), but, fortunately, span the three basic classifications of materials: metals, polymers and ceramics. The metals that are used in total joint arthroplasty (TJA) are: titanium alloys, Co-Cr alloys and, to a much lesser extent, stainless steels. The bearing surfaces in many TJAs are made from UHMWPE and bone cement is poly(methyl methacrylate) or PMMA (both polymers). Ceramic bearing surfaces are made from both alumina and zirconia. Coronary stents are made from 316L stainless steels and nitinol, a superelastic shape memory material, whose properties depend on interesting phase transitions between martinsite and austenite. Human bone, of course, is an interesting natural composite. Because these biomaterials span the breath of the material classifications used in a basic course, applications of them provide great platforms to develop the depth of understanding needed by the end of the course.

The components of total hip replacements are: the femoral stem, the femoral neck and head, the acetabular cup, and the metal backing cup for the acetabular cup. PMMA may or may not be used depending on the condition of the patient, with younger patients often relying on press fit, cementless TJA and porous coatings (hydroxyapatite or titanium) on components that promote bone growth and integration. Metal screw fixation can also be part of the hip TJA. In the United States, femoral stems are either titanium alloys or Co-Cr alloys of various geometries that control overall stiffness and articulation with the stem being PMMA cemented or press-fitted. A modular Co-Cr, alumina or zirconia head articulates on a UHMWPE or alumina acetabular cup which is fitted into a titanium alloy or Co-Cr alloy cup liner that is cemented, screwed or press fit into place [28]. In addition to materials choices for components and geometry, there are also choices of surface coatings and roughness with a great deal of design competition in the market place. The typical hip replacement at a 90% success rate is 7-10 years [28]. While there are over 1500 designs on the market for total knee arthroplasty (TKA) components, the basic design aspects are similar to hips, but the loads on the bearing materials are much higher, reaching 20-40 MPa [33]. The total weight of the knee components is 425-565 g [44]. The metal replacement components for the femoral components are usually Co-Cr alloys and titanium alloys are used for tibial components. Metal backed UHMWPE is used as the tibial bearing components and the patella. Additionally, there are also oxidized zirconium (Oxinium) coated femoral components. In the United States the most common wear couple in hips and knees would be a Co-Cr alloy (ASTM F75) bearing against UHMWPE[72]. Because of the plethora of information on the web, it is not difficult to find graphics to accompany of the components to accompany your mini-lectures [31-40].

Since the number of different materials used in TJA is small and provide a controllable number of design combinations, TJA design and materials selection is almost ideal for context based active learning exercises in materials engineering. Ratner (see Table 1) provides an excellent summary of the materials property ranges for TJA biomedical materials [28]. The design requirements for TJA components, from a materials engineering perspective are challenging. For THA, the femoral stems, the yield strength should exceed 500 MPa, the tensile strength 650 MPa, have a minimum ductility of 8% and a fatigue strength in excess of 400 MPa at 10^7 cycles[30], although there is considerable disagreement surrounding design requirements in orthopedic materials. For example, two approaches in fatigue life may be used in implant materials: total life (flawless materials where damage is based on initiation then propagation) and damage tolerant (all materials have flaws, propagation based). The total life philosophy is, perhaps, best at finding the bounds for acceptable levels of stress in fatigue design, but the damage tolerant approach is better at finding the critical flaw size and in predicting the life of the component [33]. Tables 1 and 2 provide the information necessary (with the design information described later) to produce a wide range of challenging and active materials design experience for students.

Medical Device Recalls - Example Case Studies

Recall case studies create specific (and interesting) opportunities to integrate materials engineering and ethics into a basic course. [Note: during the past several years, our department has made significant progress in integrating ethics throughout our curriculum.] Sulzer Orthopedics (later Centerpulse Orthopedics, later acquired by Zimmer Holdings) recalled 25,000 of its Inter-Op® acetabular caps in December 2000 with approximately 17,500 having been implanted[47]. Later reports showed the scope of the problem to be more than 30,000 devices with more than 20,000 implanted[50]. More than 2700 revision surgeries were needed as a result[49-51] of a manufacturing process error that occurred after Sulzer brought the process to manufacture the cups in-house. A mineral oil based lubricant had accidentally contaminated the machine coolant and the acetabular cups during CNC machining (subsequent cleaning operations did not detect the contamination). The mineral oil on the cup prevented bone from bonding properly with the cup (resulting in a loose cup). A Sulzer video that was initially targeted toward its surgeon customers is available on-line[48] and shows their investigation, the outcome of that investigation and also, the serious consequences the recall had on the surgeons and their patents. The video is graphic in that it shows the surgical procedures needed in a hip implant revision surgery, but it is unlikely that the students who will be involved in manufacturing biomedical devices after graduation will ever forget the video. [Note: viewing the video is option for our students, but most of them do choose to do so.] Sulzer took full responsibility for the recall and paid for the surgeries. However, not all people agree that Sulzer had a timely response and compensated those with defective implants sufficiently, so the case is an interesting one with many complex, but tangible issues (including a class-action lawsuit and billion dollar settlement).

Table 1. Basic Materials Properties of TJA Materials [28,41] and (matweb.com)

	ASTM	Density (Kg/m^3)	E (MPa)	Yield (MPa)	UTS (MPa)	Fatigue (MPa)
Metals						Endurance Limit*
Co-Cr alloys	F75	8300	210-253	448-841	655-1277	207-950
Poisson's	F90		210	448-1606	1896	586-1220
Ratio µ ~ .29	F562		200-230	300-2000	800-2068	340-520
	F1537		200-300	960	1300	340-520
Ti alloys	F67	4500	110	485	760	300
µ ~ .30	F136	4430	116	897-1034	965-1103	620-689
Stainless steel 316L µ ~ .24	F138	8000	190	792	930	241-820
Polymers						
UHMWPE	F648	930-945	0.8-1.6	20-30	30-40	13-20
PMMA µ ~ .30	F451	1160-1180	1.8-3.3	35-70	38-80	19-39
Cortical bone** µ ~ 0.13-.3		1800-2080[46]		60-144		23-80
High Strain			40.8		400c/270t	
Low Strain			15.2	114t	150c/90t	30-45
Ceramics						
Alumina	F603	<=3940	366		3790c/310t	
Zirconia	F1873	>=6000	201		7500c/420t	
* 10^7 cycles						
** generalized as bone is anisotropic & viscoelastic						
c=compression	t=tension					

Although the acetabular case is highlighted here, there are many similar cases which may be used to advance both basic materials engineering and ethics discussions. For example, St. Gobain Desmarquest recalled over 9000 Prozyr® zirconia femoral heads in September, 2001 which were used in several different THA products designed by a number of companies such as Stryker Howmedia, Biomet, Smith and Nephew, Encore, etc. [47,52]. The basic premise is that zirconia and alumina femoral heads reduce the wear of mating UHMWPE surfaces[54], but, of course, fracture and energetic toughness values of ceramics are such that crack propagation can lead to catastrophic failure in-service (months, in this case). [It is also not all that clear in the scientific literature, that wear rates are indeed lower[56].] Within the recalled heads, the highest failure rate was reported to be 24% worldwide, but in the US failure rate for the 39 heads was 44%[54]. These failures were traced back to a change from a batch furnace process to a tunnel furnace operation that altered the cooling rates of the parts. "By changing the type of machine used for sintering, the properties of the zirconia crystal were altered (an increase in the monoclinic phase), and a high rate of fractures resulted 12-32 months after implantation"[54]. Studies examining the failures reported 100% transformation from the tetragonal phase to the monoclinic phase near the bore surface[54]. Since the presence of the tetragonal phase correlates well to fatigue strength, this case presents an excellent opportunity to reinforce the basic connections between structure, processes and properties of materials.

Table 2. Additional Helpful Properties for Case Studies [28,41,60, 61] +matweb & matbase

Material	Density (Kg/m^3)	Yield (MPa)	Elong. %	Fracture Tough Measure-Various	Hardness	Fatigue @ 10^7 MPa	E (GPa)
Co-Cr	8300	480	8	K_{1C} = 100 MPa m½	25-35 HRC	200-300	210
Ti-6Al-4V	4500	820	8-14	K_{1C} = 80 MPa m½	30-35 HRC	400-580	120
UHMWPE	930	21-28	350-525	Izod N, 9.6 J/cm K_{1C} = 4 MPa m½	61-68 Shore D	13-20	.8-1.6
UHMWPE – crosslinked	935	19-22	150	Izod N, 8 J/cm K_{1C} = 3 MPa m½			.45-.55
LDPE (ave.)	920	12	220-650	Izod N, 3.1 J/cm	49 Shore D		0.2-0.4
HDPE (ave.)	917	23.8	500-750	Izod N, 2.6 J/cm	63.6 Shore D	18-20	0.9
Cancellous bone	300-500		5-7	K_{1C} = .8 – 1.2 MPa m½	.5-1.2 HV		0.8-1.1
Hydroxyapatite $Ca_{10}(PO4)_6(OH)_2$	>3100	200 (UTS)		K_{1C} = 1 MPa m½	100-120 HV	1	80-165
Collagen		80-100 (UTS)	9-11				1-4
Cortical bone	1800-2080	60-144	0.6-1.4	K_{1C} 2-1 MPa m½	50 – 80 Shore D	23 - 80	5-26

The US Food and Drug Administration, Center for Devices and Radiologic Health, recall database contains a wealth of information for those wishing to use additional medical device case studies[53] (which can be sorted by date and device type). There are many cases that involve materials, but the database also contains numerous engineering design case studies which would be helpful in other courses. For those wishing to use silicone breast implants as case studies, there are superb references available from the National Academy Press[85-86].

Materials and Component Design

An interesting example materials selection in component design is found in the femoral head component of hip implants. Femoral heads are especially good design exercises to use since it directly correlates to the St. Gobain recall case study. A comparison of alumina and zirconia femoral heads to metallic heads correlates to specific learning objectives on mechanical properties listed later in the paper. Table 3 contains the additional data needed for these active exercises. Promotional literature lists the following advantages of aluminum oxide heads: biocompatibility, corrosion resistance, low coefficient of friction, phase stability and high fatigue resistance. The newest alumina femoral heads are "third generation" products that are hot isostatically pressed with small grain sizes (1.8 µm compared to 7 µm) and higher densities (3970kg/m^3 compared to 3940 kg/m^3). Zirconia femoral heads are yttrium or magnesium stabilized zirconium oxide (Y-TZP, for example) and alumina femoral head product literature targets the "unstable" tetragonal crystal structure of the competition. Zirconia does have a higher hardness and burst strength than alumina[56]. Zirconia femoral heads (Y-TZP) have a density of 6080 kg/m^3, a grain size < 0.5 µm and a fracture toughness of 8-10 MPa m½ [55]. Zirconia has three crystal structures: monoclinic, tetragonal, and cubic. The tetragonal has the greatest strength and approximately 5% yttria is added for stability. However, research studies continue to determine the nature and extent of in vivo mechanisms of the tetragonal to monoclinic phase transformation, with one research study finding the monoclinic content of retrieved current generation zirconia heads increased four-fold within one year (also with an increase in surface roughness from 0.007 µm to 0.010 µm)[63]. There are also studies that seem to indicate zirconia instability in the presence of body fluids and reports of failures of zirconia heads on titanium stems[57]. Roughness of the zirconia surface may also be a result of this instability. Transformation from the tetragonal phase into the monoclinic phase brings a 3% increase in volume, and extensive transformation causes an increase in surface roughness[63]. Ceramic-on-ceramic articulation in THA had a difficult beginning in the US market because of early difficulties with design articulation geometries that caused a high number of early revisions. The zirconia femoral head recalls did not improve the marketing case for either ceramic heads or ceramic-ceramic articulation in the US market. However, a review of 500,000 current generation alumina femoral heads shows a failure rate of 0.004% compared to 0.27% for femoral stems[56].

Table 3. Comparison of Alumina and Zirconia Properties for Femoral Heads [58,65,73,75,76]

	Alumina	**Zirconia** (Y-PZT, 4-5% Y)
Average Grain Size, µm	3 – 6 (<7)	0.2 – 0.8
Vickers Hardness, HV	1750-2300	1200 - 1270
Hardness, Mohs	9	6.5
E, GPa	380 – 388	200 – 205
Fracture Toughness, K_{1c}, MPa m½	3.4 – 6 (similar to cortical bone)	5.2 - 8.5
Impact Strength, kJ/mm^2	4	14
Flexural Strength, MPa	400	800
Density (kg/m^3)	>3900	>6000
Weibull Modulus	8	10
Compressive Strength, MPa	4500	5000
Burst Strength, kN	55	81
Fatigue Load, x 10^7 cycles (22 mm head)		450 kg
Load maximum in kg[76] (22 mm head)	2800	3700

Although increasingly popular, alumina heads on titanium stems are limited by loads between 5 and 10 times body weight[57] (which limits the weight of the patient or the size of the component). Increasing the femoral head from 28 mm to 32 mm produces four times the wear debris in metal on UHMWPE bearing couplings[55]. Metal-on-metal bearings (usually Co-Cr alloys) provide an alternative case study for materials engineering courses. Osteolysis caused by micron debris from UHMWPE wear[57] remains the leading cause of titanium femoral stem failure (not stress shielding), so the search for improved bearing surfaces in THA remains. Metal on metal bearings have four times the friction when compared to UHMWPE on metal[60].

Design Constraints and UHMWPE

Many of the most interesting problems associated with TJA are problems where the students examine different design constraints which usually contain complex, but tangible competing materials requirements and differing design geometry considerations. While the current successes in TJA are good, most design lifetimes are far from optimal for many patients. For example, finite element analysis studies show that the contact stresses in the UHMWPE tibial inserts in TKA are near or exceed (21-45 MPa)[33] its yield strength of 20-22 MPa. Although bone integration is superior for Ti alloy components and the "best" elastic constant match to avoid stress shielding, titanium wear rates are much inferior to other materials. In a study where wear rates were reported in material lost (mm/million cycles), the figure for titanium was 25, for Co-Cr it was 15, while for alumina it was 6-7 and it only 2.5 for zirconia[60]. The basic geometry of THA is such that the bearing surface is highly conforming with lower contact stresses, but the basic geometry of TKA is such that it is highly non-conforming, lowering its contact area and increasing its contact stress dramatically. Because of the high contact stress and the low yield stress in UHMWPE, the tibial plateau inserts should be at least 10 mm thick. The FDA recommends a minimum thickness of 6 mm for metal backed components[58]. UHMWPE debris wear which is < 1 μm remains the main cause of bone osteolysis (resorption) and subsequent component loosening. In THA, femoral heads should be as small as possible to reduce wear, but alumina heads must be on the larger side because of its material property limitations. Zirconia heads have superior mechanical properties which allow femoral head sizes to down to 22 mm, but in vivo instability a research topic of interest. Questions still remain on the use of Co-Cr heads with regard to corrosion products within the body. Overall, it is known that the smaller the head, the lower the amount of wear debris and the greater the range of motion, but the greater the chance of dislocation[55].

For TJA bearing surfaces "UHMWPE has excellent mechanical properties because of its chain entanglements, high tie molecule density, moderate crystallinity, and very high molecular weight" [69]. And, because of all those characteristics, UHMWPE makes a superb platform from which to teach about those characteristics for polymeric materials. However, in TJA inflammation and subsequent loosening from wear debris of UHMWPE in vivo and damage associated with yielding, fracture, and fatigue continue to remain problematic[69]. Since UHMWPE bearings remain one of the biggest challenges in the TJA industry, much research has been devoted to improving its in vivo performance. The recent focus has been to improve the performance of UHMWPE through different cross-linking mechanisms so that fewer wear particles <1 μm is produced. Cross-linking can be accomplished through gamma or e-beam radiation. Subsequent thermal treatments are necessary to remove remaining free radicals.

Previously, the TJA industry learned a difficult lesson as many UHMWPE components in the past experienced shelf-ageing scission and loss of mechanical properties from sterilization in air. Wear rates on cross-linked UHMWPE dropped from 10 mg/million cycles to 0 mg/million cycles at a radiation dose of 150 kGy[70,71]. However, questions still remain on the long-term effectiveness of highly cross-linked UHMWPE in service[68-75].

Because most basic materials engineering courses consider the complex mechanical properties of polymers, using UHMWPE as a platform seems to be highly effective with regard to student learning outcomes. Samples of UHMWPE (which are relatively inexpensive and widely available) are compared to samples of LDPE in our class. The students can readily "feel" the difference in the stiffness (E) between these two materials in simple bending and it is easy for them to relate the degree of polymerization to E and the tensile strength in this way. UHMWPE is both a crystalline and amorphous material, so explaining how loads are transferred through tie molecules provides key opportunities to address several learning objectives in basic materials engineering. Pruitt's research work and data (see Table 4) provide good materials properties for active exercises.

Table 4. Pruitt's Work on the Physical Properties of Cross-Linked UHMWPE [69]

(GUR 1050)	Medical Grade – UHMWPE	UHMWPE 30 kGy	UHMWPE 100kGy (150°C)
Molecular Weight	3-6 million g/mol		
Crystallinity	45-50%	51%	46%
Density	930 – 935 kg/m^3		
UTS (20-21°C)	42-44 MPa	47	37
YIELD (20-21°C)	20-23 MPa	24	21
E MPa (20°C)	830	930	780
E MPa (37°C)	650	740	570
True Strain – Max.	.45	.44	.43
True UTS – Mpa	260	220	160
Kc (MPa m½)	4	4.5	3

Current generation UHMWPE that is highly cross-linked to improve its wear resistance in vivo accounts for more than half the acetabular cups sold in the US[67]. All currently produced UHMWPE products are irradiated at dosages less than 12 Mrads and then heat treated to quench the free radicals[55]. No two products are created identically, but the elastic constant can decrease 30%, elongation to break by 45% and yield strength by 30%, fracture toughness (crack growth) by perhaps 20% - 50%, but decreases wear rates from 35mg/million cycles to 1-2 mg/million cycles[55]. There are also reports of reduced resistance to fatigue crack propagation and fatigue/delamination in retrieved components[66-68]. In general, fracture toughness as measured by J integral decreases with increasing levels of cross-linking[68]. Interesting activities can be created to answer an intriguing question whether highly-crosslinking the UHMWPE bearings will indeed provide longer in vivo life-times for implants given that so many other material properties are degraded by this same cross-linking. Wear is complex and design considerations include: type of material, contact stresses, surface hardness, surface roughness, type of articulation, presence of wear particles, oxidation and abrasion.

In addition to the information given in Tables 1-4, it is helpful to know additional design parameters. Fatigue tests for THA are usually performed at 10^7 or 5 x 10^7 cycles (newer research)[60], with many studies indicating a that a "typical person" would load a hip approximately one million times a year. Hip stem forces acting on the ball range from 2.5 – 7 kN because a typical gait cycle in a hip generates forces 6-7 times the body weight of a person[60]. In knees, the load situation is even more complex. In stair ascent, the flexion angle is 60^o and the femoral forces are up to 4.3 times the body weight of the person[77]. In chair rise the flexion angle is 90^o and the load is 3.3 times body weight, while in knee rise the flexion angle is 135^o and the load is up to 5.4 times body weight[77]. Contact areas (in mm^2) for 4 different contemporary knee designs in stair ascent ranged from 277-831, in chair rise from 311-484, and in knee rise from 287-345[77]. Thus, the knee rise problems will show the largest contact stress (even without consideration of stress concentrations, the contact stresses are quite high). Try to emphasize to the students that driving up E also drives up the contact stresses, which is often counterintuitive. Femoral head sizes range from 22 mm to 36 mm. Acetabular cups are 42 - 62 mm in diameter. UHPWPE inserts in THA are 5 – 12 mm thick.

Wear rates in femoral heads can be estimated at 0.8 – 1.4 mm/year (depending on head size)[78]. Similarly, volumetric wear can be estimated from 48 mm^3/year (22 – 28 mm head) to 85 mm^3/yr[78] (32 mm head). Femoral stems range from 110 mm to 170 mm. Long stems (~2 cm) for revision surgeries are also available. Near the mid-point of the stems, the sizes range from 9-18 mm. The stem geometries are widely available on the web. Similarly, TKA components have complex geometry, but are also widely available on the web. The total weight of the knee components is 425-565 g [44]. Good design parameters for the femoral stem: yield strength > 500 MPa, tensile strength >650 MPa, fatigue strength at 10^7 cycles > 400 MPa, corrosion rate < 2.5 x 10^{-4} mm per year and an elongation > 8%[30,41]. A stress of 25-40 MPa is sufficient to maintain the correct levels of bone to avoid bone loss through stress shielding. The FDA's web site contains a wealth of information on test procedures/standards used inn orthopedic implant devices. FDA's "Guidance for Industry and FDA Staff – Non-clinical Information for Femoral Stem Prostheses" (1647) is an example of a guide that is good for course use. In that document for femoral stems, fatigue testing is completed with a minimum load of 300 N and a maximum load of 2.3 kN for 5 million cycles. Fatigue loads in knees can be as high as12000 N or more[41]. Have the students review FDA documents and retrieve the appropriate standards for further design work. For the Co-Cr – UHMWPE couple, "wear rates are generally on the order of 0.1 mm/year, with a particulate generation as high as 106 particles per step"[28]. UHMWPE wear rates on metal are 0.1 - .2 mm/year, while alumina and zirconia ceramics are 0.04-0.98 mm/year[83]. Wear modes in hips are abrasion and adhesion, while in knee components pitting and delamination failure is more common[67]. We are fortunate in that we have ASTM standards from 2000 which we can check out from the library and can reserve volume 13.01 for in-class use.

Class Findings

We carefully reviewed all of our assessment data and of the 46 learning objectives and outcomes for the course, we identified the following 16 outcomes that we believed we could target with the new biomedical device approach. Even after several previous course transformation revisions, a few students were still making puzzling conceptual errors on their final exams and within their research papers, so a pre-class and post-class concept questionnaire was developed so we could acquire more in-depth assessment information. We chose not to use multiple choice questions and instead designed the instrument around written responses and written justifications for those responses. The questionnaires that were developed contain 22-25 questions and take approximately 90 minutes for the most detailed and thoughtful students to complete. The sample size for the questionnaires currently is about 150. Each conceptual question asks for a written answer which must include a justification for the response (i.e. the why?) and are time consuming. The questionnaires cover the following topics: the nature of bonds, properties and structures, crystalline materials, conceptual understanding of the modulus of elasticity, understanding of the term "strong", differences between materials effects and geometry effects, basic engineering design principles, conceptual understanding of wear, fatigue, creep and thermal conductivity, conceptual understanding of nanomaterials, smart materials, and composite materials. Many of the questions were developed to better understand why students were still having a difficult time near the end of the term on previously identified conceptual problems.

Targeted Student Learning Outcomes

Biomedical device course components were designed to enhance a student's ability to:

- Select the appropriate engineering materials for specific engineering applications using: yield strength, tensile strength, ductility or elongation, flexural strength, hardness, fatigue life, wear, and creep;
- Describe and use the fundamental mechanical engineering properties of materials covered in the course (stress, strain, elastic constant, creep, fatigue, wear, hardness, Poisson's ratio, toughness, ductility, flexural strength, impact strength, elongation) are each important in engineering design and how they interact;
- Explain the differences in mechanical properties for isotropic and anisotropic materials (including orthotropic materials);
- Explain the differences in mechanical materials properties for single crystalline, polycrystalline, semi-crystalline and amorphous materials;
- Describe the basic structure of and properties for engineering polymers;
- Identify key differences in the properties of and applications for thermoplastics, elastomers, and thermosetting plastics;
- Distinguish between geometric and materials properties effects in engineering designs;
- Calculate engineering stress, strain and the elastic constant from data and for basic engineering applications;
- Size basic parts for simple engineering designs using safety factors;
- Understand the basic stress/strain behaviors of viscoelastic materials and distinguish those behaviors in practice from elastic materials;
- Explain and specify strengthening mechanisms for mechanical properties;
- Describe the processes of recovery, recrystallization and grain growth as they relate to properties of engineering materials in service;
- Understand and describe the fundamentals of how engineering materials fracture or fail (and the usual causes of failure) in service;
- Predict the effect of temperature on the properties of materials, and thus their usefulness in practice;

- Evaluate the effect of the in-service operating environment on the estimated life-time of materials or fit for use; and
- Select manufacturing and other processes to produce different properties in materials based upon transformation diagrams.

It became clear in reviewing both the questionnaires and the scores for individual questions on the traditional exams the students were having difficulties making the connections between different material properties and the need to satisfy engineering design constraints. The students also needed to make additional connections on the interplay between competing design constraints to specific materials properties. For example, in TJA most device developers realize that the wear debris from the UHMWPE bearings is limiting the overall lifetime of many implants. But, increasing its wear resistance by cross-linking will certainly negatively impact other properties (like resistance to fatigue crack propagation) that are also important to long-term device success. The students were also having a difficult time linking together all the different pieces learned in course modules to the "big picture" of materials engineering. Some students seemed to need more tangible reasons so they could link together structure and properties. To illustrate this point, previously the students certainly left the course understanding how the microstructure of plan carbon steel or precipitation hardened aluminum alloys affect mechanical properties. However, student understanding in this same area in polymers and ceramics was not as well developed. Student outcomes in their fundamental understanding of performance differences among single crystal, polycrystalline, semi-crystalline and amorphous materials in service were not as clear as we had hoped. Finally, the higher order thinking needed to differentiate between material properties and geometry needed further development. Ultimately we agreed with the research literature which shows clearly that "usable knowledge" is not the same as a mere list of disconnected facts. Experts' knowledge is connected and organized around important concepts (e.g., Newton's second law of motion); it is "conditionalized" to specify the contexts in which it is applicable; it supports understanding and transfer (to other contexts) rather than only the ability to remember "[8].

After a reviewing the research literature and specific assessment data and goals, it was decided that biomedical devices which experience significant loads contained specific learning opportunities for most of the improvements necessary within the course. These biomedical devices also have the advantages of having very accessible and tangible contexts. Students who enter the course have some conceptual idea of what a hip replacement is. In addition, the theme for medical devices can be continued throughout the course, starting from the introductory lecture. Even on the first day of the course, the concept of the elastic constant can be explained in enough depth so that the students can appreciate that the elastic constant femoral stem should match the elastic constant of bone or bone loss will occur from stress shielding. And, that enough stress needs to be placed upon the bone to prevent bone loss (remodeling) in an active material. Even on the first day, a discussion can begin about stress being a function of both load and geometry. Similarly, although not emphasized in this particular paper, vascular and peripheral stents made from shape memory materials provide excellent venues for hands-on learning about phase transitions. Device recall case studies provide opportunities to link both structures and properties to in-service failures, and introduce ethics. Our initial data shows specific improved outcomes based on improvements in traditional exam scores and in pre- and post-course concept gains in the use of the elastic constant, tensile and compressive strength, specific stiffness, specific tensile strengths specific compressive strength, fatigue life, creep, and wear resistance in engineering design applications.

Initially, most of the students (91%) think that the material plays a role in determining the stress within a particular engineered part in the pre-course concept questionnaire. Virtually, all of the students predicted that a polyethylene diving board would deflect more than a steel diving board. Several of these same students made the case that a steel diving board would be under more stress than a polyethylene diving board because it was stronger (43%). By the end of the term, no student that attended the class regularly made this conceptual error since the introduction of the biomedical devices (an overall improvement of 4%). The students are now able to articulate the difference between changing the geometry to change the overall deflection and changing the material itself.

The questionnaire also examined what the students know about the connections between materials properties and structures. One question specifically examined this and others peripherally addressed these conceptual connections. Almost all the students (90%) knew that a material should get less stiff as the temperature of the material increased, and about 80% of the students gave a correct answer as to why this is so. Unfortunately, 90% of the students then think the modulus of elasticity then should go up with increasing temperature before the course. Students associate the word elastic with flexible. Previously, fifteen percent of the students answered this same question incorrectly on the post-class questionnaires or the final exam. After using the biomedical devices approach, only six percent of the students answered this type of conceptual problem incorrectly at the end of the term. That result is an impressive 9% gain in score. Since the students use E for many different materials and, to a lesser extent, examine them at an elevated temperature, it is likely this gain is certainly from improved student understanding. In the biomedical device approach, the students had to compare E values between materials and materials types and select appropriate E values, yield strengths, fatigue properties, etc. multiple times during the quarter. The structure-property-performance relationship theme was continued throughout the quarter and, perhaps, it was this repeated attention to these relationships that improved several student outcomes.

Most of the students were not familiar with smart materials pre-course. Forty seven percent answered no idea in response to this question and another 30% had the wrong idea of what a smart material is (they often confused it with a composite material or a smart use of a material) before the course. Only 23% of the students correctly knew what a smart material was and could identify a correct example of one pre-course. No student confused a smart material with a composite material or the smart use of a material at the end of the quarter, and they certainly could all give an example of a smart material at the end of the term. The preliminary learning activities centered on Nitinol then were effective in that context. Similarly, a question asking what classification of material the students would choose for a wear resistant application revealed that they really do not have a reasonably good understanding of the three basic classifications of materials as they enter the course.

In general, depending on the term and question, ten to fifteen percent of the students left the course with some conceptual misunderstanding on E, YS, UTS, fatigue strength, or creep by the end of the term. After the introduction of biomedical devices, all the same conceptual difficulties dropped to less seven percent. Less than two percent of the students left the course with conceptual difficulties with safety factors (more likely as a result of poor attendance rather than course structure issues, however).

This academic year, we also started to investigate the effect of student learning style on our activities/student outcomes, so that we might find the most appropriate balance for them in our lectures, case studies and activities. In the Felder/Silverman/Solomon/ Model, a student's learning style may be defined by four questions: "1) What type of information does the student preferentially perceive (*sensory or intuitive*)? 2) What type of sensory information is most effectively perceived (*visual or verbal*)? 3) How does the student process information (*actively or reflectively*)? 4) How does the student characteristically progress towards understanding (*sequentially or globally*)?"[16, 23,25]. Preliminary data from a small sample size of materials students (51), show that the students tend to be much more visual than verbal, more sensory than intuitive, a little more reflective than active, and a little more sequential than global. Since the data sets are small, it is too early to draw any conclusions or make recommendations, but at least baseline information is being collected. We already incorporate many opportunities in our mini-lectures and activities targeted toward visual learners as long before data was collected, previous assessments indicated this same need.

Conclusion and Next Steps

Teaching and learning strategies that are built around biomedical devices that experience significant loads in service show, based upon preliminary assessment data, improvements in targeted student learning outcomes. This assessment was based upon student understanding in pre- and post-course concept questionnaires and scores on traditional tests. The strategy was deliberately focused upon mechanical properties and in-service behavior of the three basic classifications of materials. It could be that biomedical device case studies help the students construct more pathways to new knowledge since the very tangible biomedical devices provide the appropriate contexts to build those connections to the new information. However, this construct leads to basic questions about what and which existing scaffolds are in place for the students to build upon then as they enter the course. New questions on future pre-course questionnaires will attempt to probe deeper into understanding this important area.

In might also be that the theme of the biomedical device case studies interwoven into the other course changes we have made during the last several years simply provide more opportunities and repetition in materials selection and design so the students are able to more fully develop specific higher order skills The added benefit of enhanced student learning in the broad area that encompasses other than isotropic, elastic material behaviors, though, can only be from introducing biomedical devices into the course. The small number of biomaterials materials which also encompass all three basic materials classifications seems to help the students sort out what is a design constraint/goal and how those can be accomplished with appropriate materials choices or geometry changes. The comparisons among LDPE, HDPE and UHMWPE did improve student learning in conceptual understanding of the degree of polymerization, and the different properties of crystalline, semi-crystalline, and amorphous materials. However, those same skills can surely be built out with different contexts. Understanding fatigue life, creep, and wear also improved. There was some improvement in understanding of isotropic/anisotropic materials, but likely those improvements were also from other changes within the course (musical instrument design). We also speculate that some of the improved student outcomes also are the result of a change to a team based written research project and oral presentation that the students complete by the end of the term. Perhaps the previous changes in the course, coupled to these new focus areas, coupled to the written/oral work has produced more gains than would otherwise be made. We have also had six years to help us understand in practice how to better implement the many best practices outlined in the research literature. We did not attempt to sort out how the various components interacted at this point in our research.

There are still many challenges that remain for the course. Even though we administer a pre-course concept questionnaire, our understanding of preexisting misconceptions and existing scaffolds remains far from complete. For example, only recently did we uncover at least one reason why some students had a difficult time conceptually connecting polycrystalline materials to isotropic properties (poly means "many" and iso "one"), and we do not know what the students understand in detail about biomaterials and biomechanics as they enter the course. We also have an incomplete picture of student learning styles for our student population. Our student population in this course is increasing in diversity in that it is now the introductory course for an interdisciplinary minor in materials science which also draws upon majors in chemistry, physics and geology. It remains challenging to sort out how all the changes to the course impact student outcomes. Certainly, reliable and valid indicators of successful enhancements in student outcomes are needed for this course. Although the National Council of Examiners for Engineering and Surveying (NCEES) exams are reliable and valid indicators of student outcomes, our students do not as a matter of practice take NCEES exams since they graduate in engineering (and industrial) technology and science disciplines. Clearly much more work is needed in these important assessments!

Since the data we have points toward improving opportunities for visual learners, we also need to focus our next course improvements there as well. We still need more (tested and fully developed) concept questions for the course. Because of the initial success of using a biomedical device theme within the course, the approach will be continued and further development will continue. Learning opportunities in arterial and peripheral stents which utilize either stainless steels or Nitinol will be expanded in the course as student outcomes that focus on phase transitions and structures still are below expectations. We will also continue to seek opportunities to build student excitement (and motivation) for what is certainly a challenging course. Overall, the preliminary data that was gathered does seem to indicate that certain important student learning outcomes may have been improved in this course enough so that the approach will be continued, developed and studied in more depth.

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