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The Analysis of Orthopedic Steel Implant by Static and Dynamic Electromagnetic Signatures

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Abstract

Steel remains a commonly used metal in orthopedic implants. However, it is often difficult to confirm the exact chemical compositions of the implants during quality control, as the process requires extensive analysis procedures in the laboratory. Nevertheless, this information is important, as it has been shown that variability of steel composition may be responsible for some of the early prosthetic failures.

We previously developed a technique to identify metal alloys based on their magnetic signatures. We demonstrated that metals of different chemical compositions would exhibit different electrical conductivity, and thus different magnetic field strengths when evoked by different levels of electric current. We further demonstrated that the electromagnetic signatures could be detected by the internal magnetometers located inside most smartphones as a part of the internal compass. Since 316L is the most commonly used steel in orthopedics implants, in this manuscript we now publish the electromagnetic signatures and magnetic force vectors of 316L steel alloy. This standard signature will now allow implant manufacturers to verify the purity of the 316L steel from suppliers.

Keywords: Orthopedics; Steel; Implant; Chemical composition; Physical properties; Electromagnetism; Surgery; Medical device

Introduction

While a number of materials have been used to construct orthopedic implants, stainless steel remains a commonly used metal [1]. Stainless steel is relatively resistant to bacterial colonization and infection and is commonly used for orthopedics plates, screws and nails [2,3]. The implant manufacturers purchase steel alloys, which are subsequently cut by computerized tools, buffed, electropolished, laser marked, and ultrasonically cleaned for medical use [4].

It has been shown that medical metal implants can fail because of the impurities of the metal alloy material [5]. However, it is very difficult for patients and doctors to find the exact alloy ingredients of orthopedic implants [6]. Even implants manufacturers have difficulties verifying the exact metal ingredients of each production run of metal alloys used for orthopedic implants. The situation is severe enough such that FDA issued an announcement calling for labelling of the metal alloy components in medical implants [7].

Our previous work showed that steel alloy ingredients can vary from one production run to another, even from the same manufacturer [8]. We patented and developed a method of using the magnetometer inside iPhones to extract unique electromagnetic signatures from metal alloys and demonstrated that the signatures correspond to steel microhardness, tensile strength, and chemical composition [9,10]. This technique can provide medical device makers with the ability to perform spot analysis of the steel alloy and medical implants. We now report the mechanical properties, chemical composition, and electromagnetic dynamic signatures of 316L steel alloy, one of the most commonly used medical grade stainless alloy [11].

Material and Methods

316L steel alloy was purchased from BuyMetal.com (Bensalem, PA): Stainless Steel Round Bar 316\316L 0.25" (A) x 12"; SKU: SSR316.00.2500.12.

Chemical analysis of the 316L steel alloy specimen was performed and reported by the manufacturer.

Physical analysis, including Brinell hardness test, tensile strength and ductility properties were

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performed at the site of manufacturer.

A smartphone can be used to analyze electromagnetic profiles at different levels of electric current to construct its unique magnetic signature. The exact methodology was previously published and will be summarized here [12].

Smartphone with magnetometer and software

An iPhone 13 Max, Apple (Cupertino, CA), running iOS 15.6 was used in the current study. Magnetscape 2.0 (Toon, Osaka, Japan) was used as the magnetometer software to record electromagnetic signatures.

Electric source

In order to obtain magnetic signatures at different voltage levels, a variable energy source was used: Tekpower TP3016M Portable Handheld Variable DC Power Supply with USB Port, 0.3V-12V @ 0-3.75A or 0.3V-30V@ 1.6A with VC and CC Control, Upgraded TP3005D, HY3005 (Tekpower, Montclair, CA). Power can also be supplied with V current of 9V and 1.5V.

Resistor

In order to accommodate the variable currents needed for the extraction of magnetic signatures, a Resistance Substitution Box Model RS-400 (Elenco Electronics, Wheeling, IL) was used.

Results

316L steel was first verified chemically and physically and then assessed for both static as well as dynamic electromagnetic signatures at different voltages.

Table 1 shows its chemical composition. The steel alloy sample is a combination of different elements, which determine the specific characteristics of the steel. It is known that 316L steel contains 16% chromium, which hardens the steel and prevents corrosion, and 2% molybdenum, which helps to prevent corrosion and also increases tensile strength. The chemical analysis of the sample confirmed that it is indeed pure 316L steel.

Table 2 shows the physical properties. It is known that 316L steel demonstrates the hardness of 227, on a Brinnell hardness scale of 15 to 750, with 120 being mild steel [13]. 316L possesses the yield strength of 97.8, which is on the mid-range of standard steel, ranging 30 to over 200 in common steel alloys, suggesting some flexibility to allow metal deformity [14]. The 316L alloys also possesses the Ultimate Tensile Strength of 110.45, strength before breakage (ranging 30 ksi (cast iron) to 390 ksi (maraging steel) [15]. Both the RA (Reduction of Area) and Elongation are measurement of ductility [16]. 316L steel has an RA of 71.07% and Elongation of 35.20%. Metal bolts require a minimal RA of over 40% [17]. Elongation ranges from 8% for 1144 "Stressorproof" steel to 1018 mild low carbon steel [18]. The physical properties of the 316L sample confirmed the identity of the sample.

Having identified the sample as indeed 316L steel by chemical and physical methods, the steel alloy was then tested for its electromagnetic signatures. Measurements were first taken to acquire baseline magnetic signatures, and then electric charges were applied to each alloy to induce an electromagnetic field. Voltages were set at 1.5 and 9.0 levels. Electromagnetic signatures were measured in MicroTesla (μT), and the angle of maximum force was recorded in angles of degrees (°). Electromagnetic vectors were calculated by multiplying the strength of the electromagnetic signal by the angle of maximum force as MicroTesla-Angle (μT × °) units.

Table 3 demonstrated the changes of electromagnetic strength, as well as the maximal angle of force, when the steel alloy is placed in magnetic field of different voltage. A unique electromagnetic signature, which is a reflection of the unique chemical composition of the alloy, was observed at each voltage strength.

Discussion

Orthopedic implants of increasing complexity have been developed over the years, but steel remains an important material for the implants due to its unique physical and chemical properties. Since medical implants require the most precise manufacturing processes, the verification of sourced steel is critical.

Traditionally the analysis of steel requires elaborate laboratory processes, which are expensive, laborious, and not always performed. We recently developed a method of identifying steel based on its unique electromagnetic signatures [9]. We showed that electromagnetic signatures could be used to correlate to microhardness and chemical compositions to steel alloys [8,10,12]. We further extended the work to analyze bronze and copper alloys and showed the electromagnetic signatures could be used in a number of fields, including archaeology, by matching excavated metal antiques to the civilization of origin based on the chemical compositions [22-25].

In this study we first verified the purity of the 316L sample via its chemical and physical analysis, and the results conformed to the published chemical and physical identity of 316L steel.

We then acquired the electromagnetic signatures of 316L steel. This set of information will now allow manufacturers to quickly verify the purity of their steel supply. One can easily examine the steel shipment against the electromagnetic signatures published in this manuscript for verification, much like matching fingerprints. In addition to the steel supply, the method can also be used to test the

Table 1: Chemical Analysis: 316L steel alloy's identified was confirmed by its chemical composition. Results are expressed as percentage based on weight (%).

		316L Steel Alloy									
Chemical Composition	C	CO	CR	CU	MN	MO	N	NI	P	S	SI
% by weight	0.018	0.35	16.74	0.29	1.47	2.012	0.04	10.52	0.028	0.025	0.26

C: Carbon; CO: Cobalt; CR: Chromium; CU: Copper; MN: Manganese; MO: Molybdenum; N: Nitrogen; NI: Nickel; P: Phosphorus; S: Sulfur; SI: Silicon

Table 2: Mechanical Analysis: 316L steel alloy identity was further confirmed by their mechanical properties.

		316L Steel Alloys			
Mechanical Properties	HB	.2YS KSI	UTS KSI	RA %	Elong %
	227	97.08	110.45	71.07	35.2

HB: Hardness, Brinnell Number; .2YS KSI: 0.2% Yield Strength, Kilopound per Square Inch before Metal Deforms [19]; UTS KSI: Ultimate Tensile Strength, Kilopound per Square Inch before Metal Splits or Breaks [20]; RA %: Reduction of Area in Tensile Strength; Elong %: Percentage of Elongation as Compared to the Original Sample at Structural Failure [21]

Table 3: Static and Dynamic Electromagnetic Signatures: 316L steel alloy was analyzed at baseline and then with 1.5 V and 9 V currents. Electromagnetic signatures were measured in MicroTesla (μT), and the angles of maximum force were recorded in angles of degrees (°). Electromagnetic vectors were calculated by multiplying the strength of the electromagnetic signals by the angles of maximum force as MicroTesla-Angle (μT × °) units.

	316L Steel		
Electromagnetic Signatures	Static	1.5V	9 V
MicroTesla (μT)	37.4	44.7	42
Angle of Maximum Force (°)	-165	-162	-166
Vector (μT × °)	-6171	-7241.4	-6972

finished medical product. For example, a surgeon or hospital can scan the implant with their iPhones to ensure the identity of the implant and also to avoid fake or impure medical implants.

This manuscript, in addition to reporting 316L electromagnetic signatures and their angle of maximum force, also reported the vector of electromagnetic force. This vector scale was previously shown to be useful in metal excavated from archaeological sites and has undergone erosion. The manuscript hopes the electromagnetic vector can help Pathologists to examine explanted orthopedic implants to see if there has been chemical degradation that may have contributed to the failure of the implant.

In conclusion, the current study is the first in a series of manuscripts to provide a comprehensive database of electromagnetic signals and vectors in order to provide a database of different orthopedics steel alloys for comparisons. Future research will examine the electromagnetic signatures of other commonly used metals for orthopedic implants, such as the titanium-steel alloy.

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