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SCHOLARLY ARTICLE

Regenerative Corrosion Index of Beta Phase Titanium Copper Alloy for Intrauterine Gynaecological Application

[1]Udeh O.U., [2]Nwogbu C.C., [3]Nwogbu P.I.

[1]Department of Mechanical /Production Engineering, Caritas University Amorji-Nike, Nigeria
[2]Department of Metallurgical and Material Engineering, Enugu State University of Science and Technology, Enugu, Nigeria
[3]Department of Chemical Engineering, Enugu State University of Science and Technology, Enugu, Nigeria

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ABSTRACT

The investigation of corrosion regenerative index on performance reliability of Intrauterine contraceptive beta phase Titanium Copper Alloy for gynecological application within the endometrium environment is investigated in comparative analysis with existing mono-element copper prototype, the Cu-T380(IUD).The existing Cu-T380(IUD) is associated with induced biocorrosion problems of fragmentation micro-structural load deformation - failure mode which cause expulsion phenomenon, biocompatibility - cell cytotoxicity phenomenon, microbial pathogenic skin rash reactions, Pelvic Inflammatory Disorders(PID), with copper allergenic cramp resulting in infection phenomenon. These adverse phenomenal effects of expulsion, biocompatibility and subsequent infection associated with copper Intrauterine Device necessitated the development of an optimally improved beta phase biomaterial alloy, Titanium Copper alloy (TiCu alloy). This research innovated the design and production of Beta((β) phase TiCu alloy in the categories of specimens; Ti0.5%Cu, Ti1.0%Cu, Ti2.0%Cu, Ti5.0%Cu, Ti10.0.0%Cu, Ti15.0%Cu and Ti17.0% Cu, using Copper element as the experimental control reference biomaterial. The TiCu alloy specimens were produced by powder metallurgy technique in an inert environment. Experimental investigations and Minitab Software Design analyses of corrosion resistance was carried out by Electrochemical Impedance Spectroscopy (EIS) using Hanks and Ringers solutions (Simulated Body Fluids) at body temperature of about 37°c. The corrosion potential of the samples showed that Ti 17%Cu have value of -0.304 and -0.303 While copper indicated a corrosion potential of -0.242 and -0.243 for Hanks and Ringers solutions respectively. The Corrosion rate showed that Ti17%Cu sample has corrosion rate of 1.4mg/cm2yr and 1.6mg/cm2yr in the Hanks and Ringers solution respectively in comparison with 6.9mg/cm2yr and 7.0mg/cm2yr observed for the Copper specimen. The findings established Ti17%Cu alloy as a possible replacement to the existing prototype biomaterial (Cu-T380 (IUD).

Keywords: *Regenerative Corrosion Index; Beta Phase Titanium Copper Alloy; Intrauterine Gynaecological Application*

Background

Simulative research design of Corrosion phenomenon is exhibited in the gradual degradation of biomaterials by electrochemical attacks, usually in the electrolytic human environment, and experimentally assessed in vitro in simulated body fluid (SBF), usually in Ringers and Hanks simulated solutions. Biomaterial corrosion is of great concern to research studies because of the requirement of these materials to function effectively and efficiently in human beings that suffer from orthopedic/bone fragmentation, neurosurgical related problems, osteoporoses, arthritis, gynecological complications and other heart/cardiovascular diseases. The poor regenerative response of the protective oxide films are the causes of implant failure, hence the need for corrosion assessment processes and susceptibility, which will result to establishment of mechanical strength criteria, and tissue biocompatibility of the materials (Liu, 2015).

The various cases of macro and micro electrochemical corrosion occurrence create research analysis for the investigation of uniform and localized corrosion, and their effect on the strength and microstructure of the biomedical implant (Coatings, 2003). The rate of occurrence of biomaterial corrosion (susceptibility) suggests for the experimental investigation of their effect on failure rates and service life of the implant (Sutter and Bonni, 2005). Susceptibility of the medical implants to corrosion is illustrated with Figure1 below.

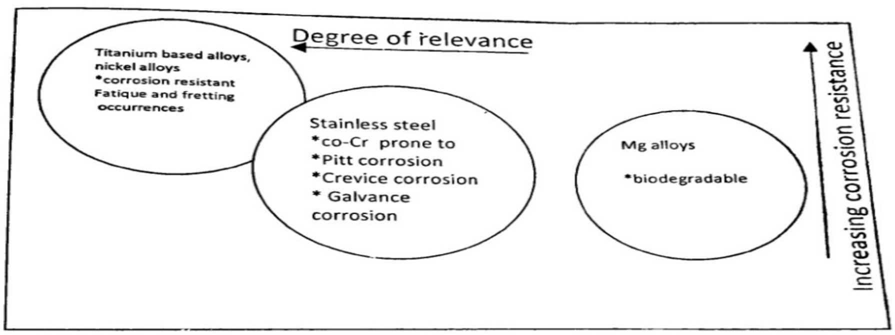


Figure1: Corrosion resistance (susceptibility) diagram Ref; (Manivasgram, 2010)

The metallic biomaterial is always known to be protected by oxide layer which ensures that corrosion resistance also prevents (pitting) breakdown when in very hostile environment. The shapes of the biomaterials affect and influence crevice corrosion, whilst the coupling of dissimilar materials results to galvanic corrosion effects (Ali, 2004). These two types of corrosion (crevice and galvanic) occur simultaneously, since crevice is created when two dissimilar materials are in contact, and as such electrochemical corrosion investigation is used to detect the release of toxic ions which is a phenomenon that causes implant failure. Titanium alloys are corrosion resistant whilst Magnesium alloys are very reactive, and classified as biodegradable biomaterial, which after being surgically installed, disappear at a particular duration into the body (environment), without any toxic effect (Sammons, 2011). Titanium biomaterials are less affected by electrochemical *corrosion, unlike stainless steel and cobalt based alloys which are prone to corrosion attacks (Congelo.1974). Electrochemical study of corrosion behavior of Titanium and its alloy* indicates that its microstructure and XRD examination have good corrosion passivity behaviour on the surface, and they are susceptible to fatigue failure and crevice than electrochemical corrosion. Stainless steel alloys are also affected by both pitting and galvanic corrosion, whilst with a lot of localized corrosion attacks. Titanium and its surfaces usually react as a cathode, when aligned with other metallic biomaterials (Sutter & Bonni, 2005)

Corrosion, fatigue and crevice examination of Ti-AL-V biomaterial showed crack propagations and breakdown of the implant 6 months after implantation (Singh et al, 2006). Stainless steel and cobalt based implants are usually attacked by localized corrosion attacks (pitting), and 316L alloys (stainless steel) is studied, and investigations confirmed that they are mostly prone to pitting as well as crevice corrosion. The corrosion research study of Ti-AL-V indicates localized corrosion and crevice corrosion which are at high risks of infection and toxicity (Starvetskey, 2001). Much of the uncertainty about relative corrosion resistances which have been reported for different metallic biomaterial, without doubt, is as a result of differences in the methods used in determination of these values, as noted by American society for testing of materials (ASTM) (Shrier, 1988; Okazak, 2009). There are corrosion methods classified as full and complete immersion methods and anodic corrosion at very low current density (Liu, 2004).

Research reports that established the effect of corrosion on biomaterials confirm that human tissue is mainly organized of self-assembled polymers (proteins) and ceramics (bone materials), having metal constituents as trace elements (Qizh and George, 2015). There is a phase transformation from alpha to beta phase at temperatures above 883^{0}C. Below 882.5^{0}c, Titanuim exists as alpha-phase (*α)* material and the crystal structure is hexagonal close packed (Hcp), but above 883^{0}c it changes to body centered cubic system (bcc) in beta*(β) phase,* because it possesses high passivity and regenerative properties that is, ability to repair itself and form protective covering, with dense oxide film (Coating, 2003). *Titanium alloys are differentiated into three metallurgical groups, which are; alpha (α), Beta (β) and alpha+beta. Research has shown that copper phase stabilizes Titanium alloys, and these are qualitatively used in gynecological biomaterial application, with very low modulus of Elasticity (which is below the α and α + β phase), and very close to human femoral bone modulus of elasticity of between 38 – 40GPA (Sykaras, 2000). Titanium and its alloys in beta phase domain exhibit microstructure effects of Osseointegration, osteoconduction and osteoinduction properties of biomaterials. The Osteoinduction is an attribute of Titanium which guarantees bone healing process with formation of prosteoblasts, and the reduction of cracks and fractures initiated by corrosion process (Sutter and Bonni, 2005).*

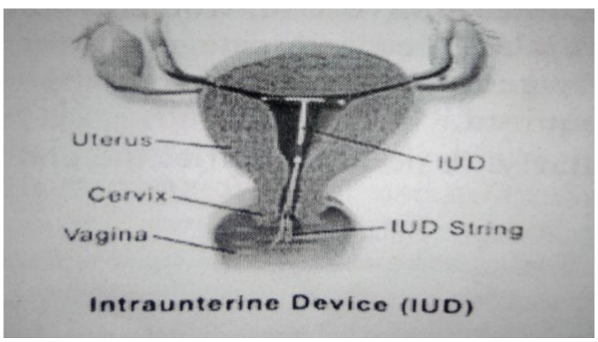


Figure 2: Insertion of IUD T380 in the Endometrium Ref; **Kalpana et al (2009)**

The problems of existing Intrauterine implants (CuT380IUD) are basically expulsion, fragmentation, corrosion and infection phenomena (Udeh, 2021). Figure2 depicts the insertion of CuT380 in the endometrium.

Materials and Method

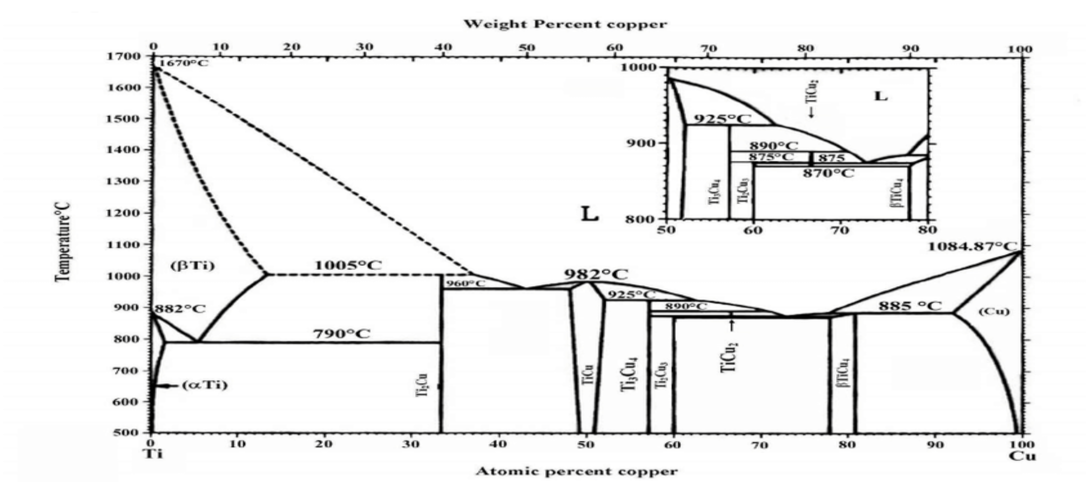


Figure 3: Phase Diagram of Ti-Cu Alloy (courtesy, Good fellow Inc, USA)

The alloy samples were prepared using Powder metallurgy approach. Commercial pure copper powder named (cp-Cu) was used for the alloying, and also for the manufacture of control reference biomaterial (100%Cu). In the material design, the production of TixCu alloy specimens (x=0.5%,1.0%,2.0%,5.0%,10.0%,15.0% and 17.0%) is by powder metallurgy in an inert environment at eutectic maximum solubility of 17.0% copper in beta Titanium phase at 1005^0C and compaction pressure of 500MPa,as depicted above, in the phase diagram of Titanium Copper alloy. The copper element (control reference material) powder is also processed in the inert environment at the temperature of 1005^0C (Udeh, 2021). The Titanium powder and copper powder were each weighed out differently, and ball-milled differently for 4-7 hrs, and then were pressure compacted up to 500MPa, to develop the specimens (TiCu Alloy), being 30mm in diameter, and under vacuum conditions of 983^0c -1005^0c for 135-190 minutes, and allowed to cool in furnace to room temperature of 30 ^{O}C. The thermocouple inserted into the bottom punch was used to measure the temperature. Titanium-copper alloy (TiCu) specimen was prepared from Titanium powder and Copper powder (99.5% purity) at different percentage weight compositions as follows: (99.5% Ti 0.5%Cu), (99%Ti 1.0%Cu), (98.0% Ti 2,0%Cu), (95.0% Ti 5.0%Cu), (90.0% Ti 10.0%Cu), (85.0% Ti 15%Cu), (83% Ti 17%Cu). Specimens of diameter 30mm and a thickness of 2.5cm were sliced-off from the TiCu specimens for the various tests using dies and punches of graphite.

Ali (2004) confirmed that the manufacturing option of powder metallurgy approach of beta- phase Ti-Cu alloy specimen was very clinically acceptable due to its high degree of affinity with tissues in the endometrin. Amir et al (2015) collaborated the results of Titanium Copper alloy fabrication and adopted the powder metallurgy approach of this research

The development and analysis of the beta phase Ti-Cu alloy (Bcc) specimens was innovated, using the highlighted characterized parameters which influenced the acceptability of the researched alloy, Titanium Copper alloy (Paul et al, 1988). Titanium as an element is allotropic, existing in more than one crystalline form, which at room temperature is Hexagonal close packed (HCP) and of Alpha phase (Amir et al, 2015), but when alloyed with a Beta phase stabilizer like copper, at temperature of 928°c-1005°c to form Titanium Copper alloy, there is a metallurgical phase transformation to Beta phase with Body centered cubic structure (Bcc) (Udeh, 2021).

Figure 4: Developed beta phase Titanium copper specimens and copper specimen

Table 1: Composition of samples used

Specimen	Composition
1	Ti-0.5%Cu
2	Ti-1.0%Cu
3	Ti-2.0%Cu
4	Ti-5%Cu
5	Ti-10%Cu

6	Ti-15%Cu
7	Ti-17%Cu
8	100%Cu

XRD Phase and Microstructure Examination

The *X-ray diffraction (XRD) analysis* and Scanning Electron Microscopy (SEM) Microstructure examination of the Titanium copper alloy specimens and reference copper element was conducted.

Electrochemical Impedance Spectroscopy Test for Corrosion (EIS)

The electrochemical impedance spectroscopy experiments were conducted with the use of two fluids (Simulated Body Fluids) which are simulated to be identical to human fluids, controlled at 7.1 PH value, using Hanks solution and Ringers solution, this test is carried out at approximately 37°c, with beakers containing the specimens. The open circuit potential (ocp) was measured for 1 hour (3600secs) of immersion of the specimens. The electrochemical impedance spectroscopy test for the specimens were conducted at a body temperature condition of 37°c, with scan from -190mv $v_s$ocp (open circuit potential) to +1250 mv $v_s$ocp at a scan rate of 0.5mv/s. Impedance measurements were performed at +10mv amplitude up to 1hr, recording the electrochemical impedance spectroscopy spectra at approximately every 60secs for both the potentiodynamic polarization test and impedance measurement tests.

The corrosion rate is,

$$V = \frac{MI}{nF} \quad (1)$$

Where,

M	=	molar mass of Titanium copper or Copper element
I	=	Average corrosion rate
F	=	Faradays Corrosion density
n	=	Valency of element

Table 2: Composition of Hanks solution

Substance	Composition (g L^{-1})
NaCl	8.00
KCl	0.40
$NaHCO_3$	0.35
$NaH_2PO_4.H_2O$	0.25
$Na_2HPO_4.2H_2O$	0.06
$CaCl_2.2H_2O$	0.19
$MgCl_2$	0.19
$MgSO_4.7H_2O$	0.06
Glucose	1.00
PH	6.90

(Ref; Aragon et al, 2009)

Table 3: Composition of Ringers Solution

Substance	Composition (g L^{-1})
NaCl	8.69
KCl	0.30
$CaCl_2$	0.48
PH	6.40

(Ref; Aragon et al, 2009)

Results and Discussion

Microstructure Examinations and Mechanical Strength

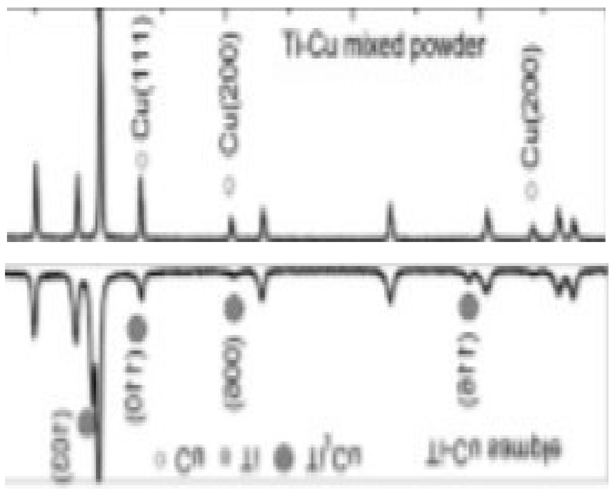
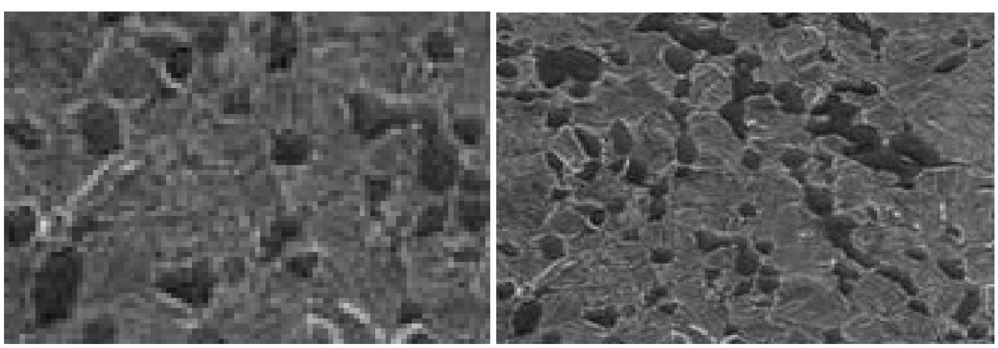
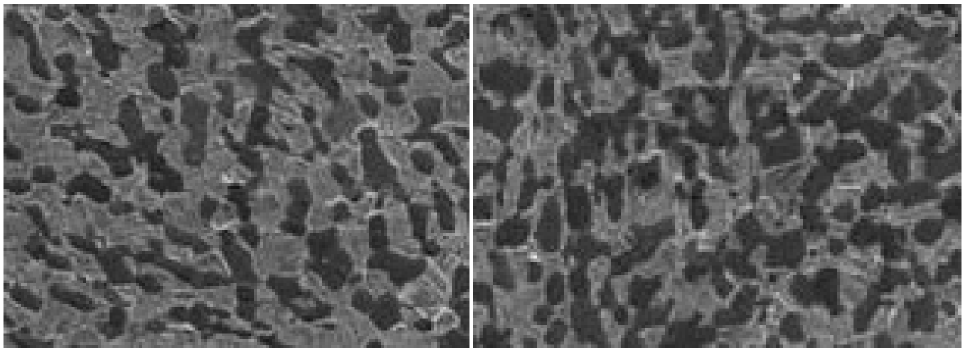


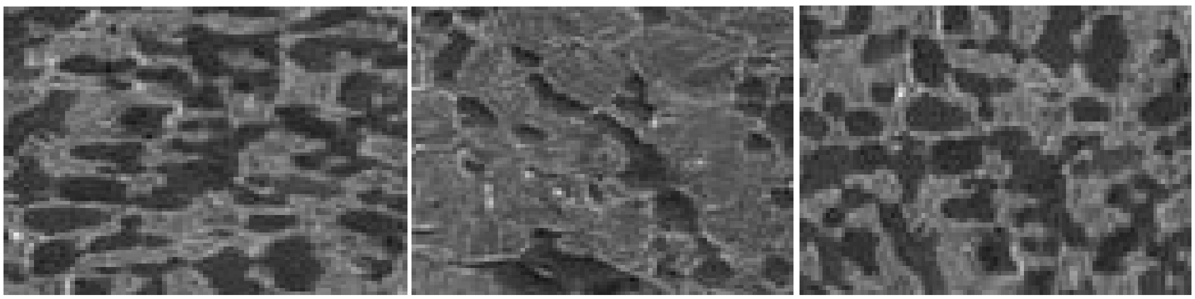
Figure 4*: XRD pattern of Ti 17% Cu and copper element*



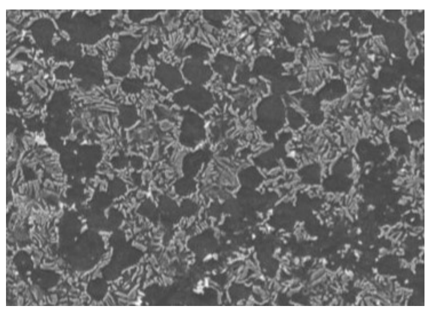
(a)Ti0.5%Cu (b) Ti1.0%Cu



(c)Ti2.0%cu (d) Ti5.0%Cu



(e)Ti15.0%Cu (f) Ti10.0%Cu (g) Ti17.0%Cu



(h)100%Cu

Figure 5*: SEM Microstructure* Examination

The SEM microstructure analyses of the samples at the various compositions of copper in the Titanium matrix at Ti-Cu (x= 0.5, 1.0, 2.0, 5.0, 10.0, 15.0 and 17.0) together with the reference copper as shown in Figure 5a-h, indicates that the Copper powder is uniformly distributed within the Titanium matrix, and is an index for good mechanical strength. The scanning electron microscopy (SEM) showed the presence of inter-metallic Titanium copper (Ti_2Cu) which provided the interface for mechanical strength and good biocompatibility properties (Hugson, et al. 2012; Sykaras, 2000). *Figure 4 shows the XRD pattern of Ti 17% Cu and copper element, it* indicated new peak identification at 40° and 70° for the Titanium Copper element. The result is in accordance with the findings of Qizh & George (2015) that the XRD and SEM microstructure analyses indicated the formation of Ti_2Cu inter-metallic beta phase, with Bcc structure for all the beta phase Titanium copper alloy specimens.

This research has proven that alterations in the surface roughness of Ti 17%Cu alloy influences the response of cells and tissues by increasing the surface area of the implant, and as such, improves the overall affinity of the biomaterial with the adjoining cells (Muddu*gaggadhar* et al 2011). The improvement of the surface texture improves the wettability of the implant (Ti 17Cu %) by the wetting fluid (blood), and ensures the cleanliness of the Ti 17%Cu alloy surface, thereby improving the cell adhesion and cell viability of the biomaterial (Sykaras et al., 2000).

Corrosion Test Results

Table 4: 0.9% Hanks Solution Simulated Body Fluid (SBF)

Sample	Composition	E_{cop} at 1hr	E_{corr}	I_{corr} (uA/cm)	Corrosion rate (mg/cm^{2}yr)
1	Ti-0.5% Cu	-0.259	-0.264	0.508	4
2	Ti-1.0% Cu	-0.262	-0.27	0.425	3.7
3	Ti-2.0% Cu	-0.265	-0.277	0.314	3
4	Ti- 5.0% Cu	-0.27	-0.285	0.295	2.5
5	Ti-10.0% Cu	-0.28	-0.291	0.225	2
6	Ti-15.0% Cu	-0,288	-0.297	0.198	1.6
7	Ti- 17% Cu	-0.301	-0.304	0.178	1.4
8	Cu	-0.231	-0.242	0.741	6.9

Table 5: E_{corr}(corrosion potential) versus Time

Sample	Composition	600sec	1200sec	1800sec	2400sec	3000sec	3600sec
1	Ti-0.5% Cu	-0.238	-0.246	-0.25	-0.255	-0.26	-0.264
2	Ti-1.0% Cu	-0.242	-0.248	-0.252	-0.259	-0.265	-0.27
3	Ti-2.0% Cu	-0.25	-0.255	-0.26	-0.265	-0.271	-0.277
4	Ti-5.0% Cu	-0.258	-0.263	-0.269	-0.274	-0.28	-0.285
5	Ti10.0%Cu	-0.262	-0.269	-0.272	-0.279	-0.284	-0.291
6	Ti15.0%Cu	-0.268	-0.274	-0.278	-0.282	-0.29	-0.297
7	Ti 17%Cu	-0.274	-0.28	-0.284	-0.291	-0.297	-0.304
8	Copper	-0.213	-0.218	-0.223	-0.23	-0.236	-0.242

Table 6: E_{corr}(corrosion potential) versus Log I(A/cm^2) (Tafel Diagram)

Sample	*Composition*	E_{corr} (potential)	Log I(A/cm^2)
1	*Ti-0.5% Cu*	***-0.264***	*-0.293*
2	*Ti-1.0% Cu*	***-0.270***	*-0.369*
3	*Ti-2.0% Cu*	***-0.278***	*-0.502*
4	*Ti-5.0% Cu*	***-0.293***	*-0.527*
5	*Ti10.0%Cu*	***-0.282***	*-0.643*
6	*Ti15.0%Cu*	***-0.293***	*-O.701*
7	*Ti20.0%Cu*	***-0.295***	*-0.752*
8	*Copper*	***-0.242***	*--0.130*

Table 7: Ringer Solution Simulated Body Fluid (SBF)

Sample	Composition	E_{cop} at 1hr	E_{corr}	I_{corr} (uA/cm)	Corrosion rate (mg/cm^{2}yr)
1	Ti-0.5% Cu	-0.259	-0.265	0.508	4
2	Ti-1.0% Cu	-0.264	-0.27	0.426	3.8
3	Ti-2.0% Cu	-0.266	-0.279	0.316	3.2
4	Ti- 5.0% Cu	-0.271	-0.285	0.296	2.5
5	Ti-10.0% Cu	-0.282	-0.291	0.228	2.1
6	Ti-15.0% Cu	-0,289	-0.298	0.198	1.7
7	Ti- 17% Cu	-0.302	-0.303	0.179	1.6
8	Cu	-0.235	-0.243	0.742	7

Table 8: E_{corr}(corrosion potential) versus Time

Sample	Composition	600sec	1200sec	1800sec	2400sec	3000sec	3600sec
1	Ti-0.5% Cu	*-0.240*	*-0.246*	*-0.254*	*-0.260*	*-0.264*	*-0.265*
2	Ti-1.0% Cu	*-0.244*	*-0.249*	*-0.254*	*-0.260*	*-0.265*	*-0.270*
3	Ti-2.0% Cu	*-0.248*	*-0.255*	*-0.260*	*-0.265*	*-0.271*	*-0.279*
4	Ti-5.0% Cu	*-0.258*	*-0.263*	*-0.269*	*-0.274*	*-0.280*	*-0.285*
5	Ti10.0%Cu	*-0.262*	*-0.269*	*-0.272*	*-0.279*	*-0.284*	*-0.291*
6	Ti15.0%Cu	*-0.268*	*-0.274*	*-0.278*	*-0.282*	*-0.290*	*-0.298*
7	Ti 17%Cu	*-0.274*	*-0.280*	*-0.284*	*-0.291*	*-0.297*	*-0.303*
8	Copper	*-0.220*	*-0.226*	*-0.224*	*-0.229*	*-0.235*	*-0.243*

Table 9: E_{corr}(corrosion potential) versus Log I(A/cm^2) (Tafel Diagram)

Sample	*Composition*	E_{corr} (potential)	Log I(A/cm^2)
1	*Ti-0.5% Cu*	***-0.265***	*-0.292*
2	*Ti-1.0% Cu*	***-0.270***	*-0.370*
3	*Ti-2.0% Cu*	***-0.279***	*-0.499*
4	*Ti-5.0% Cu*	***-0.285***	*-0.527*
5	*Ti10.0%Cu*	***-0.291***	*-0.642*
6	*Ti15.0%Cu*	***-0.298***	*-0.701*
7	*Ti 17%Cu*	***-0.303***	*-0..745*
8	*Copper*	***-0.243***	*-0.130*

The corrosion potential of the samples showed that Ti 17%Cu have value of -0.304 and -0.303 While copper indicated a corrosion potential of -0.242 and -0.243 for Hanks and Ringers solutions respectively. The Corrosion rate in both simulated Hanks and Ringers solutions showed that Ti17%Cu sample has corrosion rate of 1.4mg/cm^{2}yr and 1.6mg/cm^{2}yr in the Hanks and Ringers solution respectively. Copper specimen showed 6.9mg/cm^{2}yr and 7.0mg/cm^{2}yr

Table 10: Experimental Results for Minitab Software Design Analysis.

Specimen	Composition	Ecorr
1	Ti-0.5%Cu	*-0.317*
2	Ti-1.0%Cu	*-0.315*
3	Ti-2.0%Cu	*-0.313*
4	Ti-5%Cu	*-0.31*
5	Ti-10%Cu	*-0.308*
6	Ti-15%Cu	*-0.305*
7	Ti-17%Cu	*-0.304*
8	100%Cu	*-0.242*

Ecorr - Corrosion Potential,

Response Surface Regression: Ecorrosion Potential, versus Ti, Cu

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.0043111	97.24%	95.16%	*

Regression Equation:

$$Ecorr = 0.020 - 0.00556\ Ti - 0.00263\ Cu + 0.000027\ Ti^2$$

Corrosion Resistance and Surface Film Regeneration

The corrosion tests provided evaluation of the corrosion rate, R, based on the collected Data on parameters of E_{cop} (immersion voltage). E_{corr}(corrosion potential), I_{corr} (corrosion current density), with the plots of Tafel and Bode Diagrams. All the Data indicate that Ti17%Cu alloy specimen has the lowest corrosion rate in both Hanks and Ringers solution, with copper element having the highest corrosion rate, Kobyashi et al (1988) and Fontana (2006) in similar research concluded that Titanium alloys have very low corrosion rate when tested in both simulated body fluids (SBF) of Hanks solution and Ringer's solution. Sutter and Boni (2005) maintained that corrosion resistance of biomaterials, as in Ti17%Cu alloy, is best investigated using Electron Impedance Spectroscopy (EIS), Gonzalez and Mirza (2004) collaborated the research result on these TiCu alloys and confirmed that the low corrosion rate is due to the regenerative oxide film layer which forms protective film and prevents biological attacks by the plasma contents of Oxygen, chloride ions and other trace elements of the host environment (human system) unlike copper element with high corrosion rate. Schmitz et al (2008) in their report on biomedical alloys simulative response, opined that Ti-Cu alloys can withstand very harsh corrosive environments

Validation of Results

The Minitab software analyses confirmed the statistical Deterministic correlation of the variables (R^2) for the parametric experimental analyses as $0.85 < R^2 < 0.95$. This regressional relationship further confirms the high acceptability of the research results in conformity with the research works of Jin et al (2015) and Erlin et al (2013) on characterization of Titanium based binary alloys.

Conclusion

The corrosion resistance of biomaterials in body fluids is also a determinant for assessing its life time when used as a biomedical implant. Results from the studies shows that TiCu alloy has a very low corrosion rate in the electrochemical analysis using simulated body fluid (SBF) solution. Under normal conditions, the human body fluids have about 0.9% saline solutions of mostly $Na^+ Cl^-$ and other trace ions as well as amino acids and a range of soluble proteins. The corrosion resistance of Ti-Cu alloy was designed to monitor and evaluate the release of metal ions which is an index for cell viability status. The biological corrosion problems which tend to weaken the mechanical strength of the material was addressed by the new specimen Ti-17% Cu alloy which has the property of regenerative oxide film layer, unlike the copper element (T-380).

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