# Metallic Medical Implants: Electrochemical Characterization of Corrosion Processes

### by Patrik Schmutz, Ngoc-Chang Quach-Vu, and Isabel Gerber

he use of metallic alloys for a whole range of medical implants is justified by their superior mechanical properties (hardness, stiffness, etc.) compared, for example, to polymers. Other properties like biocompatibility or visibility in X-ray images also can be mentioned. One of their drawbacks is that electrochemical reactions take place on metallic surfaces in the human body. To replicate the real environment as closely as possible, implants should be tested in vivo in animal experimentation; but the possibility of monitoring electrochemical processes is then very limited and not straightforward. (Editor's Note: See also Hiromoto's article in this issue.) In vitro reactivity characterizations help to understand the degradation processes (failure risks) and the development of new implant materials. Different macro- and microelectrochemical methods allow the investigation of uniform and localized corrosion susceptibility and its relation to material microstructure. A major difference with classical corrosion investigations is the complexity of the physiological media with the presence of proteins (and cells). The influence of solution chemistry on degradation mechanisms, as well as of the specific temperature and atmosphere (amount of  $\hat{O}_2$  and  $CO_2$ ), has to be investigated. Electrochemical methods can also be used for implant surface functionalizing by growing tailored anodic oxide layers or deposition of coatings.

There is a whole range of issues related to corrosion processes that needs to be considered and addressed experimentally. Degradation of the implants can be uniform, but for most of the standard metallic materials used (stainless steel, Co based alloys), related localized corrosion to microstructural features is observed. The metallic surface is often covered by a native anodically grown oxide layer that guarantees a uniform corrosion resistance, but does not prevent localized breakdown when an aggressive environment is present. This is typically the case when chloride ions are present in physiological media. Crevice corrosion related to the complex geometries of implants and galvanic coupling between dissimilar materials used can also occur and can be followed in model experimental devices. These two types of corrosion often occur simultaneously because when two different materials are brought into contact, there is a crevice generated at the contact surface. Electrochemical methods further allow for monitoring of the release of "toxic" ions in the body, which is another major issue long before failure occurs.

Not all the metallic materials and alloys used for implants have a similar risk of corrosive degradation. (open circuit potential) (such as, for example, electrochemical impedance spectroscopy, or EIS) can be used to follow actively corroding systems like degradable implants.

In the next sections, illustrations of different types of corrosion phenomenon taking place are presented and discussed. For obvious confidentiality



**Fig 1.** Main types of metallic materials used for medical implants and their susceptibility to corrosion.

Figure 1 presents some of the main (or interesting) categories of materials used in implants with their respective susceptibility and the type of corrosion expected to occur. It is well known that Ti and Ti alloys are very corrosion resistant and therefore the choice of testing media and conditions is not very critical. On the other extreme, Mg alloys are extremely reactive, therefore candidates for degradable good implants. Here, an exact understanding of the corrosion mechanisms and of the influence of ions or species present in the physiological media is a major challenge. This field is a good example of positive use of corrosion processes.

Concerning the electrochemical methods used for characterization of the corrosion processes, they can be divided in two categories. First the polarization methods used to assess the susceptibility to localized corrosion for corrosion resistant materials. Second, measurements performed at the free corrosion potential reasons, no detailed indication of products or implant types and geometries can be given and this contribution is focused on a conceptual discussion of corrosion processes.

# Corrosion Resistant Implants (Ti and Ti Alloys)

Titanium and titanium alloys show a high corrosion resistance due to their stable passive layer. Therefore, titanium surfaces are mostly mentioned in relation with electrochemical corrosion processes when they react as a cathode in contact with other metallic materials. Some surface processing, such as sandblasting, induces rough and contaminated surfaces and there might be an increased risk that this surface condition results in higher corrosion susceptibility. Electrochemical investigations of the corrosion behavior of Ťi and Ti alloys have almost always demonstrated very good passivation behavior of the surface. In physiological

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media, it can be shown that some modification of the surface oxide composition occurs<sup>1</sup> or that deposition of Ca and P, in the case of exposure to Ringer's solution, delays the stabilization of TiO<sub>2</sub> surface oxide.<sup>2</sup> When the media gets acidic  $(0.5M H_2SO_4)$ , Ti alloys show dissolution and are less stable then pure Ti.3 These conditions are however extremely aggressive compared to what is supposed to occur in the human body and can only be envisaged in the crevice situation. The different buffering capacity of the physiological liquids in the body is still in discussion, and although the presence of low pH in the case of infection is always postulated, no direct evidence is available because of the difficulty of performing these measurements in very small amount of liquids.

However, to conclude that Ti alloys are totally immune to corrosive attack would be a mistake. Figure 2 shows an SEM image of a metallographic section for a Ti6Al4V bone replacement pin. The presence of a crack with secondary crack ramifications is clearly visible. This failure mode is typical of fatigue crack growth with corrosive dissolution. The pin broke after 6 months of implantation and the patient needed it replaced by a new surgical intervention. A combination of cyclic loading and a corrosive environment had to be present for this failure to occur and electrochemical characterization of crack growth is difficult. In the case of Ti and Ti alloys, it can be stated that electrochemical methods are not the best tools to assess corrosion susceptibility unless they are coupled to mechanical or tribological solicitations that are very important but not the focus of this article.

# "Corroding" Implants (Stainless Steel and Co-based Alloys)

This second category is represented by implant materials that are suffering from localized corrosion attacks. This fact is until now often neglected because this corrosion phenomena is unknown to surgeons or observed, but the consequences are accepted. This statement is worth being made because the 316L (X17Cr12Ni2Mo) stainless steel is certainly besides the 304 (X18Cr10Ni), one of the most studied alloys in terms of the pitting and crevice corrosion mechanisms. The influence of inclusions present in the material, as well as different parameters like applied stress or temperature on localized corrosion initiation susceptibility, has been investigated locally with the electrochemical microcell and documented by Suter, et al.4,5 But as soon as biomedical applications and



FIG 2. Corrosion fatigue crack propagation in Ti-Al-V implant after human implantation.

physiological media are considered, only a few detailed electrochemical investigations can be found. For the Co based alloys, there is currently an increased awareness about potential risks related to localized corrosion in relation with infection and/or toxicity of the corrosion products.6,7 Toxicity of elements like Ni, Cr for stainless steel and Co, Cr for the Co alloys is currently being debated. Molybdenum, which is present as an alloying element in both types of materials, is also included in this discussion. Tribocorrosion studies are gaining in importance in relation with this toxicity issue because of the influence of friction or fretting on the local depassivation and release of metallic ions.8 When the corrosion mechanism of Co alloys is discussed, it must be kept in mind that quite a large composition range is considered. There is the well known Co30Cr6Mo implant, but also alloys like the MP35N (Co35Ni20Cr11Mo1Fe) or other versions containing W are used such as L306 that are much stiffer.

Localized corrosion susceptibility.-When the susceptibility to localized corrosion needs to be addressed, the first electrochemical characterizations that are performed are potentiodynamic polarization measurements. A standard three electrode cell with a platinum counter and a calomel (Hg/Hg<sub>2</sub>Cl<sub>2</sub>) (replaced now by Ag/AgCl) reference electrode is usually used. Figure 3 presents these curves for 316L and an MP35N Co-based alloy. The solution used in this case is a Ringer's solution (9 g/l NaCl: 0.42 g/l KCl; 0.48 g/l CaCl<sub>2</sub>;  $0.2 \text{ g/l NaHCO}_3$ ) adjusted to pH 5 and maintained at a controlled temperature of 37°C. It can be observed that both alloys are passive at the OCP with a

slightly more negative potential for the Co alloy. The 316L stainless steel then shows a breakdown at 0.3 V (SCE) corresponding to the onset of localized corrosion in this physiological solution. The MP35N alloys demonstrate a lower susceptibility to localized corrosion and the current increase at higher potential correspond to the transpassive dissolution of chromium. This type of potentiodynamic polarization experiment is necessary for any detailed characterization of the localized corrosion susceptibility, but is not quite representative of the situation found for implanted materials. There, usually crevice conditions with very small amounts of electrolyte are found and the polarization is induced by more noble materials in the surrounding area or chemicals acting as oxidizing agents.

*Crevice and galvanic corrosion.*— Zardiackas, *et al.* published results on galvanic coupling experiments between Co based and Ti alloys<sup>9</sup> as well as with different stainless steels.<sup>10</sup> More interesting are the galvanic coupling phenomena investigated in crevice conditions, often with Ti implants being one of the materials.<sup>11,12</sup> Only a few studies of the corrosion processes investigated after *in vivo* implantation<sup>11</sup> or taking into account fretting between dissimilar materials<sup>13-15</sup> can be found in the literature.

In order to simulate this situation for *in vitro* testing conditions, a setup is used where two metallic surfaces are brought together without direct contact (Fig. 4a). The current is measured with the help of an ampere meter (usually built directly in the potentiostat). There are standard tests (for example the ASTM G71) that describe the



**Fig. 3.** Potentiodynamic polarization measurements: characterization of localized corrosion susceptibility for stainless steel and MP35N Co alloy.



**Fig. 4.** (*a*) Crevice corrosion measurement principle and (*b*) galvanic coupling current between 316L stainless steel and MP35N cobalt based alloy.

experiments to be performed but they are unsatisfactory in the sense that one of the most important parameters, the crevice width, is not mentioned. Figure 4b shows an example of typical results obtained during a galvanic coupling experiment performed between a 316L and a MP35N plate separated by a distance of 1 mm. The current flowing (blue curve) between the two electrodes is measured, and the way the electrodes are connected, the current indicates that the steel electrode acts as the cathode and MP35N the anode. The potential on the 316L electrode is also recorded during the whole experiments (red curve). The very interesting fact is that after approximately 4 hours of immersion, there is an observed potential drop that can be associated with an activation of the steel surface. This coupling phenomenon is only observed with crevice widths of 1 mm or smaller, and support the fact that standard tests with two electrodes placed far away from each other will not allow to generate the crevice solution condition required for corrosion to take place. Additional characterization can be performed simultaneously, such as pH monitoring or ion release characterization in the crevice, when optimized setups are used. Ringer's solution with slightly lower pH to simulate an infection is used for this example, but investigations performed in a whole range of other media are found in the literature. For this type of implant materials and corrosion processes, it is difficult to suggest one solution as the standard, as they do not give fundamentally different results in terms of corrosion processes. The situation is totally different for the next type of implant materials.

# Degradable Implants (Mg Alloys)

Permanent implants may induce long term complications and require surgery to replace them. An alternative for specific applications is a degradable implant made of Mg alloy. Mg is biocompatible, vital for metabolic processes, and the alloys show higher strength than polymers. The positive use of corrosion processes and a fundamental understanding of the mechanisms are here central aspects. A first requirement is temporary corrosion protection obtained by surface oxidation as long as mechanical strength is needed. Afterward, "uniform" corrosion needs to take place to induce implant dissolution. Mg alloys corrode fast in neutral electrolytes and a coating usually aims at the best possible corrosion protection. For degradable implants, a different approach with two challenges

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is necessary: (i) an understanding of the microscale corrosion mechanisms; and (ii) development of a temporary corrosion protection for at least 3 months (this aspect will not be further discussed here as it is not the focus of this article). Another constraint is that Al-free alloys (the toxicity of Al is still debated) like Mg-Y-RE (ex. Nd) need to be developed for medical applications.

For this type of implant, the degradation rates have been first assessed by in vivo tests16-19 but the main problem is that without having a better understanding of the key factors controlling the corrosion processes, life-time prediction is difficult based on the in vivo studies. An important scattering in the degradation rate is always reported. Here, more than for all other types of implants, there is a need for detailed in vitro studies. Currently, there are only very few studies using electrochemical methods to address the role of different ions and buffering strength on the corrosion rates<sup>20</sup> or considering additionally the influence of proteins (albumin).<sup>21</sup> Other studies include evaluation of cytotoxicity in the in vitro tests but without performing electrochemical characterization.<sup>22</sup>

Testing media.—From the in vitro investigation, it can be stated that a very critical aspect for biodegradable implants is the physiological medium to which the surface is exposed. This can be blood (simulated in vitro by Artificial Plasma, or AP) or other body fluids (SBF) depending on the implant location. Table I presents the ionic contents for these typical media used for in vitro testing. It has to be mentioned that SBF is a very open denomination that allows for example variation of the concentrations and the buffering strength. This absence of a clearlydefined standard is partly related to the previously mentioned fact that no large difference can be observed for different SBF when other implant materials are tested. The main difference between the two solutions presented here is the concentration of  $(HCO_3)^-$  ions, 26.2 mM in AP and 4.2 mM in SBF K9. It should also be noted, that SBF K9 is buffered (with tris-(CH<sub>2</sub>OH)<sub>3</sub>CNH<sub>2</sub>), whereas AP is a non buffered solution although carbonate species show some buffering behavior.

For these investigations, EIS is a very powerful method to investigate electrochemical processes on samples that do not show high corrosion resistance. Figure 5a presents EIS characterization of a Mg4Y3RE alloy in AP. The EIS impedance spectra obtained indicate the presence of two processes: localized attack (fast charge transfer measured at high frequency) and slower uniform dissolution (impedance value at low frequency).

Table I. Ion concentrations (mM) of blood plasma, artificial plasma, and SBF K9.			
	Blood Plasma	Artificial Plasma	SBF K9
Na+	142.0	144.5	142.0
K+	5.0	5.4	5.0
Mg <sup>2+</sup>	1.5	0.8	1.5
Ca <sup>2+</sup>	2.5	1.8	2.5
Cl-	103.0	125.3	148.8
(HCO <sub>3</sub> ) <sup>-</sup>	27.0	26.2	4.2
(HPO <sub>4</sub> ) <sup>2-</sup>	1.0	3.0	1.0
SO42-	0.5	0.8	0.5

The different reactions can be followed online as a function of immersion time without perturbing the corrosion processes too much. A qualitative comparison of the uniform dissolution rate for AP and SBF can be obtained by considering the impedance modulus amplitude value Z at low frequency (10 mHz). This real value, also called polarization resistance, is however still influenced by the localized corrosion processes that can occur in parallel, so over interpretation of the data should be avoided. However, it can still be seen that uniform dissolution rate differ by a factor of 20-30 between the aggressive SBF and AP (Fig. 5b) and this is a major concern when prediction of implant life is necessary. A critical parameter is the surface pH and the buffering ability of the different media. Figure 5c shows the pH evolution in very small amount of liquid (2 ml on 1  $cm^2$ ) for initially neutral distilled water (H<sub>2</sub>O), AP, and SBF. The pH increase as a result of Mg corrosion is the most hindered for SBF. Only at pH 9 in AP, the Mg hydroxide is starting to be stable. In SBF, a different surface oxide is needed in order to guarantee initial implant integrity. The previous example draws the attention to the fact that there is clear open question concerning the buffering strength of physiological media especially in crevice or when important reaction rates are present.

Biocompatibility testing procedures.-ISO standard 10993-5 provides detailed guidelines to perform biocompatibility tests. The cells can be exposed to an extract of the materials at various concentrations or the cells can be directly grown on the material itself. Considering the exposure of extracts, care has to be taken in the choice of the eulants such as organic solvents, e.g. dimethyl sulfoxide (DMSO) or ethanol, or the buffer system, *e.g.* phosphate buffer, bicarbonate/CO<sub>2</sub> buffer, or organic buffers like HEPES. These solutions are used in studies performed at room temperature to keep the pH stable as compared to the bicarbonate/CO<sub>2</sub> buffer system. Growth medium buffered with HEPES can generate cytotoxic

compounds when exposed to light or HEPES can produce toxic oxygen metabolites.<sup>26</sup> It is recommended to avoid HEPES and similar organic buffers in studies of oxidative compounds as it interferes with peroxynitrite and nitric oxide. For a simultaneous electrochemical characterization, solvent conductivity is an additional mandatory criterion.

The very basic requirement of a biocompatible material is that the cells stay alive and are metabolically active during long-term cultures. This can be tested with two rapid and simple quantitative assays, namely viability based on physical uptake of neutral red (NR) and metabolic activity based on an MTT (3-(4,5-dimethylthiazol-2-yl-)-2,5-diphenyltetrazoliumbromide) assay, which is dependent on the activity of intracellular enzymes (Fig. 6). Both assays are widely accepted in biocompatibility and cytotoxicity studies for the assessment of viability and growth of cells.27 Another very common parameter is the quantification of the activity of lactate de-hydrogenase in the supernatant of cell cultures. This enzyme is normally localized inside live cells and after cell death the enzyme leaks into the growth medium.

# Future Challenge: Electrochemical Testing in the Presence of Cells

One of the major criticisms of the actual in vitro electrochemical characterization of medical implants is the absence of biological species in the simulated physiological media used. (Editor's Note: See also Hiromoto's article in this issue.) There is on the other side in biology a huge experience in testing biocompatibity of metallic surfaces with cell cultures. The challenge for corrosion research will be to merge these two fields in future investigations, this means performing electrochemical tests in media containing living cells and proteins. There are three different levels of complexity for the biocompatibility testing: cell cultures,

animal models, and clinical trials. This order also reflects the increasing costs from in vitro to in vivo models. Cell lines, primary cell cultures, or organ cultures of human or animal origin are widely used and accepted to investigate biocompatibility of materials. The isolated cells or tissues can be kept in commercially available and numerous chemically-defined growth media. They are usually supplemented with foetal calf serum to allow cell survival, adhesion, and proliferation. In vitro experiments can be grouped into cell cultures with cell lines and primary cells isolated from a tissue (for a review on bone cells see Ref. 23). Cell lines are "immortalized" cells, which are generally isolated from tumors or otherwise experimentally transformed cells. The results of the experiments are quite reproducible

ow freq

don

0

5

10

15

Immersion time [h]

2 3 4 5 6

log f

4.0

3.5

3.0

2.5

2.0

1.5

-3 -2

5x10

4x10

3x10

2x10

1.0x10

5.0x10<sup>2</sup> 0.0

0

log Z [Ω.cm<sup>2</sup>] (

(a)

Impedance [Ω.cm<sup>\*</sup>]

**(b)** 

표 8.0

(C)

10.0 9.5

> 9.0 8.5

7.5

7.0

6.5

0

and can be obtained in a relatively short period of time. There are also disadvantages, which are based on the nature of experimentally immortalized or tumor cells as the regulation of adhesion proliferation or differentiation and gene expression may be changed as compared to normal cells. This can be avoided by using primary cell and organ cultures, which are time consuming and challenging. The intact tissue is used for organ cultures and single cells can be isolated from various tissues of different species and age. Organ cultures have the advantage that the natural and complex organization of a tissue is still intact, but the time for the cultures is limited dependent of the original size and growth as the nutrition by diffusion is limited. Culture conditions can have a great influence on proliferation and differentiation of osteoblasts.24,25

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60

40

20

0

angle

phase

High freq

fast reaction

SBF

20

SBF

5

4

25

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2

Immersion time [h]

3



FIG. 6. Typical procedure for biocompatibility tests.

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## **About the Authors**

PATRIK SCHMUTZ is a research group leader in the Laboratory for Corrosion and Materials Integrity at the Swiss Federal Laboratories for Materials Testing and Research (EMPA) in Dübendorf, Switzerland; and he is a Lecturer in the Department of Materials at the Swiss Federal Institute of Technology (ETHZ), in Zurich, Switzerland. His research interests are in high lateral resolution "electrochemical" methods applied in the characterization of corrosion processes. This includes the different aspects of passive film investigation (also ex situ with surface analytical techniques) and localized corrosion characterization. Investigation of degradation mechanisms of metallic materials used as biomedical implants has now become an important part of its group activities. He may be reached at patrik.schmutz@empa.ch.

**NGOC-CHANG QUACH-VU** is a scientific collaborator in the Laboratory for Corrosion and Materials Integrity at the Swiss Federal Laboratories for Materials Testing and Research (EMPA) in Dübendorf (Switzerland). She received her PhD in electrochemistry and materials sciences from the Electrochemistry Department of the Institute of Reactivity, Electrochemistry, and Microporosity at the University of

Versailles, France. Her current research interests are in materials science and the degradation of metallic biomaterials. She may be reached at ngoc-chang. quach@empa.ch.

**ISABEL GERBER** is a research assistant in the Laboratory of Biological Oriented Materials in the Department of Materials at the Swiss Federal Institute of Technology (ETHZ), Zurich, Switzerland. She received her PhD in Biology from the Institute of Biological Sciences at the University of Wales Aberystwyth in 1998. Her research interests are bone biology and cytocompability of biomaterials. She may be reached at isabel.gerber@mat.ethz.ch.

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