Evaluation and redesign of osteosynthesis plate, prodused in Indonesia

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In orthopaedic trauma surgery, osteosynthesis plates are frequently applied to stabilize bone fractures. The demand for such plates in Indonesia is higher than the world average due to the high incidence of traffic accidents and natural disasters. Osteosynthesis plates are imported from abroad. Their price however, is relatively high and prevents general use. At the same time, Indonesian-made osteosynthesis plates are available all around the country at affordable prices, but these are hardly used, because the quality of those plates is unknown due to the lack of proper scientific evaluation. Surface properties like hydrophobicity and roughness represent the surface finish of the material, and may influence microbial adhesion and associated infection risk. Surface finish, bulk material composition and residual stresses influence the susceptibility of a plate to corrosion. In this study, plates from four Indonesian manufacturers were compared to standard AO plates with respect to hydrophobicity, surface roughness, and corrosion susceptibility. The Narrow Dynamic Compression Plate (DCP) made of AISI 316L stainless steel is one of the most frequently used osteosynthesis plates and hence used in this study. Indonesian plates were equally hydrophobic and slightly smoother than the standard AO-plates. Plates from some Indonesian manufacturers possessed less resistance to pitting and crevice corrosion than standard AO-plates, due to the use of a lower quality steel. The conclusion is that Indonesian manufacturers should use 316L implant grade stainless steel, and quality control measures are recommended.
INTRODUCTION

In orthopedic trauma surgery, the application of osteosynthesis plates and screws has been one of the frequently applied methods of fixation for more than 100 years. Its use was started by Lane in 1895, and its world-wide use was introduced after the work of the Arbeitsgemeinschaft fur Osteosynthesefragen / Association for the Study of Internal Fixation (AO/ASIF) in the late 1960s. The initial plate material used in Lane’s era had a very high incidence of corrosion, when used in a biological environment. Gradual increase in knowledge of metals and alloys led to the introduction of stainless steel followed by titanium for implant materials in the early 1990s. The latest development is the application of a biodegradable material that does not require removal.

Even the most biocompatible biomaterial suffers from two major threats during its service. One is the occurrence of biomaterials centred infection (BCI). BCI is caused by an infectious biofilm adhering on the biomaterial surface. Microorganisms present in a biofilm require 500 to 5000 times higher levels of antibiotics for effective killing as compared to planktonic organisms in the blood stream or in urine. Biofilm formation starts with initially reversible adhesion of microorganisms to a surface which later matures into an irreversible bond. The initial interaction depends, amongst others, on the surface properties of the implant material, such as its hydrophobicity. The second major threat is the degradation or corrosion of metallic biomaterials, which may lead to formation of toxic corrosion products in addition to reducing the lifetime of the implant.

Osteosynthesis plates are made of 316L stainless steel, which possesses high resistance against generalized corrosion. This austenitic stainless steel follows the requirements set by the American Iron and Steel Institute (AISI), in accordance with ISO standards 5832-1 and 5832-9, and ASTM F138 and F139. Corrosion of osteosynthesis plates made of 316L stainless steels is, however, clinically observed, indicating that the susceptibility of such plates to corrosion deserves further attention. Active-passive alloys bearing a protective oxide film like stainless steel, are prone to localized corrosion i.e. corrosion in narrow spaces. Localized corrosion can take place in two ways - pitting and crevice corrosion. Pitting can take place at open, flat surfaces and is frequently induced by defects on the material surface or by randomly occurring defects in the oxide film. Crevice corrosion as the name suggests, needs crevices. When an osteosynthesis plate is applied on bone, thin gaps (crevices) will
form between the plate and screws and between the plate and bone, yielding a perfect place for crevice corrosion to take place.

The susceptibility of materials to these types of corrosion can be tested by electrochemical methods, i.e. by polarizing the surface to simulate highly corrosive conditions, from which the breakdown of the protective oxide layer can be studied. Cyclic potentiodynamic polarization is one of the electrochemical methods in which a material is polarized starting from an equilibrium open circuit potential (OCP/E$_{corr}$, the corrosion potential acquired by the sample when left alone). The potential is increased gradually in the positive direction making the sample anodic, during which the electric current density (indicator of the corrosion rate) is recorded continuously. The breakdown potential (E$_{br}$) is dictated by a sudden increase in current representing the breakdown of the protective oxide layer on plate surface and metals start dissolving. The current density under passivated conditions (J$_{pass}$) determine the quality of the passivation applied. The lower the J$_{pass}$ the better passivation is achieved. Upon reaching a certain potential, the direction of potential change is reversed till it again reaches the open circuit potential. An example of a typical polarization curve is shown in Figure 1.

Figure 1. An example of typical cyclic potentiodynamic polarization curve as one of the electrochemical testing method for corrosion of metals.
The incidence of trauma in Indonesia is high, especially due to the high incidence of traffic accidents and natural disasters. This makes the demand for osteosynthesis plates high, because most of the high energy extremity injuries and ensuing fractures need surgical treatment and stabilization with the use of plates and screws. Although Indonesian manufacturers provide cheap and affordable osteosynthesis plates, commonly used plates are imported from abroad and are thus relatively expensive. Indonesian plates are less popular, because systematic scientific evaluations of their properties are lacking. The Narrow Dynamic Compression Plate (DCP) is one of the most frequently used osteosynthesis plate (about 30% of all osteosynthesis plates) and hence used in this study.

In this chapter we determine the physicochemical properties and susceptibility to localized corrosion of Indonesian Narrow Dynamic Compression plates in comparison to the European standard AO-plate.

MATERIALS AND METHODS

Osteosynthesis plates
Narrow Dynamic Compression plates from five different manufacturers - standard AO plates from Synthes (Mathys Medical, Switzerland) (designated as S) and 4 different Indonesian manufacturers, designated A, B, C, and D were used in the study. The plates were meant for 4.5 mm screws and contained 6 holes each (see Figures 2a and 2b). All plates were said to be manufactured from stainless steel, and Indonesian manufacturers used locally available machinery for their preparation.

Plate preparation
Plates were treated according to daily clinical practice in Indonesia. After arrival from the manufacturer, plates were cleaned with tap water, put in a double sterilization pack and finally sterilized in an autoclave at 120°C for 30 min prior to evaluation.
Bulk chemical composition of the plates
Every plate from each manufacturer was cut by a rotating saw in one longitudinal and several transverse directions. The chemical composition of the transversely cut pieces was determined using a Spectrometer (WAS spectrometer, worldwide analytical system type PMI master pro 13L0086).

Water contact angles
Water contact angles quantify the hydrophobicity of the plate surface, which may indicate its cleanliness. Contact angles were measured at room temperature. An entire plate was placed on the tray of the contact angle instrument and viewed with a camera system. The position of the camera was adjusted until the position of the plate in the monitor was level. Three sessile Milli-Q water droplets of 3 µL were put on the convex surface of each plate in the middle of the plate and in between two inner screw holes. The contact angle was subsequently measured using a tangent construction from a thresholded black-white image of a droplet and recorded. Ten plates from each manufacturer were used for the measurements.

Surface roughness by profilometry
Roughness is a measure of the texture of a surface. The average roughness Ra is the average vertical deviation of a surface from an imaginary baseline. The surface roughness of the plates was determined by means of a Profilometer (Scantron, Scantron Industrial Product Ltd, England). Surface roughness was determined at 6 spots, around one innermost hole, on convex and concave surfaces, within an area of 0.5 x 0.5 mm. Ten plates from each manufacturer were used for the measurements. Measurements were done with 50 steps for each area.

Corrosion
Cyclic potentiodynamic polarization tests were performed using parameters according to ASTM standard no. F2129.
The corrosion study consisted of two parts. In the first part, the quality of the bare surface was evaluated in terms of its susceptibility to pitting. In the second part, the osteosynthesis plates were fixed to a PMMA block using screws that were tightened with a 2.5 Nm torque to simulate clinical application on bone12, creating crevices as formed between the screw-
osteosynthesis plate, osteosynthesis plate-PMMA, and screw-PMMA. To further simulate
the clinical environment, samples were immersed for seven days in phosphate buffered
saline (PBS) (NaCl 8.76 g/l, K₂HPO₄ 1.4 g/l, and KH₂PO₄ 0.27 g/l at pH 7.4) at 37 ± 1°C
maintaining an oxygen concentration below 10 mm Hg by bubbling Argon in the solution¹².
The corrosion potential (open circuit potential) of the plates (plates act as working electrodes)
was determined daily against a saturated calomel reference electrode (SCE, Radiometer) with
platinum as counter electrode. Susceptibility to pitting and crevice corrosion was assayed
by making potentiodynamic polarization curves. The specimens were polarized between
the corrosion potential and 1.2 V or a current density of 10⁻³ A.cm⁻² at a sweeping rate of
0.001 V.s⁻¹. The bone plate-buffer interface was evaluated using Electrochemical impedance
spectroscopy (EIS) and modelled the response with either the Randles circuit or porous
layer circuit (Fig. 3). All electrochemical measurements were performed on a Solartron
1280B electrochemical unit and EIS fitting was performed using a Z plot software (Z plot
for windows, Electrochemical Impedance Software Operating Manual, Part I, Scribner
Associates, Inc. Southern Pines, NC, 1998) by keeping the error less than 13% for all the
parameters.

For pitting and crevice corrosion, six plates from manufacturers A, B, C, and D, representing
the Indonesian plates, were evaluated against six standard AO plates (Figure 3a).

![Diagram](a)

![Diagram](b)

Figure 3. a) Randles circuit, b) porous layer circuit. (Rsol = electrolyte resistance; CPEdl =
constant phase element of double layer; Rt = charge transfer resistance; CPEox = constant
phase element of the oxides; Rpo = resistance of the porous or defects to the passage of the
electrolyte; Rdl = resistance of double layer)
Figure 3a. Corrosion test set up for narrow DCP. The plate acts as the working electrode.

Statistics
The means and standard deviations of all parameters were calculated and mean values of plates from different manufacturers were compared using a Student t-test. Statistical significance was accepted at p < 0.05.

RESULTS
Chemical composition
The chemical composition of implant quality 316 L stainless steel is based on the ISO 5832-1 and ASTM F138 and F139. Table 1 presents the chemical composition of the materials used for fabrication of the plates from each manufacturer. Indonesian plates B, C and D contained considerably less nickel and molybdenum than standard plate, while only Indonesian plate A falls within the ISO 5832-1 and ASTM F138 and F139 requirements.
### Contact Angle Measurements

The average water contact angle of the standard plate was $87 \pm 4$ degrees. For Indonesian plates it ranged from $89 \pm 3$ degrees (plates from manufacturer A) to $92 \pm 2$ degrees (plates from manufacturer D). These differences are not statistically significant ($p > 0.05$) (Figure 4).

![Figure 4](image)

**Figure 4.** Average water contact angles of narrow DCP from manufacturers A, B, C, D and standard plates (S) with error bars denoting standard deviations from 10 samples per bar.
**Surface properties**

**Profilometry**
The results of the profilometry showed that plates from manufacturers A and B were smoother than the standard plate (p = 0.039 and 0.012), and plates from manufacturers C and D were equally smooth as the standard plates (p = 0.216 and 0.453) (Figure 5).

![Roughness of plates from different manufacturers](image)

Figure 5. Average roughnesses of narrow DCP from manufacturers A, B, C, D and standard plates (S) with error bars denoting standard deviations from 10 samples per bar.

**Corrosion**

*Potentiodynamic polarization*

*Pitting Corrosion assays*
The average corrosion potential ($E_{\text{corr}}$) from manufacturer C was more positive than the standard plate, whereas plates from other manufacturers showed comparable corrosion potentials as the standard plate. Plates from manufacturer C showed higher current density under passivated conditions ($J_{\text{pass}}$), whereas plates from other manufacturers showed comparable $J_{\text{pass}}$ to the standard plate (S). The pitting or breakdown potential ($E_{\text{br}}$) of plates from manufacturers A, B and D were significantly lower than of the standard plate (S) (p < 0.05) (Table 2), indicating earlier breakdown of the protective oxide layer. The cyclic polarization curve for pitting corrosion is shown in Figure 6a.
Figure 6a. Potentiodynamic assays for pitting set up comparing standard plate and Indonesian plates.

Table 2. Result of pitting corrosion in potentiodynamic electrochemical experiments.

<table>
<thead>
<tr>
<th>Manuf.</th>
<th>Ecorr/ V vs SCE</th>
<th>Jpass/ A.cm-2</th>
<th>Ebr/ V vs SCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>-0.08 ±0.09</td>
<td>3.32 ± 0.12 x 10^{-7}</td>
<td>0.50±0. 08</td>
</tr>
<tr>
<td>A</td>
<td>-0.02 ±0.07</td>
<td>2.68 ± 1.21 x 10^{-7}</td>
<td>0.47±0.12</td>
</tr>
<tr>
<td>B</td>
<td>-0.08 ±0.03</td>
<td>3.31 ± 0.97 x 10^{-7}</td>
<td>0.37±0.12</td>
</tr>
<tr>
<td>C</td>
<td>0.03 ±0.01</td>
<td>6.19 ± 0.98 x 10^{-7}</td>
<td>0.53±0.09</td>
</tr>
<tr>
<td>D</td>
<td>-0.08 ±0.04</td>
<td>3.33 ± 0.67 x 10^{-7}</td>
<td>0.36±0.15</td>
</tr>
</tbody>
</table>
**Crevice Corrosion**

Comparison of the values for $J_{\text{pass}}$ and $E_{\text{br}}$ for individual manufacturers between Tables 2 and 3 shows that under crevice conditions, the osteosynthesis plates are more prone to corrosion, as the $J_{\text{pass}}$ are systematically higher and $E_{\text{br}}$ lower than under pitting corrosion conditions. Inter-manufacturer comparison shows that the average corrosion potential ($E_{\text{corr}}$) for manufacturer C and D was more positive than for the standard plate, whereas plates from other manufacturers showed comparable corrosion potential as the standard plate (S). Plates from manufacturers C and D showed significantly higher current densities under passivated conditions ($J_{\text{pass}}$) ($p < 0.05$), whereas plates from other manufacturers showed comparable $J_{\text{pass}}$ to the standard plate (S) ($p > 0.05$). The pitting or breakdown potentials ($E_{\text{br}}$) of all Indonesian plates were significantly lower than of standard plates (Table 3) ($p < 0.05$), indicating earlier breakdown of the protective oxide layer. Cyclic polarization curves for crevice corrosion are shown in Figure 6b.

![Cyclic polarization curves for crevice corrosion](image)

Figure 6b. Potentiodynamic assays under crevice conditions comparing standard and Indonesian plates.
Table 3. Result of crevice corrosion in potentiodynamic electrochemical experiments.

<table>
<thead>
<tr>
<th>Manuf.</th>
<th>Crevice set up</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ecorr/ V vs SCE</td>
<td>Jpass/A.cm-2</td>
</tr>
<tr>
<td>S</td>
<td>-0.07 ± 0.01</td>
<td>4.26 ± 0.35 x 10-7</td>
</tr>
<tr>
<td>A</td>
<td>-0.01 ± 0.01</td>
<td>2.63 ± 0.65 x 10-7</td>
</tr>
<tr>
<td>B</td>
<td>-0.09 ± 0.03</td>
<td>4.57 ± 0.25 x 10-7</td>
</tr>
<tr>
<td>C</td>
<td>-0.12 ± 0.08</td>
<td>10.1 ± 0.75 x 10-7</td>
</tr>
<tr>
<td>D</td>
<td>-0.12 ± 0.03</td>
<td>7.37 ± 0.42 x 10-7</td>
</tr>
</tbody>
</table>

Electrochemical Impedance Spectroscopy: (EIS)

Table 4 shows that the resistance offered by the porous oxide film (Rpo) was highest for the standard plates (332) and lowest for the plates from manufacturer C (152) as compared to all the other Indonesian plates. This indicated a stable layer of the standard plates, but a broken film on the plates from manufacturer C making them susceptible to dissolution as seen with high values of $J_{\text{pass}}$ during potentiodynamic polarization.

Table 4. Resistance offered by the porous oxide film of plates from manufacturers A, B, C, D, and of standard plates (S)

<table>
<thead>
<tr>
<th>Manufacturers</th>
<th>Rpo/Ωcm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>332</td>
</tr>
<tr>
<td>A</td>
<td>217</td>
</tr>
<tr>
<td>B</td>
<td>293</td>
</tr>
<tr>
<td>C</td>
<td>152</td>
</tr>
<tr>
<td>D</td>
<td>308</td>
</tr>
</tbody>
</table>

DISCUSSION

Chemical composition

Implant quality 316 L stainless steel has significantly higher nickel content than the commercial quality, which is intended to maintain an austenitic non-magnetic structure\textsuperscript{13}. Lower nickel content in the Indonesian plates could indicate that the manufacturers of such
plates use commercial 316 L instead of implant grade. The implant grade material is 316 LVM (vacuum melted) which has a chemical composition, according to ISO 5832-1 and ASTM F138 and F139. The very low molybdenum content in the plates from manufacturers B and C suggests that the material used was stainless steel 304.

**Water contact angle**
All Indonesian plates were found to be equally hydrophobic as the standard AO plates. This could represent the equal cleanliness between Indonesian plate and AO standard plate. Chemically cleaned 316L stainless steel usually has a lower water contact angle between 60 and 70 degrees\(^{14}\). Bacterial adhesion depends in part on the physicochemical properties of the bacteria and those of the biomaterial surface. Bacterial adhesion and retention is low, for example, on hydrophobic surfaces\(^{3,4,15}\). Since the difference in water contact angles between Indonesian plates and the standard plate was small, we do not anticipate a difference in the risk of biofilm formation for the Indonesian plates.

**Surface roughness**
The surface of all Indonesian plates was found to be equally smooth as the standard AO plate. This represents a good surface finish. Since the smoother the surface, the smaller the tendency of bacteria to adhere, grow and form a biofilm therefore Indonesian plates do not carry higher risk of biofilm formation\(^{16,17}\). Furthermore, the average roughness (Ra) of all plates was around 0.8 µm which is considered as an “hygienic” surface, because the roughness is less than the diameter of bacteria\(^{18,19}\).

**Corrosion**
Breakdown potential and corrosion potential in the crevice test were slightly lower than in the pitting test. This is in accordance with the expected behavior in the presence of crevices between screw head and plate hole which act as occluded regions where chemical changes can more easily lead to breakdown of the oxide film\(^{9,20}\). Plates from manufacturers B, C and D showed higher current density under passivated condition and lower breakdown potential than the standard plate. These indicate higher susceptibility to corrosion of those Indonesian plates as compared to standard plate.
Susceptibility to localized corrosion was not found to correlate with surface hydrophobicity or roughness but was clearly related to the difference in chemical composition of the material used\textsuperscript{9,20,21,22}. The stainless steel used by manufacturers B, C, and D contained lower amounts of nickel than plates used by manufacturer A. In addition, plates from manufacturers B and C contained almost no molybdenum. Resistance against corrosion of stainless steel is warranted, if the pitting resistance equivalence (PRE: \%Cr + 3.3 \times \%Mo) is more than 26\textsuperscript{o}. Accordingly, since \%Cr and \%Mo in stainless steel from manufacturer B, C, and D was found to be not in accordance to the ISO Standard, it can be doubted whether the proper stainless steel was used.

**CONCLUSIONS**

Indonesian plates are similarly hydrophobic and slightly smoother than the standard AO-plates.

However, Indonesian plate from some manufacturers possessed less resistance to pitting and crevice corrosion than standard AO-plates, most probably due to the use of lower quality steel. Indonesian manufacturers should use 316L implant grade stainless steel, and quality control measures are recommended.
REFERENCES