Evaluation and redesign of osteosynthesis plate, prodused in Indonesia
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Indonesia is known to be one of the disaster-prone countries. Earthquakes cause many victims with musculoskeletal injuries. Traffic accidents are increasing in Indonesia as a consequence of the increase in number and speed of vehicles without an increase in the infrastructures and traffic management system. Also the victims of these accidents suffer mostly from musculoskeletal injuries. Most people with musculoskeletal injury need orthopaedic surgery with the use of osteosynthesis plates to fix their fractured bones. Therefore, the need for osteosynthesis plates in Indonesia is high. The high demand for osteosynthesis plates can not be fulfilled by import only, because of their high price as compared with the income per capita of average Indonesian people. Another problem is import-limitation and distribution to provide such a large number of plates, especially during a disaster.

The solution for these problems is clear: manufacturing osteosynthesis plates locally. Locally produced osteosynthesis plates do exist from several Indonesian “back yard” manufacturers in Bandung, Surabaya, and Jakarta, but are distributed sporadically to orthopaedic surgeons. In addition, these locally produced plates have hardly been used because their quality is not known and has not been scientifically evaluated.

Our small clinical study revealed that failures during the use of these local plates (Chapter 1) are most likely caused by the quality of the plates and not by other clinical causes, such as the rehabilitation process. Thus the general doubt within the orthopaedic community in Indonesia on the quality of locally produced plates seems justified. Therefore a study was initiated to discover the causes for the lower quality of locally produced osteosynthesis plates and give possible clues for improvement.

Good quality of osteosynthesis plates should be judged from various clinically challenges, including biological, biomechanical, and metallurgical responses to use.
Biological responses are related to the reactions that naturally occur at a biomaterial surface implanted inside the human body. After implantation of an osteosynthesis plate on bone, the plate will become covered by a layer of proteins which is a normal process for a solid surface in contact with a biological fluid. Besides protein adsorption, osteoblasts and bacteria will attach, which occurs more readily on rough and hydrophilic surfaces than on smooth and hydrophobic ones\(^5,6,7,8\). The combination of surface roughness and hydrophilicity will create a surface that is favoured by living tissue cells and at the same time also by bacteria, which in turn will result in a “race for the surface”\(^9\), determining the final fate of an implant, i.e. whether it will be accepted by the body through the integration of living tissue or rejected because of bacterial colonization. Hydrophilicity or hydrophobicity can be determined by contact angle measurements on a surface. A surface with a water contact angle above 60 degrees is generally considered hydrophobic. The average diameter of bacteria is around 1 μm, and therefore any surface with average roughness less than 1 μm is considered smooth from a clinical point of view with a small tendency to attract infectious bacteria. Our first evaluation (Chapter 2) consisted of analysis of the surface properties of Indonesian-made plates which revealed that Indonesian plates were equally smooth and hydrophobic as the standard plate. This means that the surface finishes of the Indonesian plates do not increase the risk of biofilm formation and bacterial adhesion as compared to the standard plate.

Biomechanical phenomena are related to the strength of an osteosynthesis plate during its service as structural support for the fractured bone during bone healing. The plate should be strong enough as a load sharing device during the rehabilitation process until the bone has healed. During the rehabilitation process, the construct (in this case the plate, screw, and fractured bone) will be subject to several kinds of loading, i.e. bending, axial loading and torsion according to the function of the extremity. Among those kinds of loading, bending is the most important considering the placement of the plate on the tension side (convex side) of the bone surface and the bow-shape of the bone. Cyclic loading applied to the plate-bone-construct is a result of muscle contraction and weight bearing during gait in the lower extremities. This may lead to fatigue failure in the aggressive environment of the human body\(^10,11\). The strength of plates can be determined by single cycle and fatigue or cyclic bending loading according to ISO 9585: 1990 and ASTM F382-99 standards. Indonesian plates were clearly found to be less strong than the standard (Chapter 3). This is most
probably related to the inconsistency in geometry of the plates with respect the geometry of the plate hole. The inconsistency in plate geometry is the result of the lack of a reproducible manufacturing process, and again, lack of quality control. A third reason for the inferior strength of Indonesian plates is the lack of cold deformation in the manufacturing process. Indonesian plates are manufactured out of tube material with a radius that matches the radius of the bone plate. Standard plates are made from plate material and forced into a mould to obtain the proper radius. This deformation process increases the strength of the plates considerably.

Metallurgical phenomena are related to the chemical composition of the material which determines the corrosion resistance of the plate inside the human body. Corrosion resistance of stainless steel is determined by its nickel, chromium and molybdenum contents through its pitting resistance equivalent (PRE), i.e. %Cr + 3.3 x %Mo^{12}. Chemical composition of plate material can be qualitatively determined by SEM/EDX or quantitatively by spectrometry. Indonesian plates are claimed to be manufactured from stainless steel 316 L. Although stainless steel 316 L is to some extent known to be corrosion resistant, the effect of different manufacturing processes on corrosion susceptibility had to be ruled out (Chapter 2). Indonesian plates from manufacturers B, C and D showed higher susceptibility to corrosion as compared to the standard plate, which is clearly related to the chemical composition i.e. Cr, Ni and Mo content, of the material used. The composition of the material used varied between batches, and some of the manufacturers used stainless steel 304 in some batches without realizing it. This indicates that Indonesian manufacturers have serious problems in obtaining the proper material which may be due to the lack of quality control or due to discrepancies between the information obtain from the supplier of the raw material and the actual material delivered to the manufacturer. Widely known implant-grade stainless steel 316 LVM is in accordance to the ISO and ASTM Standard, but very hard if not impossible to get in Indonesia and moreover, also very expensive. Other implant materials, such as titanium, are also hardly available and if so, the manufacturers will face more difficulty due to the much higher price and more difficult processing of the material. Therefore 316 L is so far the “only” available raw material with the closest chemical composition to the implant grade 316 LVM. Orthopaedic surgeons should be aware that this is most likely the material used for locally produced osteosynthesis plates. The lower corrosion resistance of Indonesian plates will not forbid Indonesian surgeons to use them provided that they are aware of it and
consider a more careful rehabilitation program for the patient during the healing process of the bone. Most importantly, surgeons should consider implant removal as soon as bone healing is achieved.

The final goal of this research was to find ways to improve the strength of Indonesian plates, feasible to be implemented in Indonesia. There are several ways to improve the performance of the Indonesian plates:

a. Increasing the size of the plates. This, although it can be easily done by the manufacturer, will not be accepted by most surgeons since it will interfere the clinical use of the implant, such as in the use of narrow DCP on tibial bone which are directly under the skin. The thicker the plate, the more difficult to close the wound and the more risk of wound break down.

b. Using plates that are cold worked. This can be done by manufacturing the plate from sheet and then deform them by pressing into a mould.

c. Applying Surface Mechanical Attrition Treatment (SMAT). This can be done by developing a simple SMAT machine and implementing the treatment to the plate.

d. Applying shot peening treatment. This treatment needs more sophisticated equipment which can hardly be developed by local manufacturers in Indonesia.

The best option is the application of cold work and/or SMAT, because those are likely to be implemented by Indonesian manufacturers with available resources. To improve the strength of the Indonesian plate, a simple SMAT machine in the form of reflecting chamber was developed and applied to Indonesian plates from 2 manufacturers (Chapter 4). The result showed that the failure load and fatigue performance of SMAT treated Indonesian plates had significantly increased and became comparably strong as the standard plate with respect to bending stresses. Weibull analysis also confirmed these improvements.

To summarize, the following recommendations to Indonesian manufacturers results from this thesis:

a. Use proper raw material, at least stainless steel 316L, but preferably 316 LVM, according to ASTM F138.

b. Introduce a reproducible manufacturing process to acquire a consistent geometry of the plate, especially with regard to the location of the holes in the plate.

c. Use flat batch material that is forced into the proper shape to increase the strength by cold work.
Recommendations to orthopaedic surgeons especially Indonesian orthopaedic surgeons following from this thesis:

a. Orthopaedic surgeons should use locally produced plates that fulfil the manufacturing requirements, as mentioned above.

b. When using locally produced plates, orthopaedic surgeons should follow a careful and controlled rehabilitation program under close clinical and radiological evaluation. Only when sufficient callus formation is observed radiologically, progressive weight bearing may be commenced.

c. Orthopaedic surgeons should always consider clinical measures to facilitate rapid bone healing, i.e.:
   - By preserving periosteum (as the main source of vascularity to the bone) as much as possible during surgery.
   - By applying the liberal use of bone graft in conditions with any bone defect / bone loss.

d. Orthopedic surgeons should always consider removal of locally produced plates, as soon as bone healing is achieved.

In conclusion, this study shows that it is possible to manufacture an osteosynthesis plate in Indonesia with simple means, possessing a quality that is comparable to the standard plate. The proof of the pudding, however, will be a larger clinical study with these improved plates.
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