Evaluation and redesign of osteosynthesis plate, prodused in Indonesia
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Redesign of Indonesian-made narrow dynamic compression plates to enhance their mechanical behavior
INTRODUCTION

Osteosynthesis plates used for fracture fixation need to have a high strength, mainly with respect to fatigue, ductility and toughness in order to withstand severe cyclic loading conditions produced by muscle contractions and total body weight until the bone has healed completely\(^1\text{,}2\text{,}3\text{,}4\). Stainless steel 316 L is the most widely used material for osteosynthesis plates due to its proven biocompatibility, combined with good strength, ductility, cost effectiveness and ease of fabrication\(^5\). The Narrow Dynamic Compression Plate (DCP) is one of the most widely used osteosynthesis plate for fracture treatment in Indonesia. In clinical practice, plate failure does happen, either due to malpractice in the rehabilitation process or due to the weakness of a plate\(^6\text{,}7\text{,}8\). In our limited retrieval study on explanted Indonesian-made plates (see Chapter 1), 14% were found to have failed during service. Fatigue testing of Indonesian-made plates showed that they were weaker than the standard plate (see Chapter 3). This could be caused by:

- The material used; AO-plates are made from stainless steel 316 L implant grade, whereas Indonesian plates are made from a stainless steel of different and possibly varying composition.
- The type of manufacturing process. The manufacturing process of a particular narrow DCP in Indonesia uses simple machinery. Raw material in the form of a pipe instead of sheet was cut through to get the curvature form of the plate. The production methods of the Swiss AO plate are kept secret, but most probably they use a flat plate that is forced into a curved shape by cold deformation. Grain orientation and micro hardness support this theory. Controlled cold deformation will increase the strength of the plate.
- A poor reproducibility of the manufacturing process. Indonesian plates show a great diversity in dimensions. We corrected our fatigue evaluations for the overall dimensions, but could not correct the results for the positioning of the holes. The large eccentricity of the holes, as found in Indonesian plates, will decrease the strength of a plate.

Considering the above, it is necessary to improve the strength and variance of Indonesian-made plates. Metals can be strengthened either by mechanical deformation (cold work) or heat treatment. Heavy deformation is one of the conventional ways of cold work which can strengthen the metal through refinement of its microstructure\(^9\). Heat treatment such as annealing can create a more ductile characteristic of a metal\(^5\). The most recent improvement
Redesign

is the emergence of nanocrystalline materials. According to the relation between mechanical properties and observed grain size (the Hall-Petch relationship), a nanostructured material will have greatly enhanced mechanical properties compared to larger grained counterparts. Ultrafine-grained bulk material can be produced by several non-conventional, plastic deformation techniques such as torsion straining under high pressure and equal channel angular pressing, but there is a controversy of this ultrafine-grained bulk for being inferior in its fatigue strength compared to a coarse-grained bulk, and the production of bulk nanocrystalline materials is inefficient\textsuperscript{10,11,12}. Due to the presence of large numbers of imperfections on the surface and occurrence of high stresses under loading conditions, failure often starts at the surface. Surface modification by creating a nanostructured surface layer could therefore be expected to improve the mechanical properties of a material, especially the fatigue mode. Refinement of the grain size on the surface only, without changing the structure of the coarse-grained matrix, can be done either by using shot peening or a recently developed surface mechanical attrition treatment (SMAT). These treatments basically transform the microstructure of the surface into nano-sized crystallites by introducing a large amount of defects and/or interfaces into the surface layer\textsuperscript{13,14,15}. In the shot peening method, a stream of spherical particles with sizes between 0.25-1 mm is blasted against the work piece with impact velocities between 20-150 m/s, whereas in the SMAT method, balls are used with the diameter between 3-10 mm with impact velocities between 5-15 m/s\textsuperscript{16}.

The aim of this study was to test the efficacy of improving the mechanical performance of Indonesian-made narrow DCP by redesigning the manufacturing process and by surface mechanical treatment of the material applied.

MATERIALS AND METHODS

Materials
The following groups of plates were used in the experiments:
1. 20 Narrow DCP 6 holes plates from Indonesian manufacturer A
2. 20 Narrow DCP 6 holes plates from Indonesian manufacturer A, SMAT-treated
3. 20 Narrow DCP 6 holes plates from Indonesian manufacturer B
4. 20 Narrow DCP 6 holes plates from Indonesian manufacturer B, SMAT-treated
5. 20 Narrow DCP 6 holes plates from Indonesian manufacturer B, shot peened
6. 20 Narrow DCP 6 holes plates from Mathys / Synthes as the standard plate (S). A transversal cut of the minimum cross section was made and used to determine the cross sectional area and the area moment of inertia of plate from each manufacturer.

**Shot peening**
Ten plates from manufacturer B were sent to Metal Improvement Company in Belgium to undergo shot peening.

**Surface mechanical treatment with SMAT Method**
A reflecting chamber for SMAT treatment was developed in The Department of Mechanical and Industrial Engineering, Faculty of Engineering, University of Gadjah Mada, Jogjakarta, Indonesia as shown in Figure 1.

![Figure 1. Schematic representation of the reflecting chamber for SMAT.](image)

Ten plates from manufacturer B and twenty plates from manufacturer A were placed in the reflecting chamber together with 3.5 mm diameter spherical steel balls. The chamber was then vibrated with a rotating motor through a cam system with a frequency of 1480 Hz and amplitude of 2 cm for 15 min to each side of the plate. After this mechanical treatment, all plates were mechanically tested with single cycle bending test and a fatigue test in bending mode.
Mechanical test

Single cycle bending test
Single cycle bending was performed to determine the yield strength. The tests were performed using a 4-point bending test setup (Figure 2) designed according to the ISO 9585: 1990 and ASTM F382-99 standards. The setup was installed in a Dyna-mess tensile test machine (Dyna-mess Prufsysteme GmbH Aachen/Stolberg Germany, maximum load 5 kN, maximum frequency 10 Hz) with accompanying software. These tests were performed with 10 plates per group.

The tensile test machine provided an upward movement as suggested by the ISO 9585: 1990 and ASTM F382-99 standards. Fixation of the bone plate to a roller at one side of the setup prevented horizontal movement of the plate, while roller bearings reduced friction. The bone plate was immersed in phosphate buffered saline (PBS) (NaCl 8.76 g/l, K₂HPO₄ 1.4 g/l, and KH₂PO₄ 0.27 g/l at pH to7.4) kept at 37°C during measurements. The setup was manufactured from 316L stainless steel. To prevent corrosion fatigue of the setup, it was cathodically protected using a Zn anode. To avoid any ion exchange, the Zn anode was kept in a separate reservoir (Figure 3). Electrical circuit was completed via a salt bridge (PBS + 1.5% agar). The load was applied until the plate failed. The proportional limit of the plate as the reference value was taken as the point where the curve started to deviate from a straight line. The results from each manufacturer were averaged. To compensate for the differences in geometry, the bending stress was calculated using the moment of inertia. This bending stress is an estimate, since the stress concentration is not included in the calculation due to the complex shape.
Fatigue test in bending
The fatigue tests in bending mode were performed on the same Dyna-mess testing machine and set-up at a frequency of 5 Hz as the experiments of chapter 3. Ten plates from each group were used. The positive and sinusoidal load cycle were chosen such that the minimal load was 10% of the maximal load. This minimum load was chosen to keep the bone plate loaded continuously and to mimic the muscular forces which are active even in the swing phase of walking. The highest maximum load was taken as 95% of the proportional limit. Subsequently, the following samples were tested at a continuously decreasing maximum load with steps of 5% of the proportional limit. The load where the bone plate could withstand
3 million cycles was determined as the fatigue limit. This is defined as the fatigue strength. Plates from different manufacturers were compared based on the fatigue limit. After the fatigue test, the plates were photographed using a digital camera to document the location of the fracture.

Figure 3. Cathodic protection of the set up using a Zn cathode.

Statistics
Results were analyzed using Statistic Software SPSS version 17.0. As the first step, the numerical data of the single cycle bending test were analyzed using One-Sample Kolmogorov-Smirnov Test to determine whether the distribution was normal or not. If the distribution was normal, an independent sample t-test was used to compare between the means of two groups. Data of the single cycle bending test were also analyzed using Weibull Analysis\textsuperscript{17,18,19}. Data of the fatigue test in bending were analyzed using Linear Regression Analysis. Significance was set at $p < 0.05$ with confidence interval 95%.

RESULTS AND DISCUSSION

Single cycle bending test

The mean failure-load of shot peened and SMAT-treated plates from manufacturer B (B SP and B SMAT) and SMAT-treated plate from manufacturer A (A SMAT) were found to be significantly higher than that of the original plates (B and A). ($p<0.05$). The mean failure-
load of SMAT-treated plate from manufacturer A (A SMAT) had significantly exceeded the mean failure-load of standard plate (S) (p<0.05) (Figure 4). The mean of calculated bending stress of shot peened and SMAT-treated plates from manufacturer B (B SP and B SMAT) and SMAT-treated plate from manufacturer A (A SMAT) were found to be significantly higher than of the original plates (B and A). (p<0.05). Although the mean calculated bending stress of SMAT-treated plates from manufacturer A (A SMAT) is lower than that of the standard plates, this difference is not statistically significant (p>0.05) (Figure 5). The ratio of improvement between original and SMAT treated plates were 60 % for plates from manufacturer B and 11 % for plates from manufacturer A. The Weibull analysis also confirmed these improvements of SMAT treated plates (Figure 6 and 7). After incorporating the area moment of inertia as the representation of the variation in geometry, the result showed that SMAT-treated Indonesian-made plates were actually stronger than the original plate without SMAT treatment and became comparably strong as the standard plate. These results are in accordance to the recent work by Roland et al.15

Figure 4. Proportional load limit as measured from single cycle test of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S) with error bars denoting standard deviation from 10 samples per bar.
Figure 5. Calculated bending stress of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S) with error bars denoting standard deviation from 10 samples per bar.

Figure 6. Weibull Analysis of proportional load limit of the plates from manufacturers A, A SMAT-treated, B, B SMAT-treated, B shot peened, and of standard plates (S).
Figure 7. Weibull Analysis of calculated bending stress of the plates from manufacturers A, A SMAT-treated, B, B SMAT-treated, B shot peened, and of standard plates (S).

**Fatigue Test in Bending**

The fatigue limit of shot peened plates and SMAT treated plates were improved with respect to untreated plates. The ratio of improvement of SMAT treated plates exceeded that of shot peened plates for plates from manufacturer B (27% and 18%, respectively). The ratio of improvement of SMAT treated plates from manufacturer A was 73% (see Figures 8 and 9). SMAT-treated Indonesian plates and standard plates showed no significant differences ($p>0.05$) in fatigue performance (see Figures 10 to 13). SMAT-treated Indonesian plates therefore are comparably strong as standard plates with respect to bending stresses.
Figure 8. Fatigue limit of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S).

Figure 9. Fatigue bending stress limit of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S).
Figure 10. Trend lines of the fatigue limits of the plates from manufacturers B, B Shot peened, B SMAT-treated and of standard plates (S). The differences between B and B shot peened, B and B SMAT-treated were statistically significant. The differences between S and all B, B Shot peened, B SMAT-treated were statistically significant (p<0.05).
Figure 11. Trend lines of the fatigue limits of the plates from manufacturers B, B Shot peened, B SMAT-treated and of standard plates (S) corrected for the area moment of inertia. The differences between B and B shot peened, B and B SMAT-treated were statistically significant. The differences between S and all B, B Shot peened, B SMAT-treated were statistically significant (p<0.05).
Figure 12. Trend lines of the fatigue limits of the plates from manufacturers A, A SMAT-treated and of standard plates (S). The difference between S and A SMAT was statistically significant \((p<0.05)\). The difference between A and A SMAT was statistically significant \((p<0.05)\).
CONCLUSION

Mechanical properties of Indonesian plates could be improved by the application of surface mechanical attrition treatment (SMAT). The mechanical strength of Indonesian plates, treated with SMAT, therewith becomes comparable to the mechanical strength of the standard plates.
REFERENCES


