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Redesign of Indonesian-made osteosynthesis plates to enhance their mechanical behavior

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ABSTRACT

Mechanical properties determined by fatigue strength, ductility, and toughness are important measures for osteosynthesis plates in order to tolerate some load-bearing situations caused by muscle contractions and weight-bearing effects. Previous study indicated that Indonesian-made plates showed lower mechanical strength compared to the European AO standard plate. High stress under load-bearing situations often starts from surface of the plate; we therefore refined the grain size of the surface by using shot peening and surface mechanical attrition treatment (SMAT). Single cycle bending tests showed that shot-peened and SMAT-treated plates had significantly higher load limit and bending stress compared to the original plates ($p < 0.05$). Weibull analysis confirmed the improvement of proportional load limit of SMAT-treated plates. Fatigue limit also increased upon shot-peening and SMAT treatment (improvement ratio 18% and 27%, respectively). Significant improvement ratio of fatigue tests can be observed in SMAT-treated plates compared to the untreated and shot-peened plates. Fatigue performance demonstrated equivalent results between SMAT-treated and standard plate. These designated that mechanical properties of Indonesian-made plates can be improved upon SMAT treatment leading to significant enhancement of mechanical strength thus is comparable to the standard plate. Our findings highlight the benefits of SMAT treatment to improve mechanical strength of Indonesian-made osteosynthesis plates.

1. Introduction

Osteosynthesis plates used for fracture fixation need to have a high strength, mainly with respect to fatigue, and a high ductility in order to withstand cyclic loading conditions produced by muscle contractions and body weight, until the bone has healed completely (Schneider et al., 2001; Niinomi et al., 2001; Tudor-Locke and Bassett, 2004). Stainless steel

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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 (Disegi and Eschbach, 2000).

The Narrow Dynamic Compression Plate (DCP) is one of the most widely used osteosynthesis plates in Indonesia. However, the result of the fatigue and single cycle strength test showed that those plates were consistently failed at a lower stress than those manufactured in Europe (Dewo et al., 2012). Some possible reasons are:

– The material used; AO-plates (Mathys Medical, Bettlach, Switzerland) are made from stainless steel 316 L implant grade, whereas Indonesian plates are made from a lower quality stainless steel.
– The manufacturing process: In Indonesia, narrow DCPs in Indonesia are produced using simple machinery. Raw material as a form of pipe instead of sheet was cut to get the curvature form of the plate. The manufacturing process of AO plate are kept secret, but most probably they use a flat plate that is forced into a curved shape by cold deformation.
– Poor reproducibility of the manufacturing process. Indonesian plates show a great diversity in dimensions. Fatigue evaluations were adjusted for the overall dimensions, but could not correct the effects for the positioning of the holes. The large eccentricity of the holes will decrease the strength of a plate.

As a consequence, plate failure does happen, either due to malpractice in the rehabilitation process or due to the weakness of the plate (Cook et al., 1985; Cook et al., 1987; Tsaniklidis et al., 2007). In our limited retrieval study on explanted Indonesian-made plates, 14% were found to have failed during service (the study has not been published yet). Therefore, it is necessary to improve the strength and decrease the 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 (Gumbsch, 2003). Heat treatment such as annealing can create a more ductile characteristic of a metal (Cook et al., 1985). 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, 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 (Valiev, 2004; Mair and Padipatvuthikul, 2010).

The aim of this study was to test the efficacy of the surface modification techniques, shot peening, and SMAT treatment in improving the mechanical performances of Indonesian Narrow Dynamic Compression Plate within regard to (1) hardness and (2) fatigue limit.

2. Materials and methods

2.1. Materials

The following groups of plates were used in the experiments:

1. 20 Narrow DCP 6 hole plates from Indonesian manufacturer A
2. 20 Narrow DCP 6 hole plates from Indonesian manufacturer A, SMAT-treated
3. 20 Narrow DCP 6 hole plates from Indonesian manufacturer B
4. 20 Narrow DCP 6 hole plates from Indonesian manufacturer B, SMAT-treated
5. 20 Narrow DCP 6 hole plates from Indonesian manufacturer B, shot peened
6. 20 Narrow DCP 6 hole plates from Mathys / Synthes as the standard plate (S).

A transverse cut at the minimum cross section was made and used to determine the cross sectional area and the area moment of inertia of each plate from each manufacturer.

2.2. Geometry of the plates

A digital sliding caliper was used to measure the following dimensions of the plates: length, thickness, width, the maximum medial and lateral diameter of the holes and the smallest width of the plate material next to a hole (see Fig. 1). A transverse cut at the smallest cross-section was made and used to determine the cross-sectional area and the area moment of inertia.

2.3. Shot peening

Ten plates from manufacturer B were sent to the Metal Improvement Company, (Sint-Truiden, Belgium) to undergo shot peening (diameter of the balls 1 mm).

2.4. Surface mechanical treatment with SMAT method

A reflecting chamber for SMAT treatment was developed at the Department of Mechanical and Industrial Engineering, Faculty of Engineering, Universitas Gadjah Mada, Jogjakarta, Indonesia as shown in Fig. 2.

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.
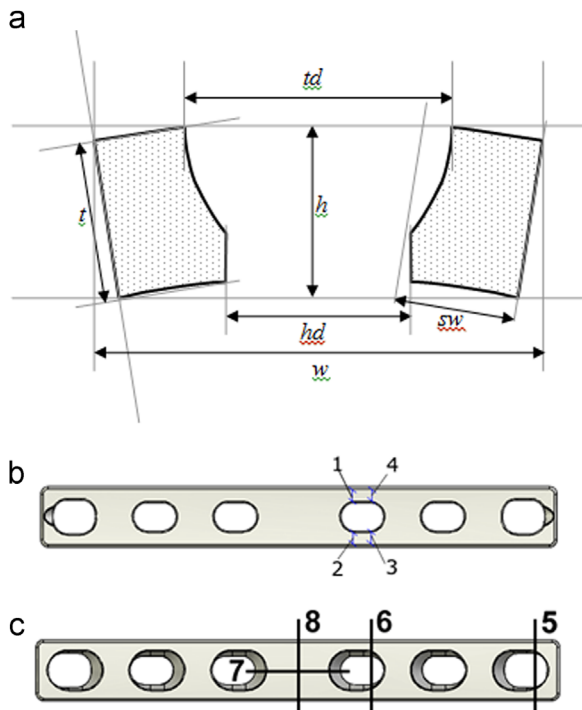
a

b

c

Fig. 1 – Geometry of the cross-section of the plate (a). w=width, hd=hole diameter, td=taper diameter, h=height, t=thickness, sw=smallest width. The four locations of measurement of the smallest material thickness next to a hole (b). Locations of the cross sections that were examined: (5) grain size, grain orientation, and hardness measurement (6) minimum cross section, (7) and (8) hardness measurenments (c).
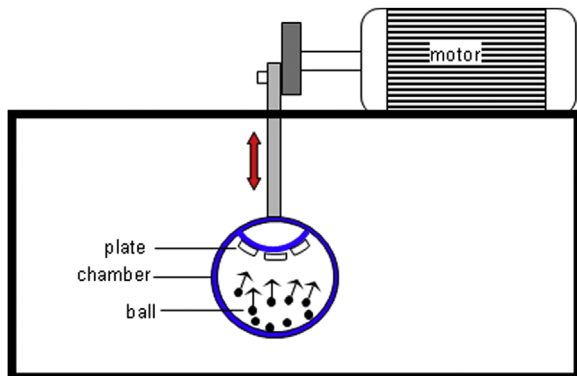

Fig. 2 – Schematic representation of the reflecting chamber for SMAT.

2.5. Mechanical test

2.5.1. 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 (Fig. 3) designed according to the ISO 9585: 1990 and ASTM F382-99 standards that describe bending tests for a general bone plates. The test setup was installed in a Dyna-mess tensile test machine (Dyna-mess Prüfsysteme GmbH, Aachen/Stolberg, Germany) with accompanying software. These tests were performed with 10 plates per group.
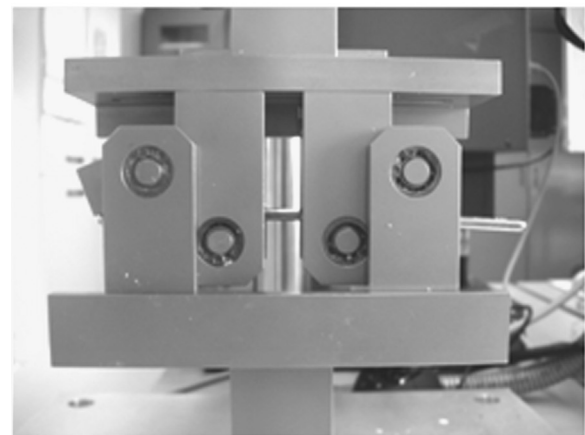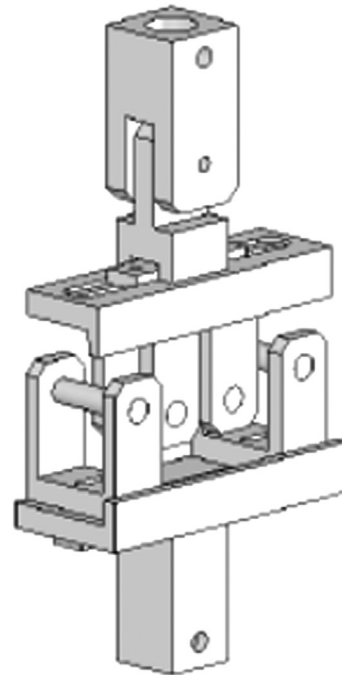

Fig. 3 – Schematic presentation and actual photograph of the four point bending test setup for single cycle and fatigue tests. The bone plate is partly visible, partly represented by a dotted line.

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, K_2HPO_4 1.4 g/l, and KH_2PO_4 0.27 g/l at pH to7.4) kept at 37 °C during measurements. The setup was manufactured from 316 L 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 (Fig. 4). Electrical circuit was completed through a salt bridge (PBS+1.5% agar). The load was applied until the plate failed. As proportional stress limit of the plate the 0.2% offset yield strength is used. To compensate for the differences in geometry, the bending stress was calculated using
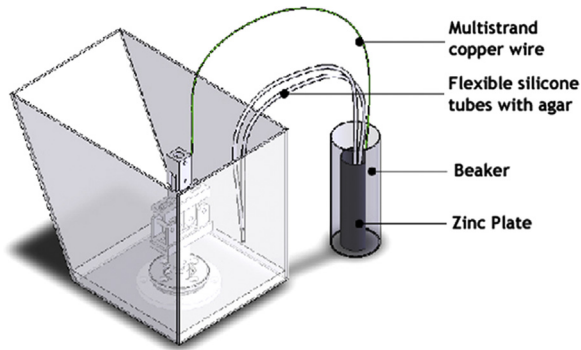
Fig. 4 – Cathodic protection of the set up using a Zn cathode.

the cross sectional area moment of inertia. The bending stress (σ) is defined as the moment about the neutral axis (M) times the perpendicular distance to the neutral axis (y) divided by the second moment of area about the neutral axis x (I). I is influenced by the geometric measurement of the plates. The results from each manufacturer were averaged. This bending stress is an estimate, since the stress concentration is not included in the calculation due to the complex shape.

2.5.2. 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 previously described (Dewo P et al., 2012). Ten plates from each group were used. The positive and sinusoidal load cycles 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 that are active during walking and standing. 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 three million cycles was determined as the fatigue limit (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.

2.6. 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. ANOVA was used to compare between the means of the six groups. Then, the data were analyzed using the Tukey post hoc test to identify the statistical difference by specific pairwise comparisons with standard plates. Data of the single cycle bending test were also analyzed using a Weibull Analysis (Burrow et al., 2004). Significance was set at $p < 0.05$ with confidence interval 95%.

3. Results

3.1. Single cycle bending test

The mean failure-load of shot peened and SMAT-treated plates from manufacturer B (B-SP and B-SMAT) and the SMAT-treated plate from manufacturer A (A-SMAT) were found to be higher than that of the original plates (respectively, B and A). The mean failure-load of the SMAT-treated plate from manufacturer A (A SMAT) exceeded the mean failure-load of the standard plate (S) (Fig. 5). The mean of the calculated bending stresses of shot-peened and SMAT-treated plates from manufacturer B (B-SP and B-SMAT) and the SMAT-treated plates from manufacturer A (A-SMAT) were found to be higher than those of the original plates (B and A, respectively). However, the mean calculated bending stress of the SMAT-treated plates from manufacturer A (A SMAT) and the shot peened and SMAT-treated plates from manufacturer B (B-SP and B-SMAT) is lower than that of the standard plates (Fig. 6). The ratio of improvement between original and SMAT treated plates is 60% for the plates from manufacturer B and 11% for the plates from manufacturer A. The Weibull analysis also confirmed these improvements of SMAT treated
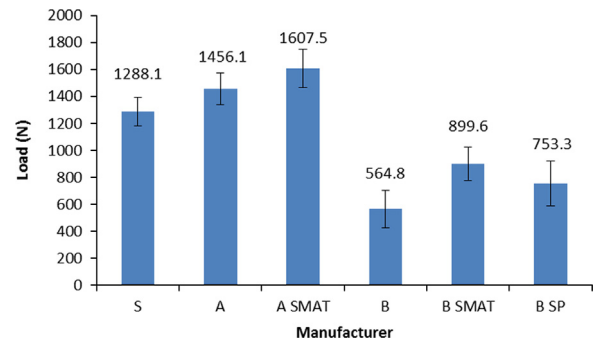
Fig. 5 – Proportional load limit as measured from single cycle test of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S) with error bars denoting standard deviation from 10 samples per bar.

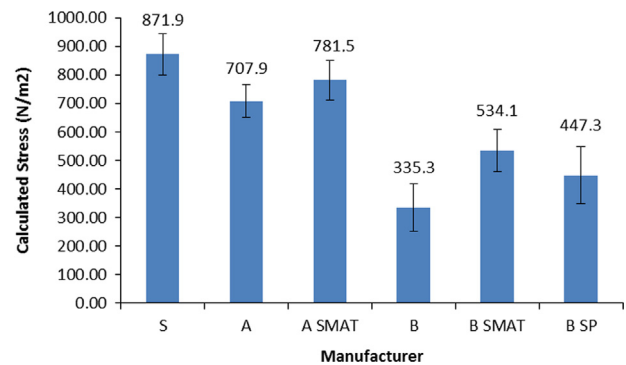**Fig. 6 – Calculated bending stress of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S) with error bars denoting standard deviation from 10 samples per bar.**

plates (Figs. 7 and 8). Based on the ANOVA analysis, the mean failure-load from six plates are significantly different (p 0.000). When compared to the standard plates using Tukey post-hoc
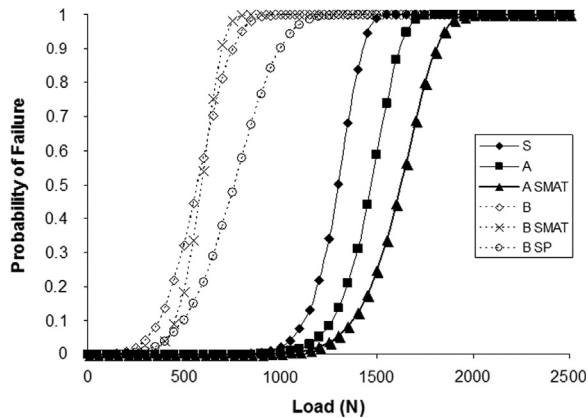

Fig. 7 – Weibull Analysis of proportional load limit of the plates from manufacturers A, A SMAT-treated, B, B SMAT-treated, B shot peened, and of standard plates (S).
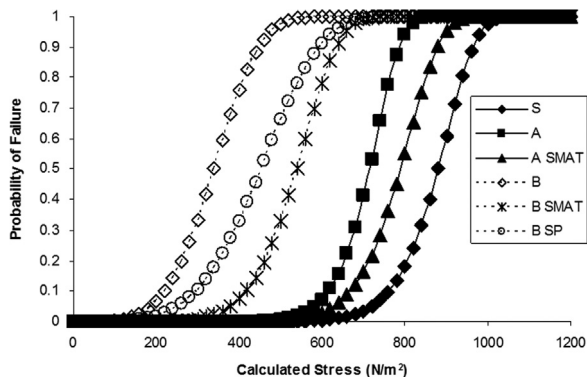

Fig. 8 – Weibull Analysis of calculated bending stress of the plates from manufacturers A, A SMAT-treated, B, B SMAT-treated, B shot peened, and of standard plates (S).

analysis, the SMAT-treated plates from manufacturer A (A SMAT) are not significantly different (Tables 1 and 2).

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 SMAT-treated plate from manufacturer A became comparably strong as the standard plate.

3.2. Fatigue test in bending

The fatigue limit of shot-peened plates and SMAT-treated plates were improved with respect to untreated plates. The SMAT treated plates from manufacturer A and manufacturer B exceeded the standard plates in fatigue limit (see Figs. 9 and 10). SMAT-treated Indonesian plates and standard plates showed no significant differences in fatigue performance (see Figs. 11–14). Based on the ANOVA analysis, the fatigue limit from six plates were significantly different (p 0.000) and when compared to the standard plates on post hoc analysis, shot-peened and SMAT-treated plates from manufacturer B (B-SP and B-SMAT) were significantly different (p 0.000). However, SMAT-treated plates from manufacturer A (A SMAT) and standard plates were not significantly different (p 1.000) (Tables 1 and 2). SMAT-treated Indonesian plates from manufacturer A therefore are as strong as standard plates with respect to bending stresses.

4. Discussion

Failure of metal parts, loaded under bending, is frequently initiated from the surface, where the stress concentration is higher than that inside. Therefore, improvement of surface strength and microstructure is a practical way to improve the overall fatigue strength of metal parts. Osteosynthesis plates also suffer from failure, caused by fatigue fractures, usually initiated at the surface. Fatigue strength and bending strength of materials can be enhanced after shot-peening and SMAT treatment as confirmed by previous publications

Table 1 – ANOVA analysis of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S).					
	Sum of squares	df	Mean square	F	Sig.
Single cycle load					
Between groups	8180728.467	5	1636145.693		
Within groups	834676.632	48	17389.096	94.090	0.000
Total	9015405.099	53			
Single cycle calculated stress					
Between groups	2005082.676	5	401016.535	72.933	0.000
Within groups	263923.029	48	5498.396		
Total	2269005.704	53			
Fatigue test load					
Between groups	3324554.454	5	664910.891	33.823	0.000
Within groups	1041917.532	53	19658.821		
Total	4366471.985	58			
Fatigue test calculated stress					
Between groups	1347054.337	5	269410.867	42.285	0.000
Within groups	337681.353	53	6371.346		
Total	1684735.690	58			

Table 2 – Post hoc power analysis of standard plates compared with plates from manufacturers B, B shot peened, B SMAT-treated, A, and A SMAT-treated.

| (I) plat	(J) plat	Mean difference (I-J)	Std. error	Sig.	95% confidence interval	
					Lower bound	Upper bound
Single cycle load						
S	A	− 168.053846*	55.466499	0.043	− 332.67258	− 3.43512
	A smat	− 319.400000*	58.973039	0.000	− 494.42577	− 144.37423
	B	723.307000*	58.973039	0.000	548.28123	898.33277
	B smat	388.500000*	72.226927	0.000	174.13808	602.86192
	B sp	534.766667*	68.096200	0.000	332.66431	736.86902
Single cycle calculated stress						
S	A	164.048462*	31.189633	0.000	71.48091	256.61601
	A smat	90.469000	33.161413	0.088	− 7.95058	188.88858
	B	536.630000*	33.161413	0.000	438.21042	635.04958
	B smat	337.828000*	40.614270	0.000	217.28912	458.36688
	B sp	424.678333*	38.291501	0.000	311.03319	538.32348
Fatigue test load						
S	A	459.450000*	61.262123	0.000	278.32853	640.57147
	A smat	− 12.843333	57.240460	1.000	− 182.07475	156.38808
	B	529.378571*	69.096202	0.000	325.09565	733.66149
	B smat	489.950000*	66.507404	0.000	293.32086	686.57914
	B sp	403.950000*	66.507404	0.000	207.32086	600.57914
Fatigue test calculated stress						
S	A	433.793052*	34.876180	0.000	330.68163	536.90448
	A smat	204.166004*	32.586670	0.000	107.82352	300.50849
	B	406.075503*	39.336077	0.000	289.77839	522.37261
	B smat	382.679041*	37.862289	0.000	270.73919	494.61890
	B sp	331.587975*	37.862289	0.000	219.64812	443.52783
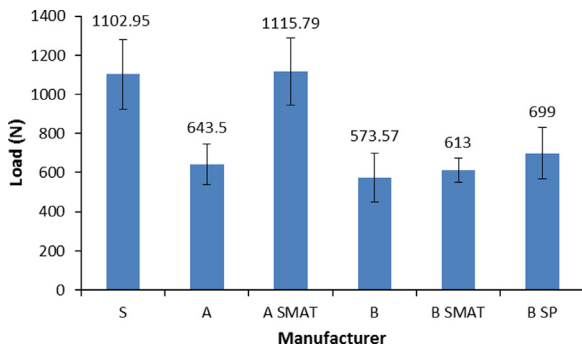
Fig. 9 – Fatigue limit of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S).
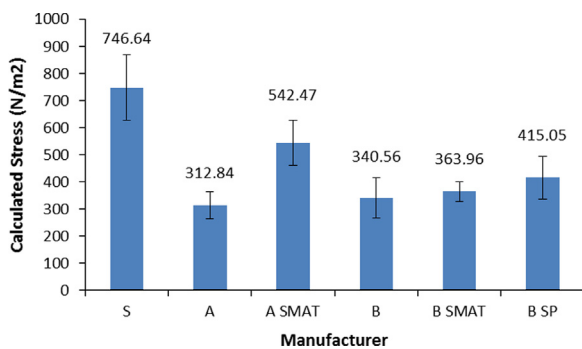

Fig. 10 – Fatigue bending stress limit of the plates from manufacturers B, B shot peened, B SMAT-treated, A, A SMAT-treated and of standard plates (S).
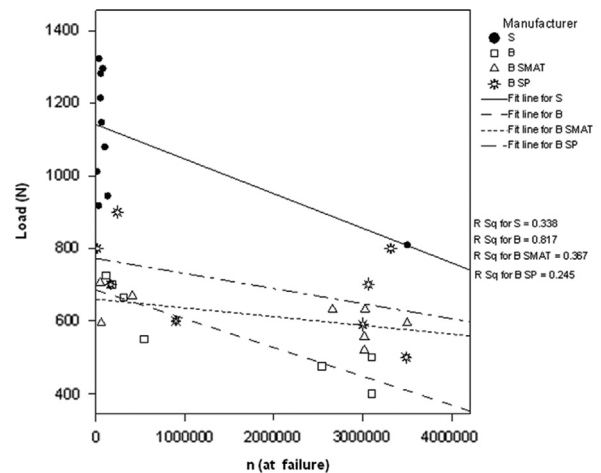

Fig. 11 – Trend lines of the fatigue limits of the plates from manufacturers B, B Shot peened, B SMAT-treated and of standard plates (S). The differences between B and B shot peened, B and B SMAT-treated were statistically significant. The differences between S and all B, B Shot peened, B SMAT-treated were statistically significant ($p < 0.05$).

(Starker et al., 1991, Bauer M et al., 2013, Huang and Han, 2013; Torres and Voorwald, 2002). Our data showed a significant mechanical strength improvement of Indonesian-made osteosynthesis plates upon surface modifications. The SMAT treated plates showed a better fatigue performance and ratio of fatigue improvement compared to the shot-peened plates. SMAT has been shown to increase compressive residual
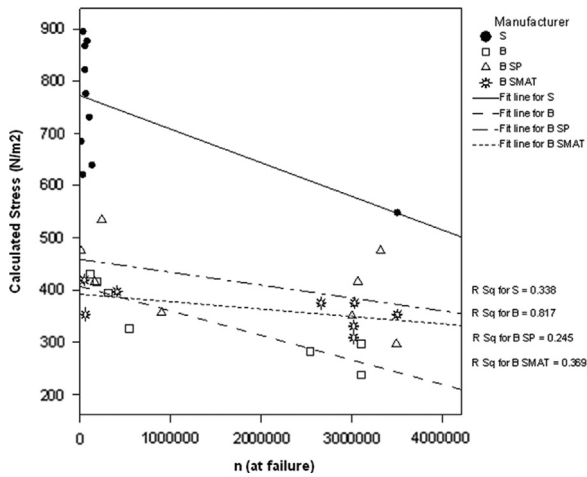
Fig. 12 – Trend lines of the fatigue limits of the plates from manufacturers B, B Shot peened, B SMAT-treated and of standard plates (S) corrected for the area moment of inertia. The differences between B and B shot peened, B and B SMAT-treated were statistically significant. The differences between S and all B, B Shot peened, B SMAT-treated were statistically significant ($p < 0.05$).
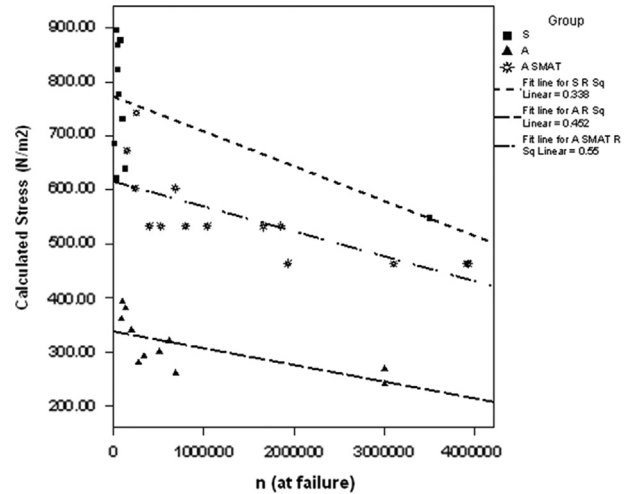

Fig. 14 – Trend lines of the fatigue limits of the plates from manufacturers A, A SMAT-treated and of standard plates (S) corrected for the area moment of inertia. The difference between S and A SMAT was not statistically significant ($p > 0.05$). The difference between A and A SMAT was statistically significant ($p < 0.05$).
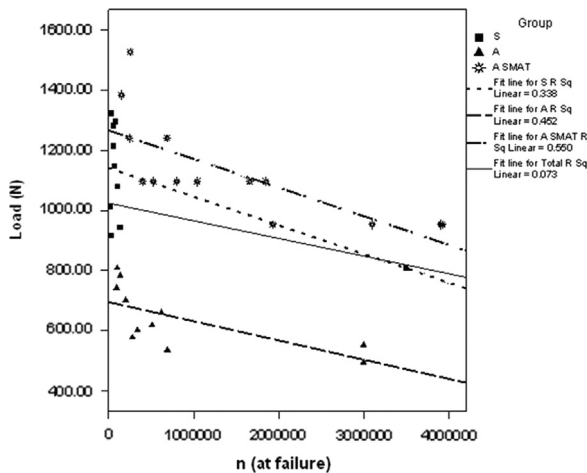

Fig. 13 – Trend lines of the fatigue limits of the plates from manufacturers A, A SMAT-treated and of standard plates (S). The difference between S and A SMAT was statistically significant ($p < 0.05$). The difference between A and A SMAT was statistically significant ($p < 0.05$).

stresses at the surface much better than other surface treatments including shot peening and deep rolling (Burrow et al., 2004). SMAT also results in better refinement of nanostructured surface layer due to the utilization of bigger and spherical smooth balls with lower velocity compared to shot peening as reviewed by Lu et al. (Lu and Lu, 2004). Study by Huang R et al. showed that SMAT can help the formation of more stable and much thicker passive protection films on the nanograined structure (Huang and Han, 2013). In addition, SMAT-treatment can enhance subsurface hardness and improve surface morphology, roughness, and wettability that might not be achieved by conventional surface treatments such as shot peening (Lu and Lu, 2004; Arifvianto et al., 2011).

Bauer et al. showed no improvement of durability with shot peening, however those study used magnesium alloy as their material (Bauer et al., 2013). On the other hand, another study using a similiar fatigue test on stainless steel showed that shot peening can indeed increase fatigue strength. These results were similiar to the result of this study (Torres and Voorwald, 2002).

Since locally manufactured low-cost narrow DCPs are not yet popularly used by surgeons in Indonesia (Dewo P et al., 2012), reassuring their mechanical properties through surface modifications is expected to decrease their reluctance and skepticisms and to convince them to use the modified local products. In addition, SMAT treatment resulting in equal mechanical strength to standard plates does not require major investments. This is therefore an opportunity to produce and expand locally made plates with high quality and affordable price throughout Indonesia as well as in other developing countries. This is especially important considering the relatively frequent occurrence of natural disasters in Indonesia with all associated bone fractures.

Despite the limited plate sample size from only two local manufacturers, a significant improvement of fatigue performance and bending stress is observed upon shot peening and SMAT treatment. For supporting more general conclusions further measurements on the mechanical strength on a larger number of plates from different local companies is required before starting local mass production of surface-modified plates.

5. Conclusion

Mechanical properties of Indonesian plates showed to 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.

Acknowledgment

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