JOURNAL OF THE MECHANICAL BEHAVIOR OF BIOMEDICAL MATERIALS 13 (2012) 93–101

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Research Paper

Mechanical properties of Indonesian-made narrow dynamic compression plate

P. Dewo[a,b,*], E.B. van der Houwen[b], P.K. Sharma[b], R. Magetsari[a], T.C. Bor[d], L.D. Vargas-Llona[d], J.R. van Horn[b], H.J. Busscher[b], G.J. Verkerke[b,c]

[a]*Department of Orthopaedics and Traumatology, Sardjito Hospital/University of Gadjah Mada, Jogjakarta, Indonesia*
[b]*Department of Biomedical Engineering, University of Groningen, University Medical Center Groningen, The Netherlands*
[c]*Department of Biomechanical Engineering, University of Twente, The Netherlands*
[d]*Chair of Production Technology, University of Twente, The Netherlands*

ARTICLE INFO

Article history:
Received 7 December 2011
Received in revised form
15 April 2012
Accepted 21 April 2012
Available online 4 May 2012

Keywords:
Osteosynthesis plate
Mechanical properties

ABSTRACT

Osteosynthesis plates are clinically used to fixate and position a fractured bone. They should have the ability to withstand cyclic loads produced by muscle contractions and total body weight. The very high demand for osteosynthesis plates in developing countries in general and in Indonesia in particular necessitates the utilisation of local products. In this paper, we investigated the mechanical properties, i.e. proportional limit and fatigue strength of Indonesian-made Narrow Dynamic Compression Plates (Narrow DCP) as one of the most frequently used osteosynthesis plates, in comparison to the European AO standard plate, and its relationship to geometry, micro structural features and surface defects of the plates. All Indonesian-made plates appeared to be weaker than the standard Narrow DCP because they consistently failed at lower stresses. Surface defects did not play a major role in this, although the polishing of the Indonesian Narrow DCP was found to be poor. The standard plate showed indications of cold deformation from the production process in contrast to the Indonesian plates, which might be the first reason for the differences in strength. This is confirmed by hardness measurements. A second reason could be the use of an inferior version of stainless steel. The Indonesian plates showed lower mechanical behaviour compared to the AO-plates. These findings could initiate the development of improved Indonesian manufactured DCP-plates with properties comparable to commonly used plates, such as the standard European AO-plates.

1. Introduction

Osteosynthesis plates are often used in orthopaedic trauma surgery to provide fixation and positioning of a fractured bone. Currently three types are used in Indonesia, (i) the Dynamic Compression Plate (DCP) (Allgower et al., 1969; Perren et al., 1969), (ii) the Limited Contact Dynamic Compression Plate (LC-DCP) that claims to have 50% less bone contact surface and (iii) the Locking Compression Plate (LCP) that was introduced especially for porous bones. Nonetheless, the DCP is often used, because it has a better fatigue strength, whereas the contact area appeared comparable to the LC-DCP (Disegi and Eschbach, 2000; Field et al., 1997; Sod et al., 2005).

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*Corresponding author at: Universitas Gadjah Mada/ Dr. Sardjito Hospital, Dept. of Orthopaedics and Traumatology, Jl. Kesehatan 1, Sekip Yogyakarta, Indonesia Tel.: +62 274 515054; fax:+62 274 553143.
E-mail address: dewo777@yahoo.com (P. Dewo).

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http://dx.doi.org/10.1016/j.jmbbm.2012.04.018

Commonly used material is austenitic stainless steel (Disegi and Eschbach, 2000). The stainless steel 316LVM (vacuum melted) is often used for its good biocompatibility and high modulus of elasticity. Compared to 316LVM, both lower material costs and ease of fabrication make plates from stainless steel 316L cheaper (Disegi and Eschbach, 2000; Leffler, 2000; Whitaker, 1982).

The types of load acting on an osteosynthesis plate are compression, bending, and torsion in which bending forces cause the highest stress (Hoppenfeld, 2000). Osteosynthesis plates should have a high fatigue strength to withstand cyclic loads produced by muscle contractions and total body weight (Schneider et al., 2001; Uhthoff et al., 2006). An average person takes 4,500 steps for each leg per day (Tudor-Locke, Basset, 2004). After surgery using an osteosynthesis plate, the weight bearing phase lasts for about 4 months until solid union of the bone occurs (Hoppenfeld, 2000). Thus, an osteosynthesis plate needs to withstand about half a million cycles (4.500 steps × 120 day) and the complete body weight and muscle forces. Factors, known to influence the fatigue strength, are the material and the manufacturing process, expressed by stress concentration caused by the geometry, residual stresses, microstructure (grain size), and surface defects that initiate cracks (Pilliar, 1999). The yield strength of bone plates is another important property, since a plate has to bear impact loadings as well (Cartz, 1995).

The demand for osteosynthesis plates in developing countries like Indonesia is very high as the result of the high incidence of trauma. Imported osteosynthesis plates are expensive. Moreover, importing and distributing many of them during disasters like earthquakes or tsunamis, is very difficult. Therefore, using locally produced osteosynthesis plates is a good alternative. However, they are hardly applied, since the mechanical strength of these plates is unknown. The manufacturing process of a narrow DCP in Indonesia involves simple machinery. Raw material in the form of a pipe instead of sheet was used to get the required curved form of the plate.

The aim of this study was to determine the proportional limit and fatigue strength of Indonesian-made Narrow DCP's and their relationships to the material and manufacturing process. Since there are no standards for strength we used the European AO standard plates as comparison.

2. Materials and methods

2.1. DCP plates

Narrow DCP's with 6 holes were obtained from 4 Indonesian manufacturers, designated as manufacturers A, B, C, and D. Plates produced by Synthes (Mathys Medical, Switzerland) were used as the standard plate (designated as S). Twenty plates were collected from each company. All plates were manufactured of stainless steel. The material composition was analysed by Spectrometer (WAS spectrometer, Worldwide Analytical System type PMI master pro 13L0086). Screws were not studied, since screws are always imported from European manufacturers.

2.2. Geometry of the plates

The following dimensions of the plates were measured using a digital sliding caliper: length, thickness, width, the maximum medial and lateral diameter of the holes and the smallest width of the plate material next to a hole. The eccentricity of the hole is determined by the ratio between the radius of the hole (hd) and the smallest width of the material next to the hole (sw, see Fig. 1a and b), since this ratio influences the stress amplification (Markenscoff, 2000). A transversal cut of the minimum cross (Section #2 in Fig. 1c) was made and used to determine the cross-sectional area and the area moment of inertia. The dimensions of 10 plates of two different batches per manufacturer were determined.

2.3. Surface defect study

The plates were studied visually for scratches and rough areas. Subsequently, nondestructive liquid penetrant inspection (LPI) was used to detect surface cracks up to 5 μm wide and 10 μm deep (Cartz, 1995). LPI was carried out on 10 bone plates of each manufacturer using Spotcheck Dye Penetrant Test (Magnaflux, Glenview, USA) according to the instructions. Stereo-microscopic analysis was used to determine the

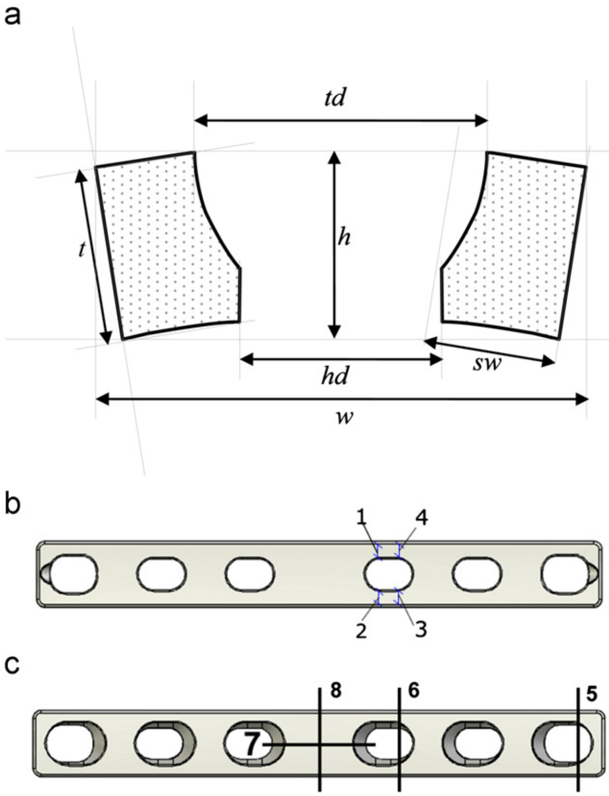

Fig. 1 – Geometry of the cross-section of the plate (a). *w*=width, *hd*=hole diameter, *td*=taper diameter, *h*=height, *t*=thickness, *sw*=smallest width. The four locations of measurement of the smallest material thickness next to a hole (b). Locations of the cross sections that were examined: (5)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

nature of the scratches. Per manufacturer, the total length of the scratches on both sides (top and bottom side) of all ten plates was taken as a measure of the amount of surface defects.

2.4. *Monotonic loading test*

At first a mechanical monotonic loading test was performed to determine the proportional limit. The tests were performed using a 4-point bending test setup (Fig. 2) designed according to 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) with accompanying software. These tests were performed with 10 plates per manufacturer.

Fixation of the bone plate to one roller prevented horizontal movement; roller bearings reduced friction. The bone plate was immersed in Phosphate Buffered Saline (PBS) kept at 37 °C during measurements. The setup was manufactured from 316L stainless steel. To prevent corrosion, it was cathodically protected using a Zn-anode. To avoid any ion exchange, the Zn-anode was kept in a separate reservoir and electrically coupled to the setup via a salt bridge (PBS+1.5% agar).

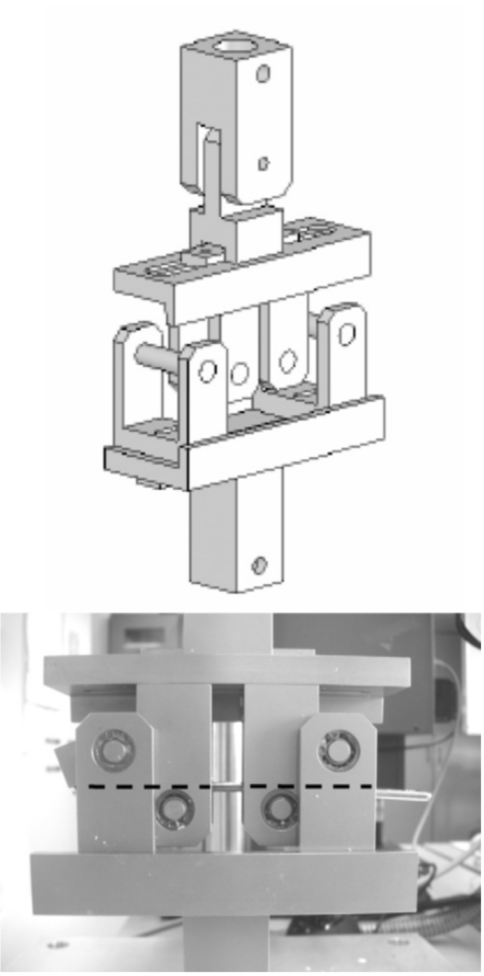

Fig. 2 – Schematic representation and actual picture of the four point bending test setup for monotonic loading and fatigue tests. The bone plate is partly visible in the lower picture, partly represented by a dashed line.

The load was increased until the plate failed. The proportional limit of the plate was defined as the point where the load displacement curve started to deviate from a straight line which is noted by the software of the tensile test machine. The results from each manufacturer were averaged. To compensate for the differences in geometry the bending stress was calculated using the moment of inertia.

2.5. *Fatigue test in bending*

Secondly, high cycle fatigue bending tests were performed using the same setup at a frequency of 5 Hz. Ten plates from each manufacturer were used for this test. The positive and sinusoidal load cycle was chosen such that the minimal load was 10% of the maximal load ($R=0.1$). This minimum load was chosen to mimic the muscular forces that keep the bone plate loaded continuously. The highest maximum load was taken as 95% of the proportional limit. After failure the following samples were tested at a continuously decreasing maximum load with steps of 5% of the proportional limit until a load (fatigue limit) was achieved where the bone plate could withstand 3 million cycles. This load is defined as the fatigue strength. Further testing was done by increasing the maximum load with steps of 5% of the proportional limit until failure occurred. Wöhler curves were fitted to the applied load versus the number of cycles. Plates from different manufacturers were compared based on the fatigue limit and Wöhler curves. After fracture, the plates were photographed to document the fracture.

2.6. *Grain size determination (Metallographic examination)*

After fatigue testing, all plates were cut to obtain four cross sections (Fig. 1c) with a Struers Discotom 5 table-top-cut off machine and embedded in a 6 HQ compression mounting compound using a fully automatic Struers Labopress-3 mounting press with the following settings: heating time 6 min at 180 °C, force 40 kN, cooling time 6 min. Grinding of cut 1 was done with abrasive paper with grit numbers 240, 400, 600, 1200, and 4000, respectively. To remove deformations from fine grinding, polishing was done with colloidal silica particles finer than 1 μm on a neoprene cloth. Subsequently, the samples were etched to achieve microstructural contrast. The etching solution used was a mixture of 1/3 distilled water, 1/3 HCL 37%, and 1/3 HNO_3 65% at room temperature. Samples were immersed for 4 min in the solution, subsequently rinsed in water and alcohol, and dried under hot air.

Samples were analysed under a Leica DM 2500 optical microscope and pictures were taken. Lines were drawn on top of a micrograph, and the number of grains that crossed each line was counted and the average number of grains over multiple images was calculated. The real grain size was obtained employing the scale bar accompanying the respective micrograph.

2.7. *Hardness measurements*

All 10 cross sections 5, 7 and 8 of the plates from each manufacturer were used for hardness measurement. The Vickers indenter was forced into the surface of the plate. The extent of the indent determined the specimen's hardness. Measurements were performed with a manual Leitz microhardness system and with a Leco AMH43 automatic micro indentation testing system with a 200 g weight.

2.8. *Statistics*

The numerical data of monotonic loading test were analysed using One-Sample Kolmogorov–Smirnov Test to check for a normal distribution. Then, an independent sample t-test was used to compare the means of two groups. Data of the fatigue test in bending were analysed using linear regression analysis. Significance was set at $p<0.05$.

3. Results

3.1. *Material composition*

The data of material composition of the plate showed that Indonesian plates from manufacturers B, C, and D contain less Nickel. The plates from manufacturer B and C contain very low Molybdenum and high Carbon (Table 1). This could indicate that another material than stainless steel 316LVM was used for manufacturing of the Indonesian plates.

3.2. *Geometric data of the plates*

Geometric data for the plates were shown in Table 2. Plates from manufacturer C and D appear to be thicker than the others. Consequently, they also have a larger cross sectional area and area moment of inertia. Concerning stress amplification, Indonesian plates do not score worse than the standard plate.

3.3. *Surface defect study*

Liquid Penetrant Inspection (LPI) showed scratches and rough areas on most plates. They were present at the inner side of the gliding holes (as seen in Fig. 3); less prominent irregularities were found on the lateral sides and on the concave bottom side. The total length of the scratches of all plates is depicted in Table 2. The Indonesian plates clearly show more scratches than the standard plate.

3.4. *Monotonic loading test*

Almost all Indonesian plates failed at a lower load than the standard plate, and after including the area of moment of inertia the results showed that all Indonesian plates were

Table 1 – Chemical composition of materials of narrow DCP's from different manufacturers, determined using Spectrometer and the required composition according to ISO 5832-1 and ASTM F138 and F139.

Manufacturer	Elements (wt %)			
	Cr	Ni	Mo	C
ISO 5832-1 and ASTM F138 and F139	17–19	13–15	2.25–3.5	≤0.03
S	16.80	14.60	2.66	0.03
A	16.80	13.80	2.53	0.03
B	17.70	8.56	0.12	0.05
C	16.70	7.94	0.20	0.05
D	16.20	11.20	2.01	0.03

Table 2 – Average and standard deviation of geometric plate data from manufacturers A, B, C, D, and for the standard plates (S). See Fig. 1 for exact measurement sites.

Geometry	Manufacturer				
	S	A	B	C	D
Hole diameter (mm)	5.58±0.07	5.45±0.11	5.35±0.12	4.72±0.04	6.14±0.11
Taper diameter (mm)	8.05±0.09	8.02±0.04	8.50±0.00	7.78±0.10	7.93±0.05
Height (mm)	4.29 ±0.06	3.98±0.06	3.92 ±0.10	4.90±0.08	4.92±0.09
Thickness (mm)	3.77±0.11	3.65±0.03	3.44±0.07	4.41±0.08	4.63±0.15
Width (mm)	12.00±0.09	11.80±0.08	12.75±0.24	11.62±0.12	11.88±0.36
Length (mm)	102.62±0.59	103.77±0.24	97.44±3.27	103.24±0.13	103.74±0.55
Smallest width next to a hole (mm)	3.21±0.03	3.22±0.21	3.19±0.25	3.34±0.22	3.54±0.14
Stress concentration factor (hd/sw)	1.74	1.69	1.68	1.41	1.73
Area (mm^2)	24.10	23.00	26.30	30.80	29.40
Area moment of inertia (mm^4)	39.10	50.88	41.66	55.01	55.59
Total length scratches (mm)	1.00±0.30	2.80±0.20	4.90±0.40	3.40±0.30	3.60±0.60

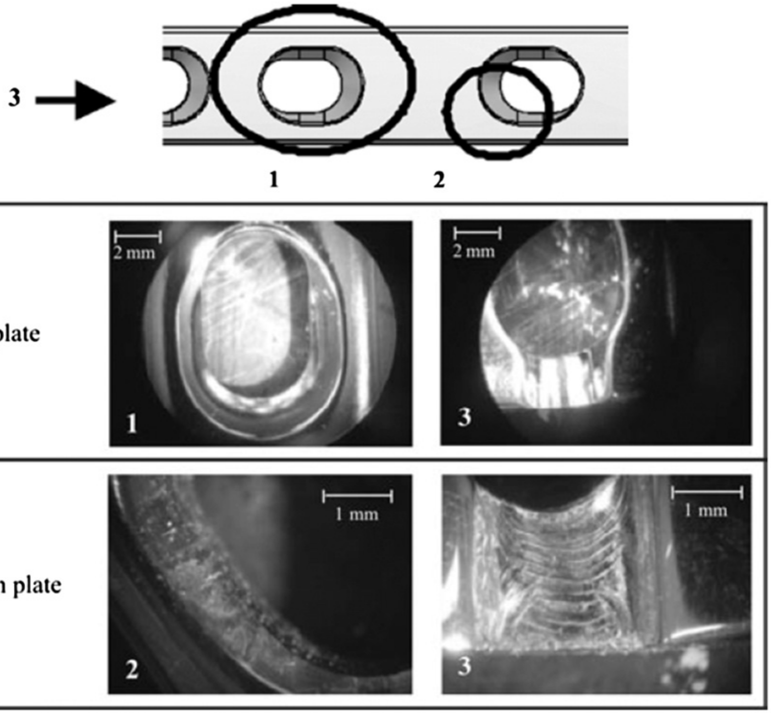

Fig. 3 – Photographs of the plate holes viewed from above showing typical surface defects visible on an Indonesian Narrow DCP (Manufacturer D) as compared to the standard plate. The location of the pictures is presented above.

Table 3 – Proportional limit and fatigue limit at 3 × 10^6 cycles of the plates from manufacturers A, B, C, D, and of the standard plates (S) and after correction for the area moment of inertia.

Mechanical test	Manufacturer				
	S	A	B	C	D
Proportional load limit (N)	1288±106	1456±118	565±141	912±215	731±144
Proportional bending stress limit (N/ mm^2)	872±72	708±57	335±84	434±102	279±55
Fatigue limit (N)	810.0	552.8	500.0	806.3	746.2
Fatigue bending stress limit (N/ mm^2)	548.33	268.78	296.88	464.11	400.53

significantly weaker than the standard plate ($p<0.001$), as shown in Table 3.

3.5. *Fatigue test in bending*

Indonesian plates showed worse fatigue performance as compared to the standard plate, as shown in Table 3, Fig. 4. All Indonesian plates were significantly weaker than the standard plate with respect to bending stresses. Fatigue fractures occurred at both sides of the holes ($p<0.01$) (Fig. 5).

3.6. *Metallographic examination*

The microstructure of all plates is characterised by equi-axed crystals. The Indonesian plates show the presence of annealing twins indicating a relatively soft material, whereas the presence of slip lines in plate S indicates cold deformation prior to or part of the manufacturing process. No preference in grain orientation was visible in the different cross sections of plate S, indicating a relatively small amount of cold deformation. Plates B, C and D contain a lot of particles in a length direction, probably related to the rolling orientation and the casting process employed. The relatively low amount of Ni in the Indonesian plates as compared to the standard plate, promotes the development of a non-homogeneous microstructure of austenite with ferrite in the Indonesian plates. This follows from the use of the Schaeffler diagram for stainless steel (Davis, 1994). The compositions of the plates (see Table 1) can be expressed in a so-called Cr equivalent and Ni equivalent. Then, the diagram predicts the typical microstructural components. Especially, the lower Ni content of the Indonesian plates causes a smaller value of the Ni equivalent which in turn promotes the presence of small amounts of ferrite. Exploratory magnetic measurements that are sensitive to ferrite (and/or martensite), performed on the outside surfaces and the cross sections of the plates, employing a Fischer FMP30 Feritscope, support this observation as the Indonesian plates all showed a magnetic response, whereas the standard plate did not, indicating the absence of ferrite Fig. 6.

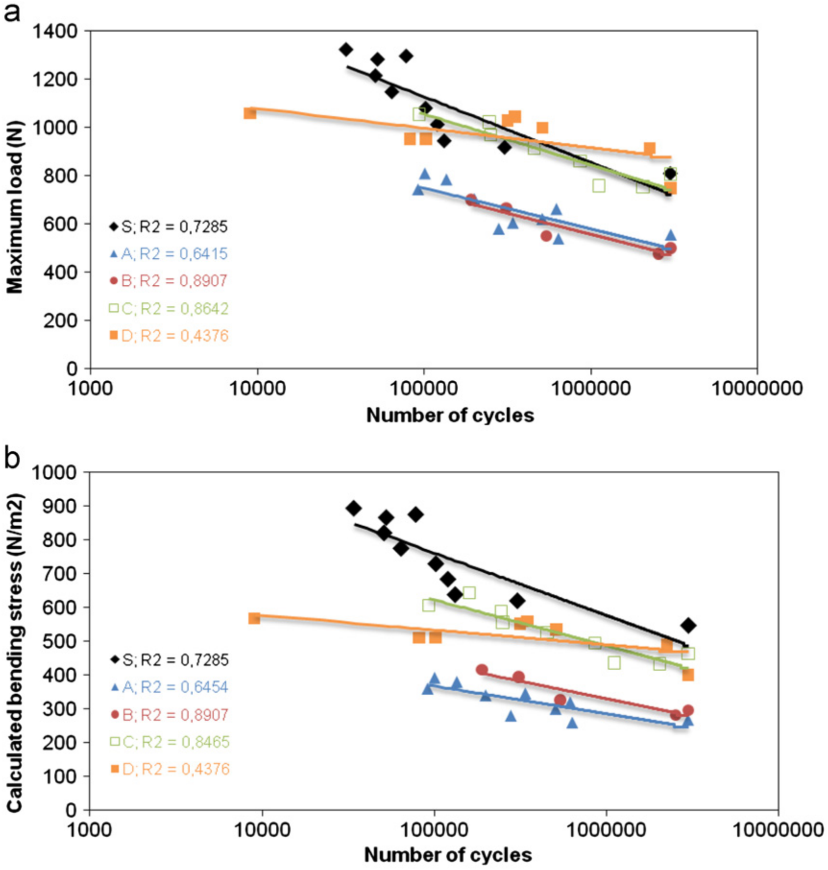

Fig. 4 – Wöhler curve of the plates from manufacturers A, B, C, D, and of the standard plates (S) (top) and corrected for the area moment of inertia (bottom, with trendlines).

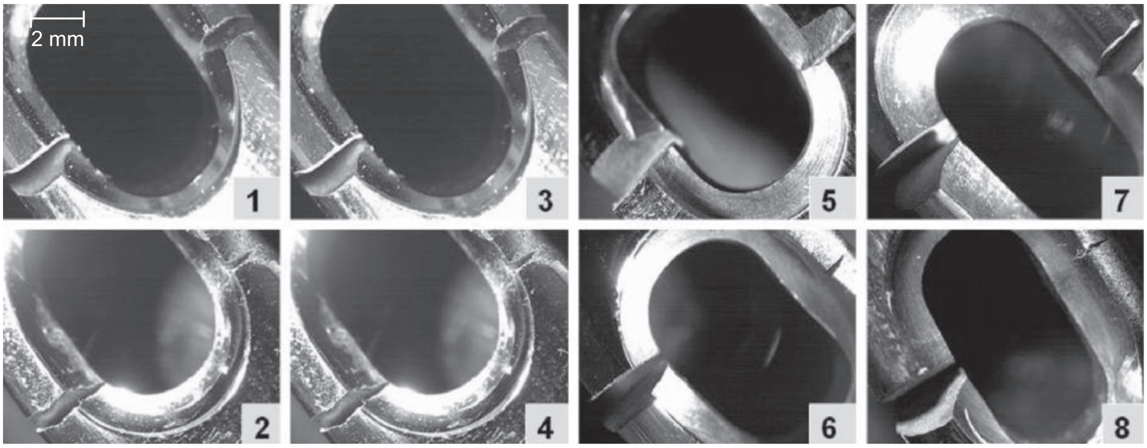

Fig. 5 – Fatigue fracture of the plates; photos 1–2: standard plate, photos 3–8: Indonesian plates. All photos were taken with the same magnification.

The average grain sizes and standard deviations are shown in Table 4. The standard plate showed larger grain sizes than the Indonesian plates ($p=0.02$).

3.7. *Hardness measurement*

The standard plates were significantly harder than the Indonesian plates ($p=0.02$). The average hardness values are shown in Table 4.

4. Discussion

Low-cost Narrow DCP's produced in Indonesia are not often used. When the quality of local products is proven, the reluctance to use local products by surgeons from developing countries may disappear and larger scale production can be initiated. In this study the mechanical properties of plates from four Indonesian companies were compared with the mechanical properties of the standard AO-plate (S).

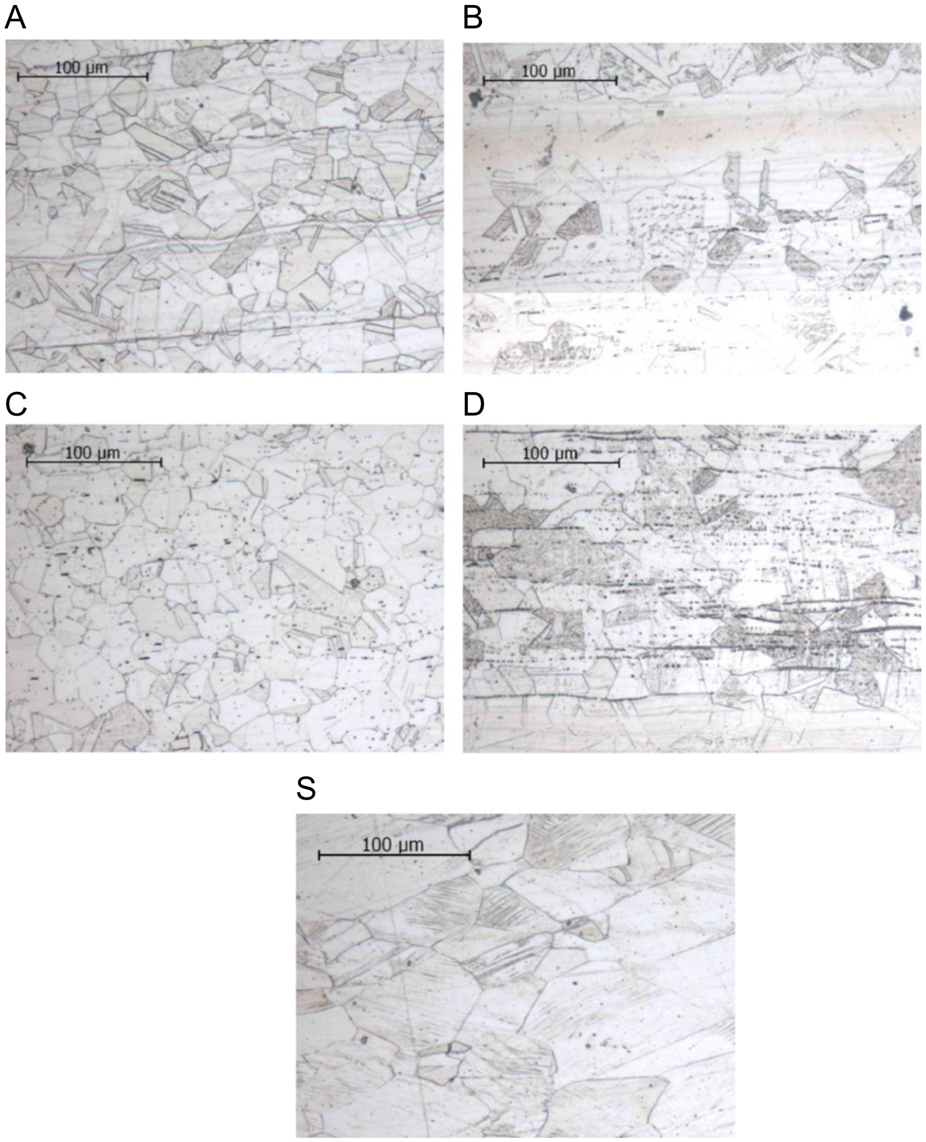

Fig. 6 – Representative pictures of the microstructure of plates from manufacturers A, B, C, D and of the standard plates (S).

Table 4 – Average grain size and hardness value of the plates from manufacturers A, B, C, D, and of standard plates (S).

Manufacturer	Grain size in μm	Hardness value in HV (cross section 5)	Hardness value in HV (cross section 7 and 8)
S	32 ± 19	302 ± 21	332 ± 21
A	26 ± 6	279 ± 23	202 ± 22
B	19 ± 3	212 ± 17	212 ± 21
C	19 ± 9	203 ± 23	206 ± 21
D	16 ± 1	203 ± 14	206 ± 23

4.1. *Chemical composition*

The chemical compositions of the Indonesian plates from manufacturers B, C, and D do not fulfil the requirements from ISO and ASTM. In the plates from manufacturers B and C the lower Nickel and Molybdenum content, and high Carbon content indicates that the materials were most probably stainless steel 304. The plate from manufacturer D which contained lower Nickel and Molybdenum was most probably a 316L stainless steel which is a commercial grade stainless steel and not an implant grade one.

High Nickel content in implant grade material is an important determinant as Nickel is known to influence the ductility, toughness and corrosion resistance of stainless steel material. Molybdenum content in stainless steel 316L is needed to substantially increase the resistance to both general and localised corrosion (Leffler, 2000).

Biocompatibility of stainless steel 316L was studied and presented in the literature (Cook et al., 1984; Cook et al., 1987).

4.2. *Surface defects*

Clear differences were observed between plates from different manufacturers. LPI revealed the presence of defects mainly at the inner side of the holes and in the grooves at the end of the plates which represent a weak step in the production process, most likely due to the use of inappropriate polishing tools by Indonesian manufacturers. Therefore, a relation between the number of cracks and the site of fatigue failure could be expected.

4.3. *Geometry*

Indonesian plates have a wider range in geometry than the standard plate. The width next to a hole in Indonesian plates was found to vary largely, indicating that the position of the hole varied. The smallest width of Indonesian plates was larger than that of the standard plate, so the stress amplification factor of Indonesian plates was smaller than that of the standard plate.

Also the overall geometry differed between the Indonesian manufacturers. This difference necessitated the determination of the area moment of inertia to correct the fatigue data for these geometrical differences.

4.4. *Mechanical properties*

Although 4-point bending is not an actual representation of the clinical situation, which is actually a three point bending, we followed ISO 9585 and ASTM F382-99. Advantage of a 4-point bending is a larger area where the plate is loaded maximally, so this set-up is less critical for correct location of the applied load. In the monotonic loading and fatigue bending tests, all Indonesian-made plates failed consistently at a lower stress as compared to the standard plate. These results of the mechanical test thus showed that Indonesian plates are biomechanically weaker.

Plate A has a high monotonic loading strength, but a low fatigue strength. Since surface roughness is not higher than other plates, this could only be caused by high roughness of the screw holes.

We decided to use 3×10^6 cycles as fatigue endurance limit. This number of cycles is six times more than needed for normal bone healing (Hoppenfeld, 2000). This safety factor amply accommodates with cases of abnormal bone healing, due to complicated fractures, mal- or non-union, and thus represents actual clinical situations. As a consequence, we did not find the fatigue limit, because for austenitic metals like 316L it is only present at more than 10^7 cycles in this case (Dieter and Bacon, 1988; Niinomi, 2000).

4.5. *Metallographic examination and hardness measurement*

Metallographic examination revealed indications of cold deformation in the standard plates, which explains their higher hardness and better strength. Indonesian plates showed a smaller grain size. Since smaller grains should theoretically yield better material strength, the effect of cold deformation on hardness and strength in standard plates appears to be stronger than the effect of a larger grain size in this case (Disegi and Eschbach, 2000).

4.6. *Overall evaluation*

The result of the fatigue and single-cycle strength test of Indonesian-made plates showed that those were less strong than the standard plate. Three causes for this phenomenon were found:

4.6.1. AO-plates are made from stainless steel 316LVM, whereas Indonesian plates are made from stainless steel 316L or even 304 with a lesser quality.
4.6.2. The production methods of the standard plate are kept secret, but most probably a flat plate is forced into a curved shape inducing cold deformation. Grain orientation and micro hardness support this theory. Cold deformation will increase the strength of the plate.
4.6.3. The Indonesian plates show a poor reproducibility of the manufacturing process, often resulting in a great diversity in dimensions. We corrected the fatigue results for the overall dimensions.
4.6.4. Although Indonesian plates show a large eccentricity of the holes, the stress amplification factor of Indonesian plates was smaller than that of the standard plate, so this will not explain the difference in strength.

These findings could be the starting point for a next generation of DCP-plates, manufactured in Indonesia. All three causes can be improved without major investment, resulting in future DCP-plates, produced locally for an affordable price, allowing easy distribution during and after disasters.

5. Conclusion

In conclusion, the Indonesian narrow DCP-plates show an inferior fatigue and monotonic loading strength when compared to the AO standard plate. This is caused by using inferior material, the absence of strengthening plastic deformation in the production process and a poor reproducibility of the manufacturing process.

Conflict of interest statement

All authors disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) this work.

Ethical board review statement

This was an in vitro study. No human or animal subjects were used.

Acknowledgements

The contributions of R. Marius and M. Timmer on performing fatigue experiments and J. Beyer for stimulating discussions are very much appreciated.

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