Mechanical behaviour of low-cost dynamic compression plates correlates with manufacturing quality standards

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Abstract

Purpose This study compares the mechanical properties of low-cost stainless steel dynamic compression plates (DCPs) from developing-world manufacturers, adhering to varying manufacturing quality standards, with those of high-cost DCPs manufactured for use in the developed world.

Methods Standard-design ten-hole DCPs from six developing-world manufacturers and high-cost DCPs from two manufacturers in the developed world were studied. Nine plates from each manufacturer underwent mechanical testing: six in four-point monotonic bending to assess strength and stiffness and three in four-point bending fatigue. Statistical comparisons of the group means of monotonic bending test data were made, and a qualitative comparison was performed to assess failures in fatigue.

Results Low-cost DCPs from manufacturers with at least one manufacturing quality standard had significantly higher bending strength and fewer failures in fatigue than did those from low-cost manufacturers with no recognised quality standards. High-cost DCPs demonstrated greater bending strength than did those in both low-cost groups. There were no differences in stiffness and fatigue failure between high-cost DCPs and those low-cost DCPs with quality standards. However, high-cost DCPs were significantly less stiff and had fewer fatigue failures than low-cost DCPs manufactured without such standards.

Conclusion Significant differences were found in the mechanical properties of ten-hole DCP plates from selected manufacturers in the developing and developed worlds. These differences correlated with reported quality certification in the manufacturing process. Mechanical analysis of low-cost implants may provide information useful in determining which manufacturers produce implants with the best potential for benefit relative to cost.

Keywords dynamic compression plates · mechanical behaviour · international variation · fracture fixation · developing world

Introduction

The dramatic increase in orthopaedic injuries in the developing world has been associated with an increase in the demand for implants used in fracture fixation. In many countries, the cost of such implants is borne by the patient [1]. Regardless of whether an indigent patient or a resource-constrained health system must pay, the high cost of the implants used in high-income countries (HICs) is prohibitive in low and middle-income countries (LMICs). The demand for lower cost implants is currently being met by manufacturers in LMICs, who sell them for a fraction of the price of similar devices from HICs. Many of these manufacturers do not adhere to quality standards of the type recognised and required by governing agencies in the developed world. Required adherence to manufacturing quality standards in the developed world is one factor that is assumed to result in the relatively low incidence of failures in fracture fixation attributable to implants themselves [2]. Despite such requirements, there are no clinical data documenting the minimal mechanical performance of DCPs and the specific manufacturing quality standards required to minimise implant-related failures.

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Table 1 Descriptive data for bone plates, including quality certification

Manufacturer	Location	List price/unit	International quality management systems standards for the manufacture of medical or orthopaedic implants		
			ISO 9001	ISO 13485	CE (EU-based certification body)
HIC(1)	USA	\$232.00	FDA approved for sales in the United States and the EU		
HIC(2)	USA	\$244.00	FDA approved for sales in the United States and the EU		
LMIC(A1)	Pakistan	\$18.75	Yes	No	Yes
LMIC(A2)	Thailand	\$30.00	Yes	Yes	No
LMIC(A3)	India	\$7.00	Yes	Yes	Yes
LMIC(B1)	India	\$12.50	No	No	No (CE 1293 issued by Chinese certification body)
LMIC(B2)	Pakistan	\$6.50	No	No	No
LMIC(B3)	India	\$23.90	No	No	No

The most predictable outcomes in fracture surgery are expected if the implants used are well designed, manufactured to an accepted quality standard, properly implanted, and protected from excessive loading during the early phases of bone healing. Deficiencies in one or more of these factors may explain premature failure of implants used in fracture fixation. Little or no objective test data have been published detailing either the mechanical properties of implants manufactured in LMICs [3] or their clinical performance. Although low-cost implants may appear identical to those manufactured in HICs, anecdotal reports indicate unexpected failures [1, 4].

This study was designed to assess the mechanical characteristics of ten-hole dynamic compression plates (DCPs) from different manufacturers in the developed and developing worlds. Some developing world manufacturers reported adherence to at least one recognised manufacturing quality standard, while others reported no adherence to such standards. We postulated that the mechanical behaviour of DCPs from low-cost manufacturers would correlate with the reported adherence to manufacturing quality standards accepted in the developed world. We further hypothesised that the mechanical behaviour of low-quality, low-cost implants would differ significantly from that of high-cost implants certified for use in the developed world. The primary outcome measures in the study were the results of the mechanical testing of DCPs in bending and fatigue.

Materials and methods

Nine stainless steel ten-hole DCPs from eight different manufacturers (72 plates, total) were used for this study. Two manufacturers with FDA approval for sale of their DCPs in the United States provided 18 plates (Table 1). FDA approval requires that manufacturers obtain certification indicating adherence to certain established quality standards

(see Appendix). The plates from these two manufacturers were sub-grouped as HIC(1) and HIC(2) respectively. Twenty seven DCPs were obtained from three different manufacturers in the developing world that had obtained at least one of the standard manufacturing certifications recognised either in the United States or in the European Union. These plates were divided into three subgroups of nine plates each: LMIC(A1), LMIC(A2), and LMIC(A3). The final three subgroups, designated LMIC(B1), LMIC(B2), and LMIC(B3), each included nine plates obtained from three developing world manufacturers that had no quality certifications from the United States or European Union.

Testing protocol All biomechanical tests were carried out in the Biomechanical Testing Facility at San Francisco General Hospital using American Society for Testing and Materials (ASTM) protocols for testing metallic bone plates (ASTM F382-08) (Fig. 1) [5]. The requested plate dimensions were: 4 mm thickness, 12 mm width, and 170 mm length, with 16 mm centre hole spacing. The thickness, width, screw-

Fig. 1 The four-point bending fixture was configured and set according to ASTM F 382-08

Table 2 Four-point monotonic test data, incorporating the area moment of inertia

Manufacturer	Yield load (N)	Area moment of inertia (mm ⁴)	Normalized bending strength (N/mm ³)	Normalized bending structural stiffness (N/mm ²)
HIC(1)	606.5±55.5	29.9±1.0	325.6±36.7	185100±6273
HIC(2)	632.5±46.0	28.2±0.5	359.4±23.2	182200±6835
LMIC(A1)	530.2±59.7	32.7±0.4	259.5±29.8	188300±8039
LMIC(A2)	817.5±19.6	34.5±0.4	379.3±9.6	203600±2295
LMIC(A3)	644.5±252.1	41.1±5.2	245.7±63.9	183800±8643
LMIC(B1)	322.5±37.2	25.0±1.5	207.1±24.7	190400±13190
LMIC(B2)	415.8±30.6	28.7±0.7	231.6±15.7	192300±7779
LMIC(B3)	342.8±29.9	28.3±2.9	197.3±37.6	204400±24550

hole area, centre span, and hole-to-hole parameters of all DCPs were measured. Because there were slight variations in the width and thickness of plates from different manufacturers, the area moment of inertia (AMI) for each plate was used in calculating *normalised* values for bending strength and bending stiffness (Table 2). The AMI is a property derived from the width multiplied by the thickness to the fourth power, with larger values reflecting a greater resistance to bending forces [6], which were assumed to lie about the neutral axis of the plates [7].

The number of samples per mechanical test was determined based on recommendations from the ASTM F382-08. Six plates from each manufacturer were subjected to monotonic testing to determine bending strength and stiffness, while the remaining three plates were subjected to fatigue testing to determine the fatigue life. All testing was conducted with a servo-hydraulic testing machine (858 Mini Bionix, MTS, Eden Prairie, MN) using a four-point bending fixture. The loading and support rollers were positioned as described by ASTM F382-08 (Fig. 1). The distance between the loading rollers

was 41.2 mm and between the support rollers was 105.2 mm. In monotonic testing, each DCP was loaded in the four-point bending fixture with the bone contact surface of the plate in contact with the loading rollers. For the bending tests, plates were loaded at a displacement rate of 2 mm/min, and data collected until the ultimate load was surpassed.

Outcome measures The primary outcome measures were the normalised values for bending strength and stiffness and the results of fatigue testing. Bending stiffness (*k*) was determined by measuring the slope of the linear portion of the load-displacement curve (Fig. 2). The bending structural stiffness (*EI*) was derived from the four-point bend loading apparatus and was determined per ASTM F382-08 as:

$$\text{Bending Structural Stiffness} = EI = [(2h + 3a) kh^2/12,$$

where *E* is the modulus of elasticity, *I* is moment of inertia, *h* is the loading span distance between the loading roller and nearest support roller (32 mm), *a* is the center span distance between

Fig. 2 This load-displacement curve represents the behaviour of most solid materials. Bending stiffness is calculated from the slope of the linear elastic portion of the load-displacement curve. The yield load (point C) is derived from the intersect point created by constructing a line with the same slope as the elastic portion of the curve, drawn from the point A representing 0.2 % offset displacement. The ultimate load (point D) is the load leading to fracture

Fig. 3 Mean values for normalised bending strength (N/mm^2), with standard deviation bars, in the three experimental groups

the loading rollers (41.2 mm), and k is the measured bending stiffness. Bending strength was calculated using the formula:

$$\text{Bending Strength} = Ph/2,$$

where h is the loading span distance, and P is the yield (proof) load, defined by a 0.2 % offset of the linear portion of the load-displacement curve (Fig. 2).

Fatigue testing was carried out by first determining the mean yield load for the plates from the HIC subgroups. A load corresponding to 75 % of the HIC mean value was used to load all LMIC (A) and LMIC (B) plates in fatigue testing. The fatigue tests were run using a sinusoidal cyclic load waveform at a constant frequency of 5 Hz in the four-point bending apparatus (ASTM F382-08) [5]. Fatigue testing was considered complete when either the limit of one million run-out-cycles was reached or when failure occurred earlier, either through cracking or plastic deformation, resulting in displacement greater than twice the initial displacement [8, 9].

Statistical methods Mean values for normalised bending strength and stiffness were calculated for plates from the HIC group, the LMIC (A) group, and the LMIC (B) group. Statistical comparisons between these groups were made using a one-way ANOVA with Bonferroni post-hoc test of multiple comparisons with a significance level of $p < 0.05$. Because fatigue testing was done on a small number of plates, a qualitative comparison of fatigue performance was performed.

Results

Normalized bending strength and stiffness Significant differences were noted in the normalized bending strength and the stiffness of plates in the three groups (Figs. 3 and 4). The plates from manufacturers with at least one quality standard certification (LMIC(A) plates) demonstrated

Fig. 4 Mean values for normalised bending structural stiffness (N/mm^3) in the three groups with standard deviation bars

significantly lower normalised bending strength than the HIC plates, but higher strength than those from the manufacturers with no quality standard certifications (LMIC(B)). In terms of normalised bending stiffness, the LMIC(A) plates were no different than either the HIC group or the LMIC(B) group. The LMIC(B) plates had significantly lower normalised bending strength and higher bending stiffness when compared with HIC plates. In summary, the HIC plates had the highest bending strength and the lowest bending stiffness. In contrast, the LMIC(B) plates, manufactured without documented quality standards, tended to have the lowest bending strength and the greatest bending stiffness.

Fatigue testing Fatigue testing revealed failures in ten of the 24 plates tested (42 %): two of six from the HIC group, one of nine from the LMIC(A) group, and seven of nine from the LMIC(B) group (Table 4). Of the ten failures, five occurred due to cracking and five to deformation (Fig. 5a and b). The three plates that failed due to cracking, consistently developed cracks at a screw hole adjacent to and central to a loading roller. The finding of fatigue failure in two of the six plates in the HIC group was unexpected and is of interest because the failures occurred at 310,001 and 780,000 cycles, well within the limit of 1,000,000 cycles used in the test. Five of the seven

Table 3 Comparison of group means for normalised bending strength and stiffness

Group comparisons	Normalised bending strength (N/mm^3) Statistically significant difference ($p < 0.05$)	Normalised bending structural stiffness (N/mm^2)
LMIC(A) versus HIC	Yes	No
LMIC(B) versus HIC	Yes	Yes
LMIC(A) versus LMIC(B)	Yes	No

Table 4 Results for the 24 DCPs that underwent fatigue testing in a four-point bending mode

Manufacturer	Plate #1 fatigue cycles	Failure	Plate #2 fatigue cycles	Failure	Plate #3 fatigue cycles	Failure
HIC(1)	1,000,001	Passed	1,000,001	Passed	1,000,001	Passed
HIC(2)	310,001	Cracking	1,000,001	Passed	780,000	Cracking
LMIC(A1)	1,000,001	Passed	1,000,001	Passed	1,000,001	Passed
LMIC(A2)	1,000,001	Passed	1,000,001	Passed	1,000,001	Passed
LMIC(A3)	505,001	Cracking	1,000,001	Passed	1,000,001	Passed
LMIC(B1)	245,001	Cracking	180,001	Cracking	297	Deformation
LMIC(B2)	1,000,001	Deformation	1,000,001	Passed	1,000,001	Passed
LMIC(B3)	95,001	Deformation	1,000,001	Deformation	235,001	Deformation

plates that failed in the LMIB(B) group did so due to deformation. Of note is the finding that two of the five plates that failed due to deformation completed the course of 1,000,000 cycles, at which time permanent deformation was observed. The remaining three failed in deformation early in the testing—at 297 cycles, 95,001 cycles, and 235,001 cycles.

Discussion

In resource-constrained settings, where the burden of orthopaedic trauma is greatest, a major roadblock in the surgical care of fractures is the high cost of surgical implants, a problem that is mitigated to some extent by the manufacture

of low-cost implants in the developing world. To date, there has been little or no information about the mechanical performance of such implants nor about which factors, such as adherence to manufacturing quality standards, might affect such performance [6, 8, 10–13]. This study shows that bone plates from selected implant manufacturers in the developed and developing worlds display significant differences in mechanical performance. Among the implants studied, there is an apparent correlation between manufacturing quality standards and the results of mechanical testing.

The mechanical properties of fracture fixation implants are of key importance during the initial healing period when there is lack of bone continuity. After surgery, patients in developing countries may begin unrestricted weight-bearing as soon as possible, when pain permits, due to socio-economic factors or inadequate postoperative supervision. In such settings, fracture fixation implants must be sufficiently strong to counteract any excessive mechanical forces that might disrupt bone healing. Such implants are not designed, in themselves, to withstand long-term repetitive loading of the magnitude to which intact femoral and tibial diaphyseal bone is subjected [8, 14]. The goal in the design of implants such as DCPs is to provide a balance between strength and stiffness. Sufficient bending strength is required to prevent early failure under excessive loading conditions. However, DCPs that are too stiff may shield the fracture site from the minimum stresses required to enhance periosteal callus formation essential for bone healing and remodelling. For this reason, it is desirable to design fixation devices that are sufficiently strong, yet flexible enough (less stiff), to promote optimal fracture healing [14, 15]. Those low-cost plates made by developing world manufacturers that adhered to at least one manufacturing quality standard exhibited strength and stiffness closer to that of FDA-approved high cost implants than those low-cost DCPs made without any such standards.

The study also demonstrated that test failures due to permanent deformation and fatigue fracture occurred at a higher rate in the lower quality DCPs. The conditions for fatigue testing were designed to reflect the conditions present

Fig. 5 a. Five DCPs failed in fatigue due to cracking (arrow). b. Five DCPs failed due to deformation.

during fracture healing, which normally occurs in three to four months. The 1 M cycle testing limit is based on an estimate of 5,000–14,000 load cycles per day during the approximate 12–16 weeks required for fracture healing. It was estimated that 0.5 to 1.6 million loading cycles might occur during the time required to achieve bone union [9, 16]. In most cases where permanent deformation occurred and in all cases where fatigue fracture was observed, failure was encountered at less than 1 M cycles.

In those bone plates that failed by fracture, the occurrence of cracks at the screw hole adjacent to the loading roller is consistent with previous studies in which it was shown that plates are most susceptible to fracture at the level of the screw holes [3, 11]. Manufacturing issues, including gross defects in the processing of the screw-hole and surface finishing, can influence implant fatigue life, and have been identified in bone plates [3]. Fatigue crack initiation has been attributed to non-metallic inclusion bodies embedded in the surface, perhaps due to processing [9, 16]. It is not known which, if any, of these possible causes may have led to the cracking failures observed in our study.

This study has some limitations. The first is that the conclusions are limited by the fact that a small number of implants from a few manufacturers were tested. A second limitation is that testing was carried out on the plates alone rather than on a fracture fixation scenario. It can be contended, however, that the four-point bending conditions in this study do approximate the actual bending forces encountered by fracture implants in vivo. A third limitation is that the constant cyclical loading in the fatigue testing protocol does not reflect discontinuous loading conditions in vivo. The final limitation is a lack of published reference data on the minimum strength, stiffness and fatigue characteristics for DCP plates required to achieve reliable fracture union. Without such data, one can only speculate as to whether adverse clinical outcomes might be related to suboptimal mechanical characteristics of the type observed. Considerable difficulties exist in performing clinical studies in low-income countries to answer such questions, given both the lack of research funding and the challenges in publishing such studies in high-impact orthopaedic journals [17].

Adherence to accepted quality standards in the manufacturing process and mechanical testing may lead to the use of fracture fixation implants in the developing world with the best potential for benefit relative to cost. The cost difference for such implants is significant compared with those manufactured in the developed world. The mean price of the low-cost DCPs in this study was 3–13 % of that of the high-cost implants. Of note is the fact that those low-cost DCPs from manufacturers with at least one quality standard had relatively good mechanical characteristics and a mean price that was only 8 % of that of the high-cost plates.

Economic necessity will require the continued use of low-cost fracture implants in the developing world. The minimal acceptable mechanical characteristics for such implants is unknown and can be determined in the future only by properly conducted prospective studies. Nonetheless, it is reasonable to predict that implants most likely to perform poorly in clinical practice will have characteristics similar to those of the low-cost, lower quality plates in this study, which were found to be significantly weaker, stiffer, and more prone to fatigue than those manufactured with recognised quality standards.

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Conflict of interest The authors declare that they have no conflict of interest.

Appendix

- i) **International Organization for Standards (ISO) 9001** is a Quality Management System (QMS) that describes the requirements that manufacturing organizations must fulfill to meet the needs of consumers. This standard requires third party certification to confirm independently that the ISO 9001 requirements are met.
- ii) **ISO 13485:** This certification contains requirements for a comprehensive quality management system specific for the design and manufacture of medical devices. It requires that the quality system be implemented and maintained. Unlike ISO 9001, it does not require a third party to confirm continued compliance.
- iii) **GMP:** Good Manufacturing Practice requirements represent a quality management system covering the manufacture of medical devices. GMP covers aspects of production and testing that can have an impact on the quality of a product, involving processes in design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. This certification is issued locally, and designated cGMP if current.
- iv) **Medical Device Directive (MDD) 93/42/EEC:** this guideline ensures that devices are designed and manufactured in a way that does not compromise the clinical condition or safety of a patient and that they fulfill the manufacturer's intended purpose. It requires manufacturers to demonstrate safety, quality, and efficacy before their product can be sold to consumers.
- v) **European Conformity (CE):** This certification is issued by an independent certification body after verification that a medical device manufacturer is in compliance with MDD 93/42/EEC.

- a. **CNC:** Issued by a German certification company in compliance with Medical Device Directive MDD 93/42/EEC.
- b. **CE 1293:** Issued by a Chinese certification company in compliance with MDD 93/42/EEC.
- c. **CE 0086:** Issued by a UK certification company in compliance with MDD 93/42/EEC.
- d. **CE 1023:** Issued by a Czech Republic certification company in compliance with MDD 93/42/EEC.
- e. **CE 0434:** Issued by a Norwegian certification company in compliance with MDD 93/42/EEC.

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