Evaluation and redesign of osteosynthesis plate, produsedin Indonesia

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1 Introduction

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1.1. Preface

Problems in developing countries with regards to orthopaedic trauma surgery

There are many problems in developing countries which may, more than in the western world, result in the occurrence of musculoskeletal injuries. First of all, natural disasters like earthquakes are known to happen in several developing countries, especially in Indonesia. Secondly, traffic accidents, giving rise to an enormous number of musculoskeletal injuries are expected to increase due to the swelling number of vehicles on the roads. Also the speed with which these vehicles are being driven is higher than in former days, without a concomitant increase in the proper infrastructure such as the roads and traffic management system. Since these accidents involve a great number of fractures there is a growing need for orthopaedic implants such as plates and screws and other appliances in the developing world.

There are economic disparities between the developed and developing world, for instance insurance coverage in developing countries is low. The majority of the patients who suffer from injuries sustained due to traffic accidents have to pay cash out of their pockets to get proper treatment. This is for many of them very hard due to their low income, since most of them require surgery with the use of implants to stabilize the fractures sustained. These implants are mostly imported from the developed countries, in particular Switzerland where they are being manufactured. This in turn prevents some medical centers from obtaining the most recent applications of this expensive technology. ”Yesterday” technology may however, still be used safely in Indonesia if a good quality of the implant together with an appropriate medical indication and technique of the operation involved is applied.

Biomaterials issues in orthopaedic trauma surgery

Since the beginning of fracture treatment, the implantation of plates and screws as well as other orthopaedic devices like intramedullary devices and external fixators has been the standard treatment of surgical stabilization. Plates for internal fixation of fractures have been used for more than 100 years, i.e since it was introduced by Lane in 1895. Initial shortcomings such as corrosion and insufficient strength have been overcome to some extent after the utilization of implant grade materials such as 316 L stainless steel and titanium alloys. Since the cost of imported implants is high, and 316 L stainless steel is available in Indonesia, there are small home based manufacturers producing orthopaedic devices to fulfill

the community need. These devices have gone freely to the market, and are being used by some orthopaedic surgeons in their daily clinical practice. There is unfortunately no scientific evaluation of the quality of these Indonesian-made orthopaedic devices. Most orthopaedic surgeons are aware of this shortcoming and therefor are reluctant to use them.

1.2. Treating natural disaster victims is dealing with shortages – An orthopaedics perspective

A heavy earthquake, with a magnitude of 6.3 on the Richter scale, struck the Indonesian island Java on 27 May 2006 at 05:54 local time around 25 km south-southeast of the city of Jogjakarta. The earthquake caused 5,782 deaths, while 36,299 people were injured, 135,000 houses damaged, and an estimated 1.5 million people were left homeless. The Tsunami of 26 December 2004[1] caused world-wide 186,983 deaths, 125.000 injured and 42,883 missing persons.

Earthquake and Tsunami casualties are known to suffer mainly from musculoskeletal injuries, especially fractures due to collapsed walls and other building structures. After the Jogjakarta earthquake, almost 60% of all injured people were casualties with fractures requiring orthopaedic surgery (Figure 1). This constituted an impossible task for the seven orthopaedic surgeons practicing in the city of Jogjakarta. In addition, many paramedics happened to live in the Bantul district, which suffered most from the earthquake. The board of directors of the Indonesian Orthopaedic Association (PABOI) and the National Coordination Board for Disaster (BAKORNAS) responded fast to this disaster and directed orthopaedic surgeons and surgery teams from almost all over Indonesia to Jogjakarta to assist in treating the casualties. These and foreign relieve teams had to reach Jogjakarta by car or via the nearby airport of Solo, since the Jogjakarta airport and railway station were closed due to heavy damage. During the first days after the earthquake, surgical teams worked around the clock, mostly doing debridement of wounds and provisional stabilisation of fractures.

Figure 1. Earthquake and tsunami victims

In Sardjito General Hospital, the referral hospital in Jogjakarta, 15 surgery teams worked simultaneously, and within 3 x 24 hours the acute phase for all casualties was considered over (Tables 1 – 4). That was only the beginning, however, of the overall work to be done, because now patients either needed definitive surgery for their fractures, or a second operation for infected wounds. Infections were rampant since antibiotics, mandatory in the treatment of open fractures, were not available for such large numbers of casualties. Moreover, often the definitive fixation of fractures was impossible due to lack of osteosynthesis plates, screws, nails and external fixators, which all have to be imported from Western countries (Figure 2).

The lack of bone plates has three causes. First, imported bone plates are very expensive. Although not officially stated, the Indonesian ministry of health initially said that their budget could only provide surgical implants for one thousand patients, which is only a fraction of the number of patients in need of a bone plate. Moreover, most people in Indonesia have no health care insurance. When they suffer from illnesses, like fractures due to

Table 1
Number of casualties treated in Dr. Sardjito hospital by age and gender after the May 2006 earthquake on the Indonesian island java

Age (y.o)	Gender		Total	Death
	Female	Male		
0-10	24	21	45	
11-20	48	36	84	
21-30	253	111	364	21
31-40	265	176	441	13
41-50	167	86	253	11
51-60	122	96	218	18
61-70	55	36	91	31
71-80	29	24	53	24
>81	15	13	28	11
TOTAL	978	599	1577	129 (8.2%)

Table 2
Number of casualties treated in Dr Sardjito hospital by age and region after the may 2006 earthquake on the Indonesian island java

Age (y.o.)	Region			TOTAL
	Lower extremity	Upper extremity	Upper and lower	
0-10	24	21	-	45
11-20	44	34	6	84
21-30	196	76	12	284
31-40	244	117	8	369
41-50	182	36	5	223
51-60	86	56	4	146
61-70	53	22	-	75
71-80	18	14	11	43
>81	5	4	3	12
TOTAL	852	380	49	1281

Table 3
Number of multiple injured casualties treated in Dr. Sardjito hospital after the May 2006 earthquake on the Indonesian island java

Lesion site (Primary)	Head	Chest	Abdominal	Pelvic	Spine	TOTAL
Upper Extremity	23	6	3	-	-	32
Lower Extremity	31	29	-	13	17	90
Head	25	-	-	-	-	25
Chest	17	46	-	-	-	63
Abdominal	-	-	40	-	-	40
Pelvic	14	-	-	32	-	46
Spine	33	-	-	14	75	122
TOTAL	**143**	**81**	**43**	**59**	**92**	**418**

Table 4
Number of casualties with open fractures treated in Dr. Sardjito hospital after the May 2006 earthquake on the Indonesian island java

Gustilo Classification	Upper Extremity	Lower Extremity	Number of patients	Intervention treatment		
				ORIF	External Fixatio n	Plaster cast
Type I	17	31	48	12	-	36
Type II	13	34	47	24	8	15
Type III:						
A	31	114	145	-	145	-
B	37	116	153	-	153	-
C	1	11	12	-	-	-
Total	99	306	405	36	306	51

Figure 2. Fracture fixation using osteosynthesis plate

the frequently occuring traffic accidents, and need surgery, they usually cannot afford the high costs of an operation and imported osteosynthesis plates. An orthopaedic operation using an osteosynthesis plate in Indonesia costs about USD 700 or more. Considering that the Gross Domestic Product (GDP) in Indonesia is USD 3,390, while only USD 110 is spent on health care per capita per annum[2], it becomes clear that adequate treatment for the earthquake victims according to Western standards is impossible. Secondly, importing bone plates from Europe is performed by Synthes Indonesia, the local representative of the European bone plate manufacturer (Synthes Representative Office Indonesia, through PT Merapi Utama Farma). Synthes Indonesia does not have that many implants in stock and even collecting plates and screws from nearby countries did not yield a sufficient number of plates to treat all victims. Thirdly, donated surgical instruments and implants from overseas were delayed after arrival due to custom procedures and destroyed transport connections[3].

In order to overcome the shortage of surgical implants, implants can be re-used after appropriate cleaning[4], but this is only done reluctantly and the availability of used bone plates is decreasing. The second alternative is utilization of local resources. Locally produced osteosynthesis plates are much cheaper and can be obtained faster than from abroad. In Indonesia there are at least four local manufacturers producing bone plates. Until recently, only a few Indonesian orthopaedic surgeons were willing to use locally produced osteosynthesis plates because there is no scientific evidence available of their quality. Locally produced bone plates have to be proven safe to use, and meet the international standards with regard to surface properties like roughness and wettability in relation to the biomaterial centered infection, and with regard to mechanical properties like strength and resistance to fatigue, in order to convince orthopaedic surgeons to use them. Lack of knowledge on testing procedures and lack of testing equipment in Indonesia and other developing countries prevents rigorous studies on the quality of bone plates produced locally in the developing countries. Simultaneously, unawareness, lack of scientific challenge and associated poor chances of acceptance of scientific manuscripts dealing with evaluations of biomedical products made in developing countries, have demotivated scientists in the Western world to undertake such necessary studies. Incidentally it is noted, that other major disasters, like the south Asian Tsunami in the Indian ocean, and Katrina Hurricane in New Orleans experienced similar problems[5,6]. Long-term recovery and rehabilitation in the presence of the above described shortages are poorly understood, which constitutes a continuous threat to the victims, even many years after the disaster. Because the international attention is fading rapidly within days after a disaster[7], international support for long-term recovery and rehabilitation programs is only limited.

Through this paper we would like to urge the international community to include locally produced biomedical products, like osteosynthesis plates in their scientific evaluations and communications. International research on these products should be stimulated and considered in peer-reviewed journals. When the quality of local products is proven, the reluctance to use local products also by surgeons from developing countries, will disappear and larger scale production can be initiated. This in its turn, solves many transport problems after natural disasters. As an extra advantage, local economies will be stimulated on an efficient and effective way.

1.3. Analysis of Indonesian explanted bone plates

In order to study the quality of locally produced Narrow Dynamic Compression Plates Narrow DCP), the most commonly used osteosynthesis plates in orthopaedic trauma surgery in developing countries, a small retrieval study was set up. Five surgeons from four different centers across Java were approached and agreed to cooperate in this study. A larger scale study would have been envied, but turned out to be impossible due to the reluctancy of most surgeons to cooperate, while in addition most of the patients wanted to keep their bone plates in order to sell them to other patients. Informed consent was asked from patients to have their explanted plates kept by the surgeon. Surgeons were asked to provide relevant clinical information of each patient such as the age of patient, body weight, the duration of in situ (inside the body) use of the plate, and the reason for explantation. During a 1-year retrieval period of study, only 21 explanted Indonesian Narrow DCPs were received out of about 30 operations, as several patients refused the consent. Fourteen plates were from Marthys (local home-industry in Surabaya), three from Osfix (local home-industry in Surabaya), two from FAB (local home-industry in Bandung), and two from Cimahi (local home-industry in Bandung). Note that the ratio between the number of plates involved from each company is roughly in accordance with the market shares of the four different local manufacturers across Indonesia.

Plates were examined for evidence of mechanical damage and corrosion. Three plates appeared to be broken. One broken plate was from a 70 year old male and broke only 3 months after operation, while the other two broken plates were from 40 and 35 year old males and these broke six months post-operatively. All broken plates were from Marthys. The weights of all patients with broken plates were about the same, i.e. 60 kg, while the average weight of the entire group of patients was 55 ± 13 kg. All plates were broken at the inner most screw hole, which did not contain a screw. All plates broke during their service before the required time for bone healing had elapsed (about 6 months for solid union of bone[8]), while surgical procedures during implantation were considered correct and a proper rehabilitation program after the operation had been initiated in all patients. Signs of corrosion on the surface of the plates nearby the screw hole and crevice/interface corrosion in screw holes were found in three plates that had been in situ for more than 18 months (two plates from Marthys and one from Cimahi).

From this limited study, it can be concluded that the risks involved in using locally produced Indonesian osteosynthesis plates are considerable, justifying the reluctance of many Indonesian orthopaedic surgeons to use locally produced osteosynthesis plates. This small study furthermore suggests that the quality of locally produced plates is lower than of the standard AO Narrow Dynamic Compression Plates (Arbeitsgemeinschaft für Osteosynthesefragen / Association for the Study of Internal Fixation Davos, Switzerland)[9].

1.4. Goals of this thesis

The first goal of this thesis was to determine the quality of locally produced Narrow Dynamic Compression plates, as defined by their surface physico-chemical and mechanical properties. Surface properties like corrosion resistance, roughness and wettability determine the acceptance of the material by the body, and their infection resistance[10,11]. Mechanical properties like strength, resistance to fatigue and stiffness determine their lifetime and effectiveness in maintaining a relatively motion-free environment for bone healing. These aspects are important tools to convince orthopaedic surgeons to use or not to use locally produced bone plates.

The second goal was to suggest changes in the local manufacturing processes in order to realize improved osteosynthesis plates, with properties that are comparable to the golden standard, i.e. the AO Narrow Dynamic Compression Plate.

Plates produced by the four Indonesian manufacturers, mentioned in Chapter 1.2 were evaluated for surface and mechanical properties. In chapter 2, surface properties were evaluated, including water contact angles, surface roughnesses and elemental surface compositions by X-ray photoelectron spectroscopy (XPS) in order to reveal the surface condition after the manufacturing process. Bulk chemical composition was evaluated using energy-dispersive X-ray spectroscopy (EDXS). The corrosion resistance of the plates in vitro was determined in phosphate buffered saline (PBS), which mimicks natural body fluids with respect to ionic strength.

In chapter 3, mechanical properties of the locally produced plates were evaluated, including their elastic limit and their fatigue strength. Geometry of the plates and the bulk properties including the grain size, grain orientation and micro hardness were also taken into account.

In chapter 4, proposals are made and evaluated to increase the strength of the plates using simple means. Metals can be strengthened by mechanical deformation. Heavy deformation is one of the conventional ways which can strengthen a metal through refinement of its microstructure[12]. The most recent improvement is the emergence of nanocrystalline materials. According to the relation between mechanical properties and observed grain size (Hall-Petch relationship), a nanostructured material will have greatly enhanced mechanical properties compared to larger grained counterparts[13]. Failures of materials mostly initiate from the surface, where the stresses are highest. Therefore surface modification by creating a nanostructured surface layer can be expected to improve the mechanical properties of the material, especially its fatigue strength. Refinement of the grain size on the surface without changing the structure of the coarse-grained matrix can be done by using a recently developed surface mechanical attrition treatment (SMAT). This treatment basically transforms the microstructure of the surface into a nanostructured surface layer by means of introducing a large amount of defects and/or interfaces into the surface layer[14,15,16]. Both heavy deformation and SMAT were applied to Indonesian plates and evaluated by determining the fatigue strength of treated plates.

Chapter 5 constitutes a general discussion of what has been achieved and the feasibility of implementing the suggestions developed for local manufacturing processes in developing countries. Recommendations for the manufacturers to produce plates with a comparable performance to AO standard plate, based as much as possible on their local traditions, are listed, as well as for treating physicians using locally produced plates.

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