Comparative Study of Tissue Reaction Following Local-Made Plating and Imported Plating of Long Bone Fracture

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Background: *In the medical field, local made implants have been widely used throughout the country. However, there is less available information regarding the quality and standard of the implant.*
Objective: *To compare the occurrence of biologic tissue reactions between the uses of imported versus local plates.*
Material and Method: *Between September 2004 and July 2006, 40 united tibia fractures with satisfactory outcomes and radiographic union were evaluated for tissue reaction. Twenty patients were fixed with local plates and the other twenty patients were fixed with imported plates (AO brand). Informed consent was obtained. The evaluation was performed blinded by one pathologist. Fibrosis, foreign body reaction, inflammation, and the presence of metal particles were classified on a modified four-point scale, as described by Mathiesen et al.*
Results: *There are 38 males and two females. The average age was 30.2 years (local) and 32 years (imported). Four patients, two with imported plate and two with local plate, showed significant discoloration of soft tissue adjacent to the plate. Histologically there was no significant difference between imported and local plates by Chi-square test.*
Conclusion: *The current study emphasizes the clinical significance of corroded effects following metal fixation. The present study did not reveal any significant difference in biologic reaction between local plate and imported plate.*

Keywords: *Biologic tissue reaction, Plate fixation, Local made plate fixation, Long bone fracture*

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All metallic implants corrode[1-4]. This may be due to either from the quality of metallurgical composition or the specific design and construction by the manufacturer[3-7]. Local oxygen concentration and pH, mechanical stresses, and the presence of proteins may also influence the tendency to corrosion[8,9]. During surgical application, the corrosion resistance of stainless steel metal provided by a protective film of oxide can be easily damaged[4,9].

Worldwide, the austenitic stainless steel plate and screws are the most often used material for fracture fixation treatment[8]. In Thailand, locally manufactured products (local-made stainless plate) using imported materials are common and have been widely used throughout the country. However, there is little information available regarding the quality and standard of these implants.

The objective of the present study is to compare the occurrence of biologic tissue reactions between the uses of local-made versus imported plates.

Material and Method

Between September 2004 and July 2006, 40 patients sustained closed fracture tibia with satisfactory outcomes were included in the present

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study. The proposal was approved by the Hospital Ethical and Research Review Board. Patients were categorized into two groups based on type of plate fixation. Twenty patients (19 males and 1 female) were fixed with local-made plates (produced by Profix company) and the other twenty patients (19 males and 1 female) were fixed with imported plates (AO brand). All had clinical and radiographic union assessed by standard criteria. The films taken before plate removal showed complete obliteration of fracture line and all the patients can fully ambulate without pain and walking aids. Informed consent was obtained from every patient for implant removal.

All patients were scheduled for elective surgery without given any preoperative and post-operative antibiotics. All had a similar intraoperative and postoperative regime, and were followed up for 3 months. During the removal procedure, the tissue around the plate, approximately 1 x 1 cm was collected and preserved in 10% buffer formalin. The obtained specific tissues were stained with hematoxylin-eosin and consecutively arranged by Arabic number 1 to 40. The evaluation of the specimens was performed blinded by one pathologist.

Fibrosis, reactive new bone formation, vascularity, foreign body reaction, inflammation, the presence of metal particles, and cell components were classified on a three-class scale, as described by Mathiesen et al[10]. Chi-square test or Fisher's exact test where appropriate was used to find the difference between the two groups with p-value was set at 0.05 as statistically significant difference.

Results

There were 38 male and two female patients. The mean time to union was 8.5 weeks without malalignment. The two groups were gender-matched (Table 1). The average age was 30.2 years (local-made) and 32 years (imported). There was no significant difference of joint motion between the two groups. Intraoperative findings, all 40 fractures had definite bone union.

The consistent findings of the specimens taken were dense fibrous tissue covering the implants in 36 cases. In general, no substantial difference in gross morphology was observed between groups. Four patients (with two imported and two local-made) showed significant discoloration of local soft tissue adjacent to the plate with less fibrous covering.

The histological results are summarized in Table 2. The metal deposits were localized in nearby vessels or embedded in the fibrous tissue (Fig. 1, 2). All specimens contained mostly macrophages and lymphocrytes with proliteration of capillaries. In areas with a high concentration of metal particles, the dark

Table 1. Demographic data between local and imported plate

	Local	Imported
Male	19	19
Female	1	1
Age (yrs)	30.2	32
Site of fracture		
Proximal 1/3	2	3
Shaft	15	15
Distal 1/3	3	2
Radiological union (months)	20	19.5
Number of screws		
9	5	4
8	12	12
7	3	4

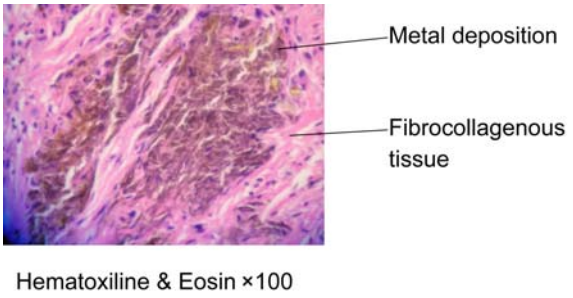

Fig. 1 Histology of soft tissues surrounding imported plate showing metal deposition

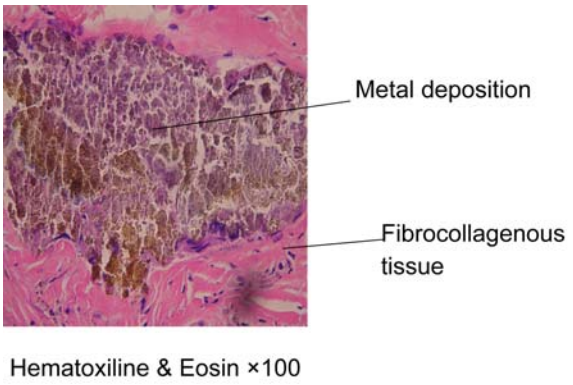

Fig. 2 Histology of soft tissues surrounding local plate showing metal deposition

Table 2. Histopathologic findings of local-made and imported plates

	Local-made plate n = 20	Imported plate n = 20	p-value
Osteoblastic activity	4 (20%)	4 (20%)	>0.05
Reactive new bone formation	5 (25%)	4 (20%)	>0.05
Grade 1	3 (15%)	3 (15%)	
Grade 2	2 (10%)	1 (5%)	
Vascularity (base line = +)	5 (25%)	7 (35%)	>0.05
Fibrosis (base line = +)	6 (30%)	8 (40%)	>0.05
Inflammatory reaction	19 (95%)	19 (95%)	>0.05
Cell components			
L	18 (90%)	18 (90%)	>0.05
M	16 (80%)	16 (80%)	>0.05
N	2 (10%)	2 (10%)	>0.05
E	3 (15%)	1 (5%)	>0.05
G	0	1 (5%)	>0.05
P	3 (15%)	1 (5%)	>0.05
H	3 (15%)	3 (15%)	>0.05
Metal deposition	10 (50%)	11 (55%)	>0.05
Grade 1	5 (25%)	6 (30%)	
Grade 2	3 (15%)	3 (15%)	
Grade 3	2 (10%)	2 (10%)	
Fibrin material	4 (20%)	4 (20%)	>0.05

Three classes scale as described by Mathiesen (O-negative finding; 1 ± the amount was small or moderate; 2 ± the amount was extensive)

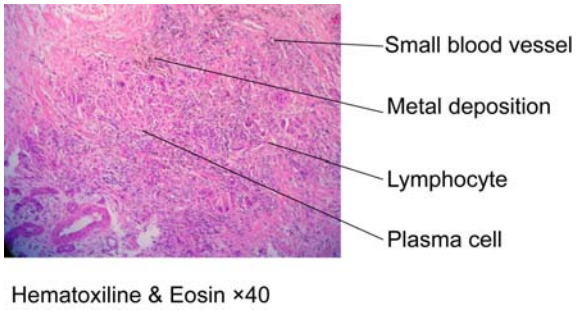

Fig. 3 Histology of soft tissues surrounding imported plate showing vascularity

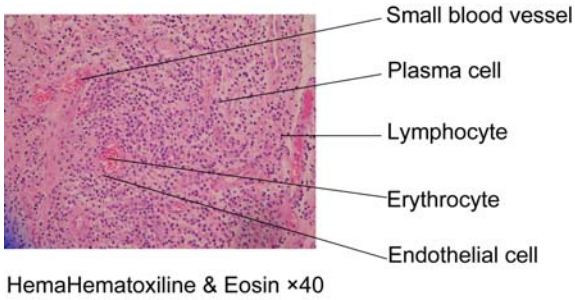

Fig. 4 Histology of soft tissues surrounding local plate showing vascularity

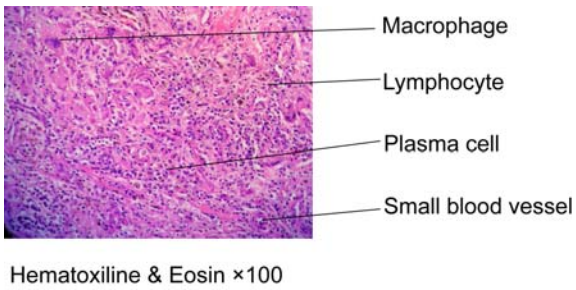

Fig. 5 Histology of soft tissues surrounding imported plate showing inflammatory reaction

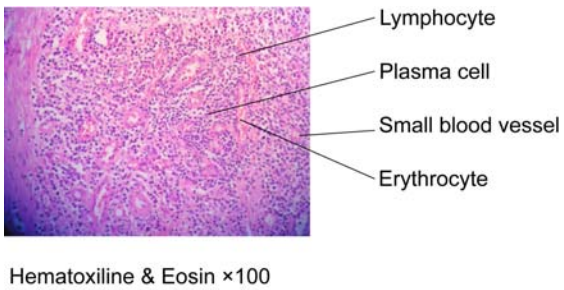

Fig. 6 Histology of soft tissues surrounding local plate showing inflammatory reaction

deposits occupied the cellular structure of the tissue. Chi-square analysis or Fisher's exact test was used to compare the histopathologic findings between groups. By the rating systems, there was no significant difference between imported and local-made plate groups.

Discussion

Complications attending the use of metal implants and degradation products in orthopedic surgery continue to occur[3,4,9,10]. Parts of these, which are caused by extreme wear and corrosion, have both local and generalized effects. Locally, by the accumulation of particles produced by wearing of metal, tissue surrounding implants are subjected to change and can be observed on the contact areas of implants and articulating prosthetic components. The gross and microscopic appearance of infiltrative tissues at the implants site termed as metallosis can be varied by various influential factors. Tissue necrosis, swelling, marked inflammation and pain has been noted as main manifestation of the consequences and has been shown to play major roles in the loosening of implants[4]. Although intended fixation and prosthesis are inserted into the bone routinely, the bio-incompatibility of the materials is always underestimated and not adequately discussed. In the present study, the findings of heavy metal deposition were demonstrated in four cases. The occurring risk may thus be small but should not be neglected.

No implants can be judged as inert. All release metallic ions to the surrounding tissue when implanted in the body[11-17]. These interacted biologic effects may be classified as metabolic, bacteriologic, immunogenic, and oncogenic reactions. Although the current study cannot reveal a clinically significant correlation between types of the implants, the presented result does substantiate the existence of biological reaction following stainless plate fixation. The findings, for the most part are consistent with other published reports[2,4,9-11]. Constant features are the covering of the device by connective tissue containing metal particles. The thickness of the fibrous tissue changes has been proposed and observed to be varied by degree of chronic inflammation. The eliminating process of foreign materials, by the appearance of various infiltrative cells can be progress to tissue damage[9,15,17]. Despite having few remarks on implant-to tissue cytotoxicity[2,13], the current study cannot reveal this chemical reactivity. Limitations were the quite small number of patients and the lack of metal analysis for mechanical damage and the presence of corrosion.

The metallurgical analysis of retrieved implants has shown that the materials do not always meet current standards[4,7,8]. More than 75% of all retrieval stainless steel components were found to be corroded all over. By the reports, the plate-screw devices are particularly prone to corrosion because of multiple sites of contact and incongruities at the points of metal apposition[8]. Although the analysis is based on relatively small numbers with less inflammatory effects tolerated by most host tissue effects, the current study would like to emphasize the clinical significance of these adverse events. Standardizing of the metal composition and the manufacturing process should be strictly controlled to improve corrosion resistance. These are the essential steps particularly for stainless-steel plates used as permanent implants and for in situ prosthesis[8].

Apart from these, the design of implant systems may also favor corrosion, as were the case with crevice corrosion in the TLS-Kluger spinal fixator[3] and modular hip prosthesis[10]. Regarding long-term function of the fixation, skill of orthopedic surgeons performing surgery is the most crucial part. Corrosion is clearly a factor to be minimized in every day practice by orthopedic surgeons. Devices should be inserted properly with less damage to both tissue and the protective oxide filming on every implant[18].

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การศึกษาเปรียบเทียบปฏิกิริยาที่เกิดขึ้นในเนื้อเยื่อระหว่างโลหะดามกระดูกแขนขา ที่ผลิตในประเทศและแผ่นโลหะนำเข้า

ธวัช ประสาทฤทธา, นิเวศน์ วิเศษไชยศรี

ภูมิหลัง: *ในปัจจุบันมีการผลิตแผ่นโลหะดามภายในและภายนอกเพื่อใช้ในประเทศอย่างแพร่หลาย แต่ยังไม่มีรายงานทดสอบปฏิกิริยาทางชีววิทยา (biologic reaction) ของโลหะดามที่ผลิตภายในประเทศ*

วัตถุประสงค์: *เพื่อเปรียบเทียบปฏิกิริยาที่เกิดขึ้นในเนื้อเยื่อรอบโลหะดามกระดูกระหว่างโลหะนำเข้า (imported) และโลหะผลิตในประเทศ (local) ที่ใช้ดามกระดูกด้ามยาวที่หัก*

วัสดุและวิธีการ: *ระหว่างเดือนตุลาคม พ.ศ. 2548 ถึง ตุลาคม พ.ศ. 2549 ผู้นิพนธ์ได้ติดตามผู้ป่วยกระดูกหน้าแข้งหัก (tibia) ที่ได้รับการผ่าตัดดามด้วยแผ่นโลหะจำนวน 40 ราย อายุเฉลี่ย 31.1 ปี แบ่งเป็นกลุ่ม imported 20 ราย กลุ่ม local 20 ราย ทุกราย มีการใช้งานขาข้างที่หักได้อย่างดีกลับไปทำงานได้ตามปกติ ระยะเวลาจากผ่าตัดถึงถอดแผ่นโลหะเฉลี่ย 24 เดือน การเตรียมผ่าตัดเพื่อถอดแผ่นเหล็กตามขั้นตอนมาตรฐาน การตัดชิ้นเนื้อ เก็บชิ้นเนื้อโดยการแช่ในน้ำยา 10% buffer formalin และอ่านชิ้นเนื้อ โดยพยาธิแพทย์ผู้ชำนาญที่ไม่ทราบชนิดของแผ่นโลหะ การคำนวณทางสถิติใช้ chi square test เพื่อหานัยสำคัญทางสถิติทั้ง 2 กลุ่ม การรายงานผล histopathology ดัดแปลงจากวิธีการของ Mathiesen*

ผลการศึกษา: *ผู้ป่วยชาย 38 ราย หญิง 2 ราย ระยะเวลาที่กระดูกติด 8.5 สัปดาห์ กลุ่ม local และ กลุ่ม imported มีอายุเฉลี่ย 30.2 ปี และ 32 ปี ตามลำดับ มีจำนวนชายและหญิงเท่ากัน จากการสังเกตด้วยตาเปล่า มีเนื้อเยื่อที่เป็นสีดำรอบแผ่นโลหะกลุ่มละ 2 ราย จากการตรวจชิ้นเนื้อทั้ง 4 ราย ไม่พบความแตกต่างระหว่าง 2 กลุ่มอย่างมีนัยสำคัญทางสถิติ*

สรุป: *ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของปฏิกิริยาของเนื้อเยื่อที่เกิดรอบแผ่นโลหะดามระหว่างชนิดนำเข้าและชนิดผลิตในประเทศ*