

Tissue Reaction to a 316L Stainless T Plate Fabricated for Pelvic Osteotomy in Dogs

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Abstract

Tissue reaction to a 316L stainless T plate fabricated for pelvic osteotomy was examined radiographically and histologically in 3 experimental mongrel dogs 52 weeks after plate implantation on the non-osteotomized ilium. The adverse effects of long-term plate implantation were assessed clinically and radiographically in 7 dysplastic hips of 5 dogs that had undergone triple pelvic osteotomy 3-5 years earlier. The plates were removed from the experimental dogs for corrosion evaluation 52 weeks after the implantation. Serial radiographs of the experimental dogs at 1, 4, 8, 12, 24 and 52 weeks and of the hip dysplastic dogs at 3 to 5 years showed no plate corrosion in the tissue surrounding the plates and no perceptible changes to indicate aggressive bone lesion. Gross examination of the tissue adjacent to the removed plates in the experimental dogs found no discoloration or trace of stainless steel debris. Histologically, the tissue surrounding the plate was composed of fibrous and adipose tissues. Infection, traces of the metallic debris and foreign-body granuloma formation in response to the presence of metallic debris were not observed in any tissue sections. Corrosion of the retrieved plate was not notably found. In conclusion, the fabricated T plate made of 316L stainless steel is safe for use as an implant for pelvic osteotomy in dogs.

Keywords : dog, dysplasia, hip, pelvic osteotomy, 316L stainless

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บทคัดย่อ

ปฏิกริยาของเนื้อเยื่อต่อแผ่นรูปที่ทำจากสแตนเลส 316 宣告ที่พัฒนาสำหรับศัลยกรรมตัดแต่งกระดูกเชิงกรานในสุนัข

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การตรวจสอบปฏิกริยาของเนื้อเยื่อต่อแผ่นรูปที่ทำจากสแตนเลส 316 宣告ที่พัฒนาสำหรับการทำศัลยกรรมตัดแต่งกระดูกเชิงกราน จากภาพเอกซเรย์และจุลทรรศน์ที่ 52 สัปดาห์ภายหลังใส่แผ่นรูปที่บันกระดูก ilium ที่ไม่ได้ตัดในสุนัขทดลอง พันธุ์สุนัข 3 ตัว และตรวจผลข้างเคียงของการใส่แผ่นรูปที่บันกระดูกไว้เป็นเวลากว่า 3-5 ปี จากการทางคลินิกและภาพเอกซเรย์ ข้อสะโพกที่เจริญผิดปกติ 7 ข้อของสุนัข 5 ตัวที่ได้รับการผ่าตัดแก้ไขโดยการตัดแต่งกระดูกเชิงกราน 3 ตำแหน่ง และตรวจสอบ การผูกร่องของแผ่นรูปที่ที่นำออกมาจากสุนัขทดลองภายหลังใส่ไว้ 52 สัปดาห์ จากภาพเอกซเรย์ที่ถ่ายเป็นระยะของสุนัขทดลอง ที่ 1, 4, 8, 12, 24 และ 52 สัปดาห์ และของสุนัขที่มีข้อสะโพกเจริญผิดปกติที่ 3-5 ปี ไม่พบการผูกร่องของแผ่นโลหะในเนื้อเยื่อที่อยู่รอบๆ และไม่พบการเปลี่ยนแปลงที่บ่งบอกรอยโรคกระดูกที่ร้ายแรง จากการตรวจด้วยตาเปล่าขณะนำแผ่นรูปที่ออกจากสุนัขทดลองภายหลังใส่ไว้ 52 สัปดาห์ ไม่พบมีการเปลี่ยนลักษณะของเนื้อเยื่อหรือมีเคลย์โลหะตกค้าง การตรวจทางจุลทรรศน์วิภาควิทยาเนื้อเยื่อรอบๆ แผ่นรูปที่ พนกการเจริญของเนื้อเยื่อพังผืดและไขมัน ไม่พบการติดเชื้อแทรกซ้อน เทคโนโลหะ และการเกิดแกรนูโลมาที่เป็นปฏิกริยาตอบสนองต่อการมีเคลย์โลหะตกค้าง ไม่พบมีการผูกร่องของแผ่นรูปที่ที่นำออกมาจากสุนัขทดลอง สรุป แผ่นรูปที่ทำจากสแตนเลส 316 宣告 มีความปลอดภัยสำหรับใช้เป็นวัสดุปลูกฟันในการทำศัลยกรรมตัดแต่งกระดูกเชิงกรานในสุนัข

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Introduction

Triple pelvic osteotomy (TPO) is an effective surgical technique for correcting canine hip dysplasia (CHD). It allows the femoral head to be captured within the shallow acetabulum with the objective of increasing hip joint stability. The procedure consists of separate osteotomies on the pubis, ischium and ilium to enhance free rotation of the acetabulum for a better coverage over the femoral head (Slocum and Slocum, 1992). The acetabular rotation is maintained by using a specifically designed TPO plate to fix the osteotomized ilium. As well as Slocum and Synthes TPO plates, the more frequently used plates (Wallace and Olmstead, 1995), Marquardp and modified Slocum-Synthes TPO plates are also available (Figure 1). Slocum, Synthes and modified Slocum-Synthes plates are specially pre-angled and made specifically for the left and the right iliums. They are available in various sizes for different sizes of the ilium. The Marquardp TPO

plate is available in two sizes, for small and large dogs, and has an elongated shaft with a perpendicular shaft at each end for the better stabilization of the osteotomized ilial shaft. Unlike the Slocum, the Synthes and the modified Slocum-Synthes plates, before application the Marquardp plate must be twisted at the shaft dent to an angle of 20 to 40 degrees depending on the case. All of the 4 TPO plates must be imported and are relatively expensive.

To increase versatility and to reduce the cost of the implant, the authors have fabricated a T plate modified from the Synthes and the Marquardp TPO plates (Figure 2). This 3.5-mm plate has only one size and one configuration that is applicable to all sizes of the dog and for either side of the ilium. Similar to the Marquardp plate, the T plate must be twisted at the shaft dent to the angle required for each case. Like pins, screws and other orthopedic implants including the Slocum, the Synthes

and the Marquardp TPO plates, the fabricated T plate is made of 316L stainless steel which is domestically available. This considerably lessens cost of the implant.

Among the metals used in manufacturing implants for fracture fixation devices are the iron-based alloys (stainless steels), cobalt-based alloys (e.g. Vitallium) and titanium-based alloys (Hulse and Hyman, 1995). Selection of a material for medical applications is usually based on biocompatibility. The susceptibility of the material to corrosion and the effect that corrosion has on the tissue are the crucial aspects of the biocompatibility (Gotman, 1997). 316L stainless steel is the least corrosion resistant. However, because of economics, stainless steel alloys are used almost exclusively in veterinary orthopedics, while the expensive titanium-based and cobalt-based alloys are popular in human orthopedics (Hulse and Hyman, 1995).

The corrosion of metallic orthopedic implants and its effect on the surrounding tissue have been reported (Traisnel et al., 1990; Beguiristain et al., 2006; Tomizawa et al., 2006). As well as osteolysis, periosteal proliferation and cortical thickening (Jones et al., 2001), osteosarcomas associated with 316L stainless steel orthopedic implants have been reported in human patients (Beguiristain et al., 2006) and dogs (Harrison et al., 1976; Boudrieau et al.,

2005; Rose et al., 2005). Several reports have proposed that there might be a relationship between metal implant corrosion and tumor development in the adjacent bone (Harrison et al., 1976; Sinibaldi et al., 1976; Sinibaldi et al., 1982; Ward et al., 1990; Stevenson, 1991).

In aware of the adverse effects in animals caused by 316L stainless steel used in manufacturing our fabricated T plate, this study was undertaken to examine the corrosion of the plate, radiographic, gross and histopathological changes of the tissue around the plates 52 weeks after the implantation in normal experimental dogs. The adverse effects of the long-term implantation of the T plates were assessed clinically and radiographically in 5 hip dysplastic dogs 3 to 5 years after triple pelvic osteotomy.

Materials and Methods

Animals: 1 male and 2 females normal mongrels dogs, 12 to 18 months of age and 10 to 15 kg body weight with no history of hip surgery, were experimentally used for the study of tissue reaction and corrosion of the fabricated plate. The changes on the radiographs, gross and histopathology were evaluated. 7 dysplastic hips of 5 dogs were assessed radiographically and clinically in the adverse effects of long-term implantation of the plate 3 to

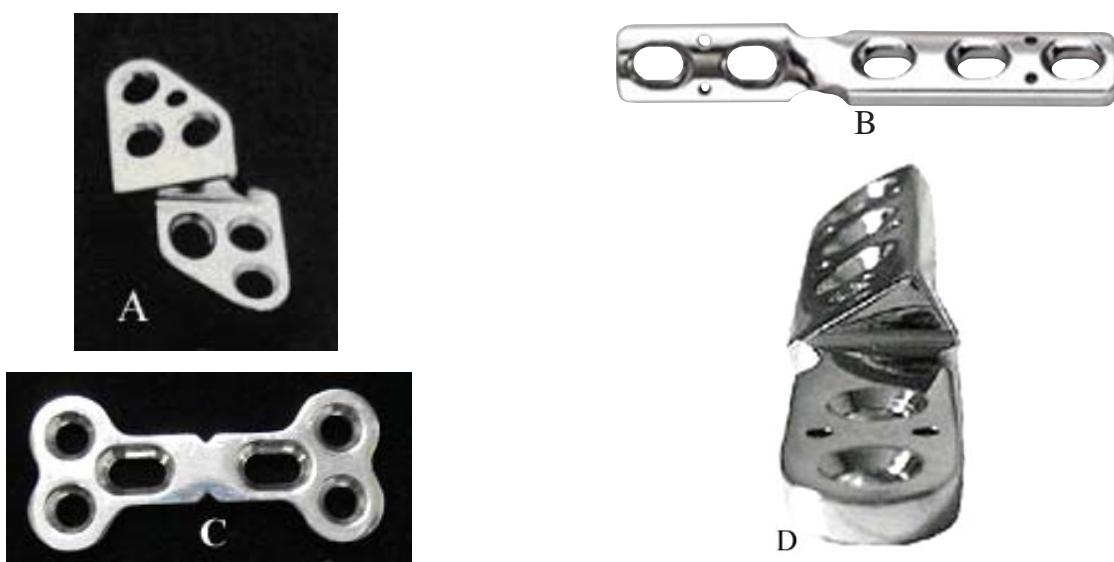


Figure 1 Bone plates for triple pelvic osteotomy; A: Slocum, B: Synthes, C: Marquardp, D: Modified Slocum-Synthes.



Figure 2 Both surfaces of the 316L stainless T plates fabricated for triple pelvic osteotomy; A: used plates, B: unused plates of the same production batch.

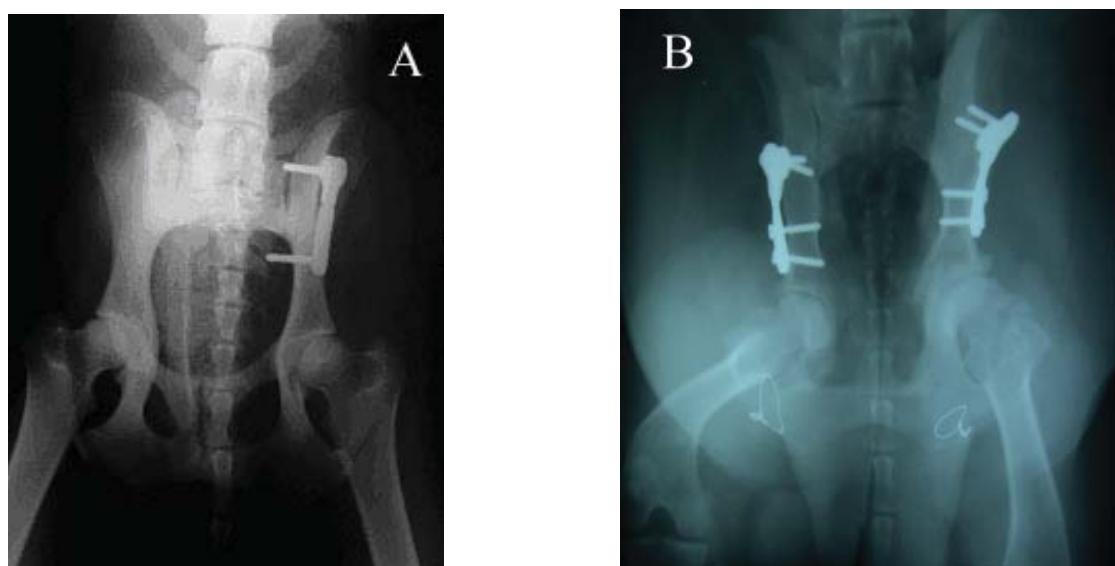


Figure 3 Ventrodorsal radiographs of the normal hips of an experimental dog 52 weeks after implantation of the fabricated T plate on the left non-osteotomized ilium (A) and of both dysplastic hips 5 years after triple pelvic osteotomies using the fabricated T plates on both osteotomized iliums (B) demonstrating no abnormalities of bone and soft tissue around the plate.

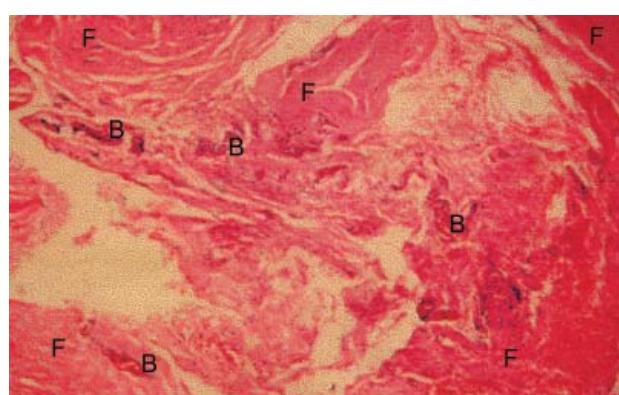


Figure 4 Photomicrograph of an H&E-stained section of the soft tissue overlying the fabricated T plate demonstrating fibrous connective tissue (F) and numerous blood vessels (B) (x 40).



Figure 5 Photomicrograph of a Masson's trichrome-stained section of the soft tissue overlying the fabricated T plate demonstrating fibrous connective tissue (F) interposed with adipose tissue (A) and numerous blood vessels (B) (x 200).

5 years after triple pelvic osteotomy. The 5 hip dysplastic dogs were 3 Golden Retrievers, 1 Rottweiler and 1 native, 3 females and 2 males, aged between 12 and 23 months when surgically treated. Pelvic osteotomy was performed on the right, the left and both hips in 1, 2 and 2 dogs, respectively (Table 1). Animal care and the study procedures have been approved by The Animal Care and Use Committee, Chulalongkorn University, Bangkok, Thailand. (No. 0631047)

Fabricated T plates: The fabricated 3.5-mm T plate (Figure 2) has the configuration modified from that of Synthes and Marquardp TPO plates. The plate is made of 316L stainless steel which is the standard material used for the manufacture of medical implants including the Slocum, the Synthes and the Marquardp TPO plates. One of the 2 axes of the plate shaft is elongated in shape and dented in a way similar to that of the Synthes TPO plate. The other axis is perpendicular to the first one and has a shape resembling that of the Marquardp TPO plate.

Surgical procedure: Two standard radiographic views of the pelvis of each dog were taken preoperatively. The dog was anesthetized, placed in a lateral recumbency and routinely prepared for surgery. A 10-15 cm skin incision was made from the midpoint of the cranial margin of the ilial wing to the point below the greater trochanter of the femur. The incision was carried on through the subcutaneous fat and gluteal fascia to the middle gluteal muscle. The deep gluteal and the middle gluteal muscles were subperiosteally elevated from the ilium. Care was taken to avoid the cranial gluteal nerve which pierces the middle and the deep gluteal muscles. The cranial circumflex iliac artery passing to the middle gluteal muscle caudal to the tuber coxae was severed, and bleeding was controlled. The cranial border of the middle gluteal muscle was incised from its ventral attachment to its craniodorsal attachment on the ilium. The muscle was elevated from the ilial body where the T plate was placed and secured with two 3.5-mm cortical screws. In the experimental dogs, an untwisted T plate was applied on the non-osteotomized ilium. In the hip dysplastic dogs, osteotomy was made

at the pubis, ischium and ilium for repositioning the acetabulum for a better coverage on the femoral head. Then a T plate was twisted 20-30 degrees, applied on the osteotomized ilium and secured with four 3.5-mm cortical screws. In closure, the periosteum of the cranial border of the ilium was sutured, using a mattress pattern, to the fibrous covering of the cranial margin of the middle gluteal muscle. The gluteal fascia was apposed with a continuous suture pattern. The subcutaneous fascia and skin were closed routinely. Postoperatively, the animals received once daily cefazolin (Zefa M.H., M&H Manufacturing Co., Ltd., Thailand) at a dose rate of 20 mg/kg for 5 days and morphine sulfate (Morphine Sulfate Injection, M&H Manufacturing Co., Ltd., Thailand) at a dose rate of 0.1 mg/kg intramuscularly for 2 days. Exercise was restricted for 2 weeks.

Gait and radiographic evaluations: Gait of the experimental dogs was observed daily for two weeks and then weekly afterwards. Osteolysis and periosteal proliferation adjacent to the plates were assessed from 2 standard radiographic views of the pelvis taken before and after implantation at 1, 4, 8, 12, 24 and 52 weeks in 3 experimental dogs and at 3 to 5 years in 5 hip dysplastic dogs.

Histological and plate examinations: The plates were removed from the experimental dogs 52 weeks after the implantation. Samples of the soft tissue surrounding the retrieved plate were taken, fixed in formalin and processed histologically into tissue blocks. Then 7-mm thick sections were cut and stained with hematoxylin & eosin (H&E) and Masson's trichrome (MT). Under a light microscope, the sections were examined with respect to the cellular components, the occurrence of metallic wear particles and foreign-body reaction. The surfaces of the retrieved plates and the unused plates from the same production batch were examined macroscopically and microscopically under a light microscope.

Results

Gait and radiographic evaluations: All experimental dogs regained normal gait and put their weight normally on their limbs within 2 weeks after surgery. According to serial radiographs, there were no perceptible changes in the bone and soft tissue adjacent to the plates. Osteolysis, periosteal proliferation and cortical thickening of the iliums were not found in any dogs (Figure. 3).

The five hip dysplastic dogs walked normally 2 months after surgery. The pelvic radiographs revealed normal union and a complete remodeling of the osteotomized iliums. There was no adverse reaction to indicate aggressive lesion in the bone and the soft tissue surrounding the implants or plate corrosion such as periosteal proliferation, cortical thickening and implant-induced osteolysis involving the ilium adjacent to the plate (Figure 3), a possible manifestation of an adverse cellular response to phagocytosable metal debris (Jones et al., 2001; Boudrieau et al., 2005).

Histological and plate examinations: By gross examination during plate removal, no discoloration of tissue or stainless steel debris can be seen over the tissue adjacent to the retrieved plates in the experimental dogs. Histological examination of the soft tissue surrounding the plates revealed fibrous connective tissue with adipose tissue interposed in some sections (Figures 4 and 5). Infection, traces of the metallic debris and foreign-body granuloma formation were not evident in any tissue samples.

Macroscopically, the upper sides and the under sides of the retrieved plates appeared smooth and were not corroded. There was no perceptible difference in surface appearance between the plates retrieved from the experimental dogs 52 weeks after the implantation and the unused plates from the same production batch. All retrieved plates maintained their metallic luster and color. There was no rust brown staining, nor crevices or a rough finish on the plate surfaces to indicate surface corrosion. Microscopically, the surface characteristics of the retrieved plates were not notably different from those of

the unused plates from the same production batch. Comparable scratches and pits were observed on the surfaces of both the used and the unused plates. These findings suggest that no corrosion occurred (Figure 2).

Discussion

Various metals are used in the manufacture of implants for fracture fixation devices. Examples are the iron-based alloys (stainless steels), cobalt-based alloys (e.g., Vitallium), and titanium-based alloys. Before an alloy can be used for internal fracture stabilization, several requirements must be satisfied. Among these requirements are the suitable combination of properties to permit fabrication of properly sized and shaped implants, suitable mechanical properties relative to allowable sizes for implantation, and compatibility *in vivo*. Another factor that plays a significant role in veterinary orthopedics is the cost of implants. Stainless steel is one of the most frequently used biomaterials for internal fixation devices because of a favorable combination of its mechanical properties, corrosion resistance and cost effectiveness when compared to other metallic implant materials. Moreover, the biocompatibility of stainless steel has been proven in successful human implantation for decades (Disegi and Eschbach, 2000).

The corrosion resistance of the currently used 316L stainless steel, cobalt-chromium and titanium-based implant alloys relies on their passivation by a thin surface layer of oxide. Stainless steel is the least corrosion resistant and is, therefore, used for temporary implants only. Titanium and cobalt-chromium alloys do not corrode in the body; however, metal ions slowly diffuse through the oxide layer and accumulate in the tissue. Krischak et al. (2004) used a scanning electron microscope to determine implant corrosion and found that stainless steel plates had a higher degree of corrosion compared with the titanium plates. It is important not to damage the surface of an implant during surgery in order to preserve the oxide layer that provides corrosion resistance (Hulse and Hyman, 1995). For example, care must be taken when

Table 1 Data on 5 hip dysplastic dogs that had undergone triple pelvic osteotomy using the fabricated T plate.

Dog	Sex	Breed	Age when treated (months)	Operated hip	Follow-up period (years)
1	F	Golden Retriever	16	Left	5
2	F	Golden Retriever	14	Both	5
3	F	Mongrel	12	Right	4
4	M	Golden Retriever	14	Both	3
5	M	Rottweiler	23	Left	3

contouring a bone plate by using appropriate bending pliers to prevent any unnecessary scratching of the plate surface. Scratching of the surface can remove the oxide layer, permitting corrosion and stress concentration that can lead to implant failure. Scratches observed on the retrieved plate were most likely related to the manufacturing process because the plates were not twisted and the extent of the defects on both the retrieved and the unused plates was not different. However, some scratches on the retrieved plates may have occurred during the implantation. Like the observation of scratches, pits found microscopically on the retrieved plate surfaces were comparable with those on the unused plates from the same production batch, therefore, the pits were possibly the result of incomplete polishing of the oxide layer of the plate surface during the manufacturing process.

Besides the support from the observation of scratches and pits previously mentioned, many more findings in this study indicated that the fabricated T plates were not corroded after long-term implantation. Macroscopically, the undersides of the retrieved plates that were in contact with the ilium maintained their metallic luster and color. No significant changes in the surface characteristics of the retrieved plates to indicate surface corrosion such as rust brown staining, crevices and rough finishing on the plate surface were observed. The result supports Matthew et al. (1996) who studied in animal model and found that there was no perceptible difference in the surface characteristics of the stainless steel miniplates retrieved up to 24 weeks after

implantation in comparison with the unused miniplates from the same production batches. In contrast to the findings in this study, Boudrieau et al. (2005) found a dull and roughened appearance of the tibial plateau leveling osteotomy (TPLO) plate retrieved from a dog associated with osteosarcoma 5.5 years after surgery. The TPLO plate was made of cast 316L stainless steel which is determined not to meet the American Society for Testing Material Standards for Implant-Grade Materials. The shorter duration of plate implantation in the experimental dogs might be another reason for the contrast findings on plate surface found in the present study.

Histological examination of the tissue surrounding the plates in the experimental dogs found only adipose and fibrous tissues. Normally when a metal implant is placed in the human body, it becomes surrounded by a layer of fibrous tissue of a thickness that is proportional to the number and toxicity of the dissolution products and to the degree of motion between the implant and the adjacent tissue. Proliferation of a fibrous layer as large as 2 mm thick has been encountered with the use of stainless steel implants whereas pure titanium can elicit a minimal fibrous encapsulation under some conditions (Gotman, 1997). Dissolution products or metallic debris that can occur was not found macroscopically and histologically in this study. Without sophisticated equipment, the presence of debris might be noticed as foreign-body granuloma (Jones et al., 2001) and implant-induced osteolysis (Boudrieau et al., 2005). To analyze the accumulation of the metals in the local tissue, energy-dispersive x-ray

(Boudrieau et al., 2005) or inductively coupled plasma atomic emission spectrometry is required (Krischak et al., 2004).

Corrosion products normally cause pain, inflammation and bone necrosis (Ness, 1998). In practice the surgeon will recognize these cases primarily as painful delayed unions which were not found in this study. Adverse reactions in the peri-implant tissue indicating corrosion such as osteolysis, periosteal proliferation and cortical thickening (Jones et al., 2001) of the ilium under the plate were not evident radiographically or microscopically. Osteolysis is possibly a manifestation of the cellular response to phagocytosable metal debris corroded from the implant (Boudrieau et al., 2005). An association between metal wear debris from surgical implants and an increased potential for osteolysis has been reported (Jones et al., 2001; Hallab et al., 2003). From this study, foreign-body granuloma formation in response to the presence of metal debris was not found in any tissue samples.

Though this study found insignificant tissue reaction and no corrosion of the plate retrieved from the experimental dogs and no aggressive bone lesions on the radiographs of all dysplastic hips 3 to 5 years after triple pelvic osteotomy, the plate should be removed once the ilium has healed to avoid complications as reported in human patients and dogs after long-term implantation. A metallotic mass related to corrosion of the implant and infection has been reported in a 28-year-old female patient 14 years after surgical correction of adolescent idiopathic scoliosis with a 316L stainless-steel instrumentation (Beguiristain et al., 2006). Corrosion of 316L stainless steel has been observed after 10, 13, 22 and 30 years of implantation in four human patients (Tomizawa et al., 2006). The longer the implanted duration, the more numerous and deeper were the crevices observed on the implant. A number of metal ions equivalent to the corroded volume must have been released into the human body, but the effect of these metal ions on the body was not apparent. Traisnel et al. (1990)

found corrosion on all 12 intramedullary nails and 12 plates and high concentrations of nickel and chromium that correlated to the implantation time in biological fluid from 24 patients.

The possibility that implant corrosion might have played a role in tumor development was of concern; however, a definite association was not established. Besides osteosarcoma in a dog reported by Boudrieau et al. (2005), Rose et al. (2005) reported an osteosarcoma at the site of a triple pelvic osteotomy using Slocum TPO plate in a 12-year-old Golden Retriever 11 years after surgery. Harrison et al. (1976) reported osteosarcomas in two dogs with no infection in either animal. One neoplasm occurred in the distal humerus of a 12-year-old Doberman Pinscher in which a stainless steel intramedullary pin had been implanted 11 years previously. Upon pin removal, corrosion of the pin was noted. The second neoplasm arose in the proximal tibia of a 12-year-old Irish Wolfhound. Six years previously, a fracture of the tibia had been repaired with a plate and screws made of 316L stainless steel, by the same manufacturer. No corrosion of the implants occurred in this case. Osteogenic sarcomas may occur spontaneously or occur in association with a previous bone fracture. Pelvic osteotomy could be described as an iatrogenic fracture which may carry a risk of tumor development similar to traumatic fractures (Rose et al., 2005). This study did not find osteogenic sarcoma in any dysplastic hips that had undergone triple pelvic osteotomy using the fabricated T plate.

Conclusion

The fabricated T plate made of 316L stainless steel is safe for use as an implant in dogs. Corrosion of the plates retrieved from the experimental dogs 52 weeks after the implantation was not notably observed. There were no radiographically perceptible changes in the bone and the soft tissue adjacent to the fabricated plate to indicate an aggressive bone lesion and plate corrosion in the surrounding tissue 3-5 years after plate implantation in 7 dysplastic hips of 5 dogs undergone triple pelvic osteotomy.

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