Material properties of and tissue reaction to the Slocum TPLO plate

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Objective—To determine the material properties of Slocum TPLO plates and assess the soft tissue reaction adjacent to these plates in dogs that had undergone tibial plateau leveling osteotomy (TPLO).

Sample Population—3 new TPLO plates, 8 retrieved TPLO plates, and 1 new Synthes dynamic compression plate.

Procedures—Metallurgic analyses were performed. Tissue samples were obtained from areas adjacent to retrieved plates and submitted for histologic examination.

Results—All of the TPLO plates had a 2-phase microstructure consisting of austenite and ferrite in various amounts. Residua, inclusions, and cavities were seen during microscopic examination of the plate surface. The major differences between new and retrieved TPLO plates were the presence of small gaps separating many inclusions from the surrounding matrix and the presence of various-sized pits on the surface of the retrieved plates. The dynamic compression plate had a nearly pure austenitic structure and was largely free from residua, inclusions, and cavities. Histologic examination of tissue samples obtained from areas adjacent to retrieved TPLO plates revealed intra- and extracellular particulate debris. Two types of particles (one consisting of chromium, nickel, molybdenum, and iron and the other consisting of aluminum and silicon) were seen.

Conclusions and Clinical Relevance—Results determined that new and retrieved TPLO plates were manufactured from 316L stainless steel and produced by a casting process, but not all plates met specifications for chemical composition of cast surgical implants (American Society for Testing Materials standard F745); tissues surrounding retrieved plates had evidence of adverse reactions, probably as a result of plate corrosion. (*Am J Vet Res* 2006;67:1258–1265)

Tibial plateau leveling osteotomy has become a common method for treatment of cranial cruciate ligament rupture in dogs. Recently, however, concerns have been raised about a possible association between use of implants from a particular manufacturer (Slocum Enterprises Inc) and subsequent development of neoplasia at the surgical site.[1,a-c] A recent case report,[1] for instance, described a dog that developed a poorly differentiated sarcoma (subsequent immunohistochemical testing indicated that the tumor was a histiocytic sarcoma) involving the proximal portion of the tibia and distal portion of the femur 5.5 years after undergoing TPLO. There was radiographic evidence of focal osteolysis immediately adjacent to the plate and gross and microscopic evidence of plate corrosion, with particulate matter in the tissues. A review of medical records of dogs that underwent TPLO at the same institution between 1997 and 2002 revealed 3 additional dogs that had osseous neoplasia involving the proximal portion of the tibia, adjacent to the implant, and 2 of these dogs had radiographic evidence of focal osteolysis immediately adjacent to the plate. The estimated incidence of neoplasia in dogs that underwent TPLO was approximately 7 times the expected incidence for naturally occurring tumors in this location. In another study,[b] dogs that underwent TPLO in which plates from this manufacturer were used appeared to have an increased risk of infection.

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ABBREVIATIONS

TPLO	Tibial plateau leveling osteotomy
ASTM	American Society for Testing Materials
DCP	Dynamic compression plate

Even taken together, these findings do not provide proof of a cause-and-effect relationship. Nevertheless, they do raise questions about the composition of implants from this manufacturer and the possibility that these implants have reduced corrosion resistance.[1,b] The purposes of the study reported here, therefore, were to determine the material properties of Slocum TPLO plates, including new plates and plates retrieved from dogs that had undergone TPLO, and to assess the soft tissue reaction adjacent to these plates in dogs that had undergone TPLO.

Materials and Methods

All new (unused) Slocum TPLO plates[d] (n = 38) in stock at the Cummings School of Veterinary Medicine at Tufts University in June 2004 were subjectively evaluated for gross magnetism on the basis of their strength of attraction to a large magnet. Plates were grouped as strongly magnetic (ie, the plate could be entirely lifted with a large magnet), slightly magnetic (ie, the plate could be partially, but not entirely, lifted with a large magnet), or nonmagnetic (ie, the plate could not be lifted with a large magnet). One plate was randomly selected from each group as being representative of that group. Material properties of these 3 plates were then tested, including the degree to which the plates conformed with ASTM standard F745 (standard specification for 18chromium–12.5nickel–2.5molybdenum stainless steel for cast and solution-annealed surgical implant applications).[2]

For comparison, a new 4-hole, 4.5-mm DCP[e] designed for use in human patients was also tested, with special reference to how well it conformed to ASTM standard F138-03 (standard specification for wrought 18chromium–14nickel–2.5molybdenum stainless steel bar and wire for surgical implants) and ASTM standard F139-03 (standard specification for wrought 18chromium–14nickel–2.5molybdenum stainless steel sheet and strip for surgical implants).[2]

Slocum TPLO plates retrieved from 8 dogs that had undergone TPLO were also tested. Time that plates were in place in these dogs ranged from 8 to 79 months. Seven of these dogs did not have any clinical abnormalities at the time of plate removal, and 1 had a poorly differentiated sarcoma adjacent to the plate (additional details for this dog have been published previously[1]). In all dogs, tissue samples were collected from areas adjacent to the plate at the time of plate retrieval and were fixed in neutral-buffered 10% formalin.

Carbon and sulfur contents of the 3 new Slocum TPLO plates and the 1 new DCP were determined by means of combustion infrared detection, and nitrogen content was determined by means of inert gas fusion. The remaining chemical composition of the plates was determined by means of direct current plasma emission spectroscopy.

The 3 new and 8 retrieved Slocum TPLO plates and the 1 new DCP were cut to reveal the cross section of each plate. Cross sections were then mounted in a metallurgic mount[f] and polished to a mirror finish. Plate surfaces and cross sections were then examined by means of light microscopy and scanning electron microscopy,[g] which included secondary electrons imaging, backscattered electrons imaging, and energy-dispersive X-ray analysis.[h] Vickers hardness of the plate cross sections was measured with a load of 98 N, according to ASTM standard E92-82(2003)e2.[3] Six randomly distributed measurements were obtained from each polished cross section, and values that were obtained were converted to Rockwell B or C hardness in accordance with ASTM standard E140.[3] Finally, these values were converted to approximate ultimate tensile strength.[4]

X-ray diffraction[i] was used to determine ferrite and austenite concentrations of each plate cross section. The diffractometer was operated at 40 kV and 30 mA, and measurements were obtained with Cu Kα radiation (wavelength, 1.54184 Å). An Ni filter was used to remove Cu Kβ reflections. The diffracted beam was detected with a scintillation counter detector. A 2-theta angle range of 15° to 90° was selected with a scanning speed of 0.4°/min and steps of 0.02°. Data obtained were evaluated with commercial software.[j] Background was subtracted from the raw diffraction pattern, and the integrated intensities of the peaks were calculated. From the peak intensities, the fraction of austenite was determined according to ASTM standard E975.[3] Because the 111 austenite and 110 ferrite peaks interfere with each other and cannot be resolved, only the 200 and 220 austenite and 200 and 211 ferrite peaks were considered.

Tissue samples were routinely prepared for histologic examination. Sections (5µm thick) were stained with H&E or Giemsa stain and examined by means of light microscopy with transmitted and reflected light. For selected regions, unstained adjacent 15- to 20-µm-thick sections were examined by means of scanning electron microscopy, which included secondary electrons imaging, backscattered electrons imaging, and energy-dispersive X-ray analysis.

Results

Of the 38 Slocum TPLO plates in stock at the time of the study, 24 were classified as strongly magnetic on the basis of attraction to a large magnet, 12 were classified as slightly magnetic, and 2 were classified as nonmagnetic. The nonmagnetic plates were of the newest design, containing a single oval hole in the proximal end of the plate and bearing an etched label of #31201.21L. The remaining TPLO plates did not have any identifying marks. The DCP was classified as nonmagnetic.

Light microscopic examination of cross sections of all 11 new and retrieved TPLO plates revealed a distinct, dendritic 2-phase structure typical of a cast alloy with many inclusions (**Figure 1**), whereas the DCP had a monophasic structure with rare, small (most < 3 µm in diameter) inclusions. X-ray diffraction revealed that all 11 TPLO plates had a ferrite microstructure. The austenite content of the retrieved TPLO plates ranged from 66.3% to 98.1% (**Table 1**). Austenite content of the new TPLO plates was 97.5% for the nonmagnetic plate, 92.8% for the slightly magnetic plate, and 78.4% for the strongly magnetic plate. Austenite content of the DCP was > 99.5%.

On gross examination, 2 of the retrieved TPLO plates had a dull appearance in those areas of the plate

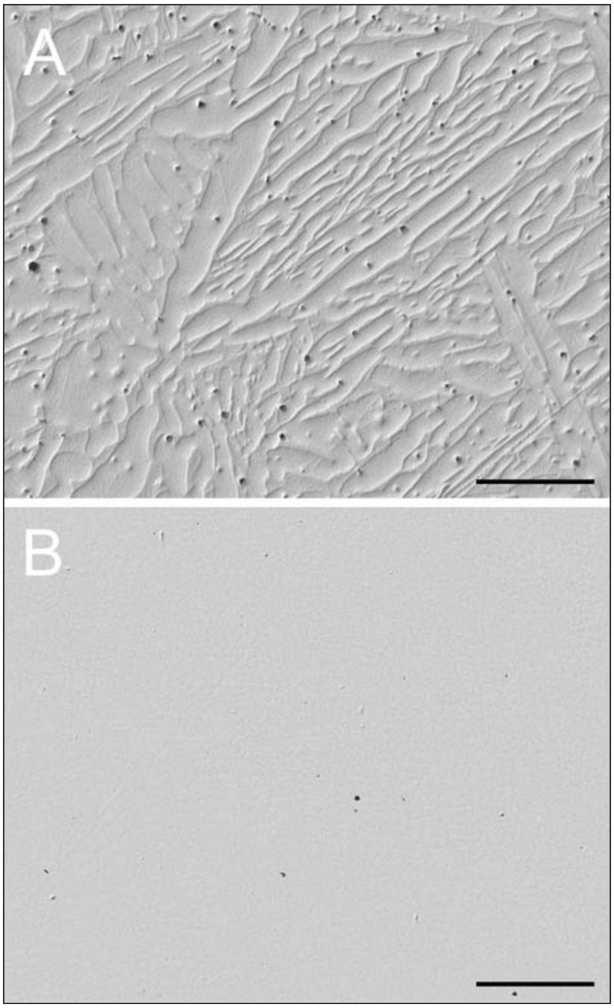

Figure 1—Photomicrograph of cross sections of a Slocum TPLO plate (A) and a Synthes DCP (B). The TPLO plate has a 2-phase microstructure, with the slightly depressed areas representing ferrite and the slightly raised areas representing austenite. Inclusions (dark round dots) frequently are observed in both the austenite phase and the ferrite phase. In contrast, the DCP has a single-phase microstructure (austenite) and almost no inclusions (dark dots) are visible. Bars = 100 µm.

that had been in contact with the tibia. Examination of these areas under low magnification revealed that they had a roughened appearance. Light microscopic examination of all 8 retrieved TPLO plates revealed many surface dents and scratches, many of which appeared to be the result of the contouring process during initial plate application.

Scanning electron microscopic examination of the surface of the 11 TPLO plates revealed morphologic differences that we classified as residua, inclusions, and cavities. Residua that were seen generally protruded above the surface of the plate, although some were located in cavities on the plate surface **(Figure 2)**. Results of energy-dispersive X-ray analysis indicated that most residua consisted primarily of aluminum and silicon. Residua generally ranged from < 1 to 5 µm in diameter, but some were as large as 10 µm in diameter. Two major types of residua could be distinguished morphologically. The first appeared to consist of granular material that had become stuck together. The second consisted of more solid-appearing, sharp-edged material.

Inclusions that were seen were embedded in the plate surface. They generally ranged from 1 to 10 µm in diameter, but rare inclusions were as large as 100 µm in diameter. Inclusions were generally round and contained a mixture of aluminum and silicon, regardless of whether they were located in the austenite or ferrite phase of the plate. Some inclusions were separated from the surrounding matrix by a small gap; this feature was only observed in the retrieved plates. Small (< 1 to 10 µm in diameter), sharp-edged holes were seen and were believed to represent areas where inclusions had fallen out of the plate matrix.

Cavities on the plate surface consisted of large, irregularly shaped excavations that gave the plate surface a cracked appearance. In the retrieved plates, but not the new plates, cavities that consisted of shallow soft-edged pits ranging from 3 to 50 µm in diameter were also seen.

Examination of the screw holes of the retrieved TPLO plates revealed very few signs of fretting corrosion (ie, locally roughened surfaces, pits, or cracks).

Light microscopic and scanning electron microscopic examination of cross sections of the TPLO plates also revealed numerous small inclusions. Inclusions generally ranged from 1 to 20 µm in diameter, although rare inclusions were as large as 50 µm in diameter. Inclusions occasionally had a biphasic structure and were found equally often in the austenite and ferrite phases of the plate. Residua, inclusions, and cavities were not seen during scanning electron microscopic examination of the DCP.

Chemical analysis of the 3 new TPLO plates revealed that the ferrite phase contained a higher chromium content and lower nickel content than did the austenite phase. Chemical composition of all 11 TPLO plates met the general requirements for a cast 316L alloy (ASTM standard F745); however, in some plates, the nickel content was lower and the silicon content was higher than the standard **(Table 2)**. Moreover, there were substantial differences in chemical content among plates and between regions in individual plates. Chemical composition of the DCP met the general requirements for a wrought 316L alloy (ASTM standards F138 and 139).

Subjectively, the TPLO plates appeared to be soft and easy to dent or scratch. For 3 of the 11 TPLO plates, approximate ultimate tensile strength, calculated on the basis of hardness value, was less than the ultimate tensile strength required for a cast 316L alloy

Table 1—Results of metallurgic analyses of 11 Slocum TPLO plates (8 retrieved from dogs that had undergone TPLO for treatment of cranial cruciate ligament rupture and 3 new) and a single new 4-hole 4.5-mm Synthes DCP.

Plate No.	Time in situ (mo)	Inclusions*	Hardness† (MPa)	Ultimate tensile strength‡ (MPa)	Composition§ (%)	
					Ferrite	Austenite
Retrieved plates						
1	8	Many	146.7	495.6	1.9	98.1
2	8	Some	133.5	455.3	2.0	98.0
3	11	Some	152.0	508.8	2.6	97.4
4	28	Some	178.7	598.2	2.2	97.8
5	29	Some	172.0	575.8	4.3	95.7
6	38	Many	194.5	651.1	17.5	82.5
7	68	Many	156.3	523.2	33.7	66.3
8	79	Many	158.7	531.3	16.5	83.5
New plates						
1	NA	Some	129.2	439.1	2.5	97.5
2	NA	Many	138.5	460.6	7.2	92.8
3	NA	Many	160.8	555.7	21.6	78.4
DCP	NA	Almost none	324.0	1,021.1	< 0.5	> 99.5

*Relative number of inclusions seen during light microscopic examination of a cross section of each plate. †Determined by means of the Vickers hardness measurement method with a load of 98 N; for each plate, 6 randomly distributed measurements were obtained from a cross section of the plate and averaged. ‡Estimated values determined on the basis of measured hardness. §Determined by means of X-ray diffraction.

NA = Not applicable.

On the basis of attraction to a strong magnet, new plate 1 was classified as nonmagnetic (ie, the plate could not be lifted with a large magnet), new plate 2 was classified as slightly magnetic (ie, the plate could be partially, but not entirely, lifted with a large magnet), and new plate 3 was classified as strongly magnetic (ie, the plate could be entirely lifted with a large magnet). Retrieved plate 7 was removed from a dog with a poorly differentiated sarcoma adjacent to the plate.[1]

(ASTM standard F745; ultimate tensile strength > 483 MPa; Table 1). In contrast, approximate ultimate tensile strength of the DCP, calculated on the basis of hardness value, was greater than the strength required for a wrought 316L alloy (ASTM standards F138 and 139; ultimate tensile strength > 860 MPa).

Histologic examination of H&E-stained tissue sections obtained from areas adjacent to the plates during retrieval of the TPLO plates from 8 dogs revealed a fibrous connective tissue membrane surrounding each plate. Interspersed amongst the fibrous tissue were many small foci of primarily mononuclear inflammatory cells (ie, macrophages with a few lymphocytes and neutrophils), fibroblasts, and some heterogeneous acellular debris. This debris included faintly granular nonrefractile deposits of light-gray material; minute shards of rarely refractile gold-green material; and fine granules of black material. Scattered macrophages were filled with a globular gold-brown dark material, presumptively hemosiderin. Fine granular pigment was observed scattered throughout the fibrous tissue and could be seen within some macrophages **(Figure 3)**. A few extracellular fragments of pale-green translucent nonrefractile crystalline material were also observed.

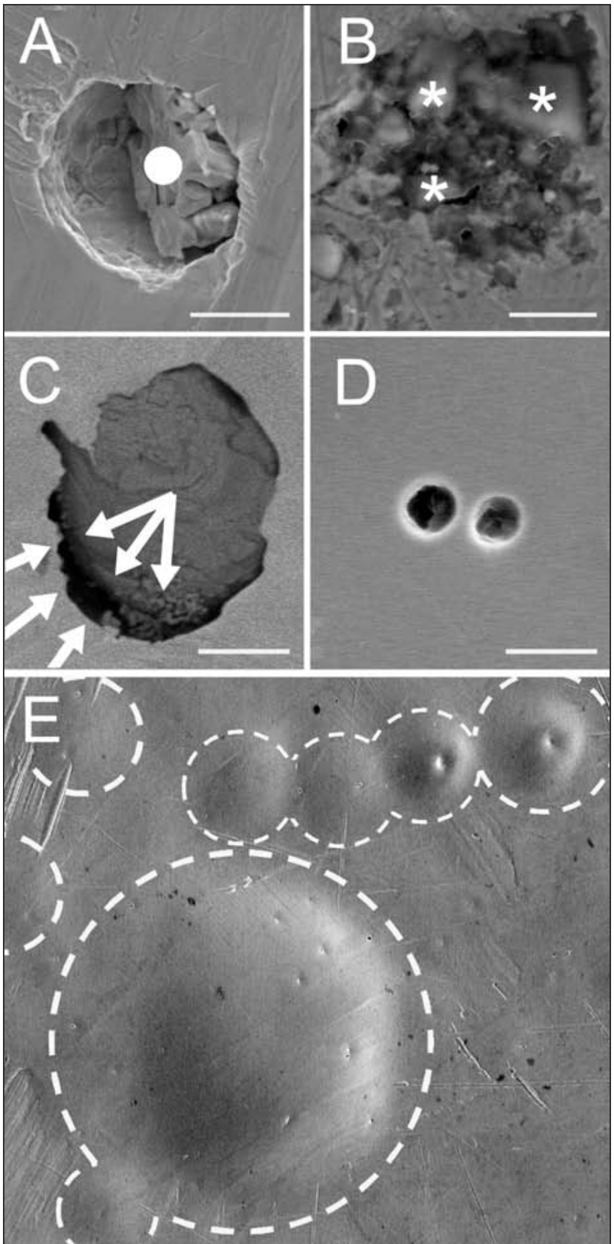

Figure 2—Scanning electron micrographs of the surface of a TPLO plate retrieved from a dog. A—Residua (dot) containing aluminum and silicon protrude from a cavity in the plate surface. B—Sharp-edged residua (asterisks) rich in aluminum and silicon are seen in a cavity on the plate surface. C—Image of a silicon-rich inclusion obtained by means of backscattered electrons imaging. Notice that the less dense inclusion appears darker than the surrounding stainless steel matrix. Also notice the gap between the inclusion and the surrounding matrix (arrows). D—Two small (< 1 µm in diameter), sharp-edged round holes can be seen in the plate surface. E—Numerous shallow, soft-edged pits (circles) resulting from local corrosion processes can be seen. For all images, bar = 20 µm.

Histologic examination of Giemsa-stained sections also revealed particles in the tissues **(Figure 4)**. These particles were not transparent, but shone brightly when examined by means of reflected light; most were < 10 µm in diameter. During scanning electron microscopy with backscattered electrons imaging, the particles appeared bright, but they were not seen during scanning electron microscopy with secondary electrons imaging. Chemical makeup of these particles, determined by means of energy-dispersive X-ray analysis, included chromium, nickel, molybdenum, iron, aluminum, and silicon. Particles ranged from 0.1 to 3.0 µm in diameter and were mostly rounded. Two types of particles were distinguished on the basis of their chemical content. The first consisted of particles that contained mostly chromium, nickel, molybdenum, and iron, and the second consisted of particles that contained mostly aluminum and silicon. Other elements that were detected in both types of particles and were regarded to be of biological origin included carbon, nitrogen, oxygen, sodium, magnesium, potassium, sulfur, phosphorus, and chloride.

Discussion

Results of metallurgic analyses in the present study determined that the new and retrieved TPLO plates were manufactured from 316L stainless steel and produced by a casting process. All of these plates had a 2-phase microstructure consisting of austenite and ferrite, and chemical composition varied among plates and even among regions of the same plate. In addition, some of the plates did not meet specifications for chemical composition of cast surgical implants (ASTM standard F745).

An important finding of the present study was that all 11 TPLO plates had residua, inclusions, and cavities. The residua most likely originated from surface irregularities embedded in the cast mold that broke free (eg, aluminum- and silicon-containing sand) during the casting process or resulted from mechanical polishing of the plates with an aluminum-containing and possibly silicon-containing abrasive.[a] Inclusions were likely a result of incomplete mixing of the metallic components during manufacture of the alloy, although some of these inclusions resembled impurities that may have been contained in the raw material.[5] Incomplete mixing of

Table 2—Chemical composition of 3 new Slocum TPLO plates and a single new 4-hole, 4.5-mm Synthes DCP.

	TPLO plates				Standard for cast implants* (%)			Standard for wrought implants† (%)		
Variable	1	2	3	DCP	Min	Max	Tol	Min	Max	Tol
Carbon	0.010–0.017	0.015–0.020	0.018	0.014	NS	0.06	0.01	NS	0.03	0.005
Sulfur	0.002–0.020	0.002–0.010	0.002	0.001	NS	0.03	0.005	NS	0.01	0.005
Chromium	18.42–18.82	17.85–18.26	17.47	17.70	17	19	0.20	17	19	0.20
Nickel	9.50–9.95	11.16–11.60	11.76	14.10	11	14	0.15	13	15	0.15
Manganese	1.04–1.13	0.68–0.83	0.82	1.75	NS	2	0.04	NS	2	0.04
Phosphorus	0.023–0.030	0.020–0.023	0.021	0.019	NS	0.045	0.010	NS	0.025	0.005
Silicon	1.01–1.12	0.70–0.74	0.75	0.18	NS	1	0.05	NS	0.75	0.05
Molybdenum	2.10–2.18	2.03–2.20	2.13	2.8	2	3	0.10	2.25	3	0.10
Copper	0.29	0.26	0.27	0.2	NS	NS	NA	NS	0.5	0.03
Nitrogen	0.035–0.068	0.082–0.083	0.089	0.07	NS	NS	NA	NS	0.1	0.01
Composition‡	25.35–26.01	24.55–25.52	24.5	26.94	NS	NS	NA	26.0	NS	NS

*Standard specification for 18chromium–12.5nickel–2.5molybdenum stainless steel for cast and solution-annealed surgical implant applications (ASTM standard F745). †Standard specification for wrought 18chromium–14nickel–2.5molybdenum stainless steel bar and wire for surgical implants (ASTM standard F138), and standard specification for wrought 18chromium–14nickel–2.5molybdenum stainless steel sheet and strip for surgical implants (ASTM standard F139). ‡Chromium content (%) plus 3.3-times molybdenum content (%).

Min = Minimum. Max = Maximum. Tol = Tolerance. NS = Not specified. NA = Not applicable.

A range of values indicates that content varied in different portions of the plate.

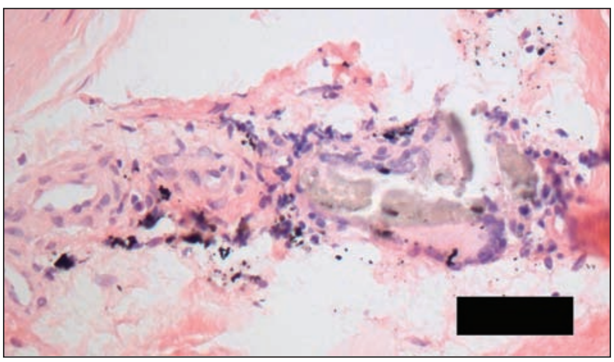

Figure 3—Photomicrograph of a biopsy sample of the soft tissues adjacent to a TPLO plate in a dog. Locally extensive fibrosis is present with scant mononuclear inflammation and intralesional foreign material. Interspersed among this fibrous tissue are many small foci of primarily mononuclear inflammatory cells (macrophages with a few lymphocytes and neutrophils), fibroblasts, and admixed debris. This debris includes faintly granular, nonrefractile deposits of light-gray material and fine granules of black material. Scattered macrophages are filled with this granular material. H&E stain; bar = 55 µm.

the metallic components might have occurred if the temperature during the manufacturing process was not sufficiently high or if this temperature was not maintained for a long enough period to allow homogeneous distribution of the various elements. The cracklike cavities that were observed were likely a result of the casting process and resembled impressions that would have resulted from the mold material. In this context, it is worth noting that surface roughness was observed in both the new and retrieved TPLO plates. Despite the mechanical polishing procedure used to obtain the final surface finish, many surface irregularities remained. Because the surface of plates used as surgical implants should be as smooth as possible,[6,7] most implants are polished with an electropolishing procedure. Electropolishing removes superficial foreign material, improves corrosion resistance, and creates a passive film on the implant surface.[7-9] Corrosion resistance is increased and bacterial attachment decreased with electropolishing, compared with mechanical polishing.[7,9-11]

The only major differences between the new and retrieved TPLO plates in the present study were the

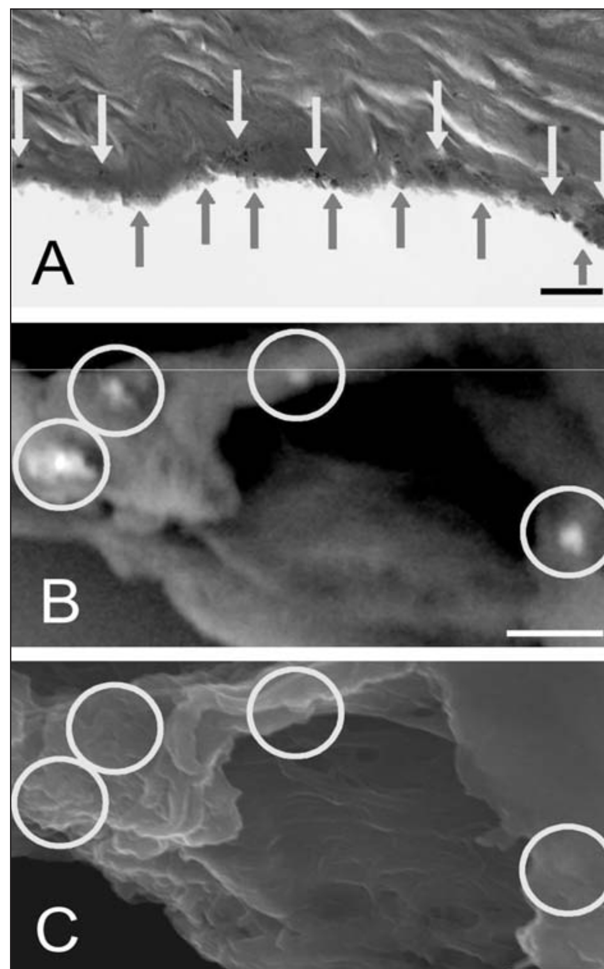

Figure 4—Photomicrograph and scanning electron micrographs of a biopsy sample of the soft tissues adjacent to a TPLO plate in a dog. A—Notice the particulate debris (dark dots, arrows) located in the connective tissue close to the surface of the plate. Giemsa stain; bar = 50 µm. B—In an image obtained by means of backscattered electrons imaging, the particles (circles) appear bright, compared with the surrounding tissue, indicating that they have a higher density than the tissue. Bar = 10µm. C—In an image obtained by means of secondary electrons imaging, the particles are not visible, indicating they are located within the tissue and not on the tissue surface. Bar = 10µm.

presence of small gaps separating many inclusions from the surrounding matrix and the presence of various-sized pits on the surface of the retrieved plates. These differences demonstrate a loss of metal from the retrieved plates, and we believe that this loss was a result of corrosion. The small gaps were likely a result of galvanic or crevice corrosion of the matrix material around the inclusions,[12] which in some instances allowed the inclusion to fall out of the matrix, leaving behind the small pits that were seen on the plate surface. Stainless steel castings generally have larger grain boundaries than do their wrought counterparts and, depending on the casting process controls and actual chemistry, can be more prone to intergranular corrosion. It is possible to cast stainless steel components, but these generally have poorer mechanical properties than do wrought stainless steel components and generally are not used for surgical implants.[13]

By comparison with the TPLO plates in the present study, the DCP had a nearly pure austenitic structure and absence of residua, inclusions, or cavities. Furthermore, this implant had a more stringent chemical composition, in that it complied with ASTM standards F138 and F139, which are the standards governing surgical plates used in humans.

All tissue specimens obtained from the 8 dogs from which TPLO plates were retrieved contained particulate debris, with some of this debris observed to be intracellular. The debris was thought to be metallic on the basis of its dark appearance in H&E-stained sections. Conventional histology, however, is not of great use in determining the nature of metallic deposits in tissues. Thus, scanning electron microscopy[14,15] was performed, which confirmed that the particulate debris was metallic. On the basis of their elemental composition, 2 types of particles were observed in the tissues. Particles composed mainly of chromium, nickel, molybdenum, and iron may not necessarily have arisen from the plates themselves, as has been previously suggested.[16] Small particles can originate from the original plate application process, arising possibly from the drilling that is involved, and can include some bore chips of metal (eg, from a drill guide). However, the loss of material observed in the retrieved plates suggests that at least some of these particles originated from the plates. Inclusions and residua that have corroded out of a plate would stay in the tissue adjacent to the plate because they represent the less soluble parts of the alloy. Some of this material may undergo phagocytosis, resulting in it being found intracellularly, particularly within macrophages. It also has been shown that particulate debris may be associated with osteolysis.[17,18] On the other hand, particulate debris composed mainly of aluminum and silicon probably arose from the cast mold or the mechanical polishing process.

The TPLO plates in the present study had variable tensile strength, as determined by extrapolation from hardness measurements. Although tensile strength was generally in the range expected for cast alloys, several plates had values less than the minimum tensile strength specified in ASTM standard F745. Interestingly, there did not appear to be a linear association between hardness values and austenitic content.

Type 316 stainless steel was established as the standard for implant-grade materials in the early 1950s,[19] and ASTM standard 55-65 was initially established to define the metallurgic requirements for 316 and 316L stainless steel. Cast products, as defined by ASTM standard F745, were used as surgical implants in the early 1970s,[13] but casting was reserved for production of complex shapes, such as the femoral stems for hip prostheses, that could not be manufactured by wrought-forming processes. Cast implants are no longer used because of concerns regarding low strength, which requires an increase in the size of the part, and the low corrosion resistance.[20] It was later established that premium melted material (remelted) would provide for improved homogeneity, controlled microcleanliness, and better corrosion resistance, which resulted in publication of specific metallurgic requirements for bar and wire stainless steel (ASTM standard F138) in 1971 and sheet and strip stainless steel (ASTM standard F139) in 1976. Subsequently, these standards were upgraded to reflect the chemical composition for implant-quality stainless steel. In particular, contents of chromium and molybdenum were specified to ensure adequate resistance to pitting corrosion in the physiologic environment.[13,21] Notably, many 316L stainless steel devices manufactured in the 1960s and 1970s were prone to accelerated corrosion because of improper selection of materials, faulty fabrication techniques, and use of mixed metals.[22] Many of these implants did not meet the standards of the time; therefore, the finding of corrosion after implantation was not altogether surprising.[22] Such problems have largely been eliminated through the use of sound metallurgic practices and fabrication processes. Ultimately, implant-grade bone plates made of 316L stainless steel that are designed to be used for internal fixation of the skeletal system should comply with ASTM standard F382-99(03),[2] which states that such plates should be wrought implants that comply with ASTM standards F138 and F139, consist of a pure austenitic structure, and comply with specific chemical and strength requirements. Furthermore, materials that comply with ASTM standard F745 are not listed as materials from which metallic bone plates can be made.

The primary differences between ASTM standard F745 and ASTM standards F138 and F139 are the more stringent requirements in the latter, including lower tolerances for chemical composition and specification of additional elements that must be included. Additionally, there is a requirement that there be no ferrite, making the material nonmagnetic. These requirements are based on maintaining a fully austenitic (single-phase) structure during the cold-working process and promote increased corrosion resistance.

The FDA recognizes ASTM standards F138 and F139 as the standards for implant-quality stainless steel devices used in humans, and these standards are required for new class II devices (eg, metal plates for fracture fixation) manufactured after 1976.[23] These ASTM standards define a very specific subset of the generic quality 316L alloy and were established to improve various characteristics of the alloy when it is used for medical devices implanted in a saline environment.

Adverse tissue responses can occur for a number of reasons, but there is evidence that adverse tissue responses seen in the present study were attributable to the TPLO plates that were implanted. Most importantly, all retrieved TPLO plates had a dual-phase structure with a high ferrite content. In addition, inclusions and residua identified during examination of the plates could contribute to an adverse tissue reaction if they were transferred to the surrounding tissues. Because the same elements that made up the inclusions and residua were found in the tissues directly adjacent to these plates, it seems certain that they were derived from the plates. Additionally, the retrieved plates were found to have undergone some corrosion. Corrosion products can accumulate and result in adverse tissue reactions, which include acute inflammation, granulation tissue and collagen formation, and tissue necrosis.[24,25] Furthermore, these corrosion products can negatively affect osteoblast proliferation and differentiation owing to their toxic effects.[18,26] Inclusions and material inhomogeneity are documented causes for corrosion,[27] and the finding that the retrieved plates had such characteristics further implicates the TPLO plates in the adverse tissue reactions that were seen.

Interestingly, the ferrite content in the plate removed from the dog with a poorly differentiated sarcoma[1] was the highest of all of the plates evaluated (33.7%). However, we cannot comment on whether there was a direct relationship between the high ferrite content and the development of this tumor, nor can we speculate on whether lower ferrite contents might have any effect on tumor development. The tolerable amount of ferromagnetic particles in the tissues is unknown; however, it has been shown that in Wistar rats with Walker 256 carcinosarcoma exposed to various concentrations of ferromagnetic particles, doses > 2 g/kg resulted in accelerated tumor growth.[28]

We conclude, on the basis of our findings, that the TPLO plates we evaluated were inferior in terms of compositional makeup to wrought implants. The TPLO plates had substantial inhomogeneity, both from a structural and chemical viewpoint, which can result in various adverse reactions within the plate, such as corrosion, and within the adjacent soft tissues. The material composition differences between the TPLO plates and the DCP can reasonably explain why wrought plates would have a greater resistance to corrosion, compared with cast plates.

The ASTM standards that relate to surgical implants are clear as to the accepted specifications for wrought implants. Our position is that cast plates are inferior to wrought plates. Although these standards relate to implants intended for human use, the current standard of care in veterinary medicine mandates that we not use inferior products in animals, despite the lack of direct oversight by the US FDA. On the basis of our findings, we no longer recommend the use of Slocum TPLO plates at the Cummings School of Veterinary Medicine, as alternative plates are available. Finally, on the basis of the adverse metallurgic and histologic effects identified, we are currently recommending removal of Slocum TPLO plates from all dogs in which they have been implanted.

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b. Boudrieau RJ, McCarthy RJ, Sisson RD. Metallurgical evaluation of the Slocum TPLO plate (abstr), in *Proceedings*. 32nd Annu Conf Vet Orthop Soc 2005;15.
c. Slocum T. Incidence of neoplasia with TPLO surgery and Slocum implant (abstr), in *Proceedings*. 32nd Annu Conf Vet Orthop Soc 2005;16.
d. TPLO plate, Slocum Enterprises Inc, Eugene, Ore.
e. Synthes GmbH, Oberdorf, Switzerland.
f. Struers MultiFast Brown, Copenhagen, Denmark.
g. FESEM S-4100, Hitachi Corp, Tokyo, Japan.
h. Link Isis 300, Oxford Instruments, Witney, Oxon, UK.
i. Siemens D5000 diffractometer, Bruker Advanced X-ray Solution, Karlsruhe, Germany.
j. DiffracPlus EVA 4.0.0.2, Bruker AXS, Karlsruhe, Germany.

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Correction: In "Serologic evidence of vesivirus-specific antibodies associated with abortion in horses," published June 2006 (*Am J Vet Res* 2006;67:1033-1039), the first 3 sentences of the first paragraph on page 1033 provided misleading information. The information should be as follows:

Abortions and stillbirths cause severe economic loss to the equine industry, and approximately one third (25% to 45%) of these losses are reportedly caused by infectious agents.[1-3]