

TECHNICAL NOTE**ANTHROPOLOGY**

Rebecca J. Wilson,¹ M.A.; Jonathan D. Bethard,^{1,2} M.A.; and Elizabeth A. DiGangi,³ Ph.D.

The Use of Orthopedic Surgical Devices for Forensic Identification*

ABSTRACT: Surgically implanted devices have become increasingly common in modern skeletal material. Therefore, having the knowledge of the variety of implanted orthopedic devices, their manufacturer, and where to find and how to use identifying numbers in such implants can assist in the identification process when traditional methods are not applicable. Orthopedic device manufacturers are required by the Safe Medical Devices Act of 1990 and the FDA Modernization Act of 1997 to track permanently implanted devices. Manufacturer information on orthopedic devices associates the orthopedic surgeon who implanted the device with the patient. By providing a current list of the most common orthopedic device manufacturers in the U.S.A. and the associated contact information, investigators will have updated tools for the individuation process. Despite numerous complicating factors regarding how device data are tracked, the information presented here can assist forensic professionals with obtaining presumptive and/or positive identifications.

KEYWORDS: forensic science, forensic anthropology, orthopedic devices, orthopedic device manufacturers, corporate logos, identification

Positive or presumptive identification of human skeletal remains is typically achieved through the traditional avenues of DNA analysis and/or investigative means, such as comparison of antemortem and postmortem radiographs (1). However, it may be necessary to take nontraditional approaches toward obtaining positive identifications, especially in situations where large numbers of unidentified decomposing or skeletal remains exist, such as in mass disasters and large-scale human rights violations, or when fragmented or otherwise damaged remains preclude other methods from being used. The conventional methods of positive identification, such as dental comparisons, may not always be available to the forensic investigator, and DNA analysis is costly and time consuming (2–5). Therefore, the presence of orthopedic devices may assist in the identification of skeletal remains, because they may provide a means through which an individual can be traced without expending similar resources (6).

The presence of an orthopedic device is an individuating characteristic that differentiates one set of remains from another. The presence of a device alone provides the investigator with valuable information about the decedent. For instance, device presence reveals some of the following information: (i) an injury or disease existed which required device implantation, which friends and family members may be familiar with and remember; (ii) the individual at least had access to the means required to have major surgery, which may be relevant particularly in certain areas of the

world in terms of narrowing down a search; and/or (iii) it may hint at possible middle or advanced age of the individual, depending on the type of implant. In both open and closed-population situations, having this basic information at the outset of a search is at least a beginning and is more information than can be garnered from the biological profile alone.

Surgically implanted devices, such as the orthopedic devices discussed in this study, provide unique information to facilitate positive identification by means of tracking a device in unknown forensic material to specific individuals. For example, Clarkson and Schaefer (7) provide an excellent review of the variety of surgical interventions useful to forensic investigation in the U.K., including the use of orthopedic devices. Simpson et al. (8) also demonstrate the utility of such devices in the identification process through their survey of eight case reports from Australia. However, their cases represent closed populations where possible identities of the victims were known prior to the investigation. In three circumstances, the identification came from the use of antemortem and postmortem radiograph comparisons and not through the actual tracking of the device. The use of radiographs for identification requires having a presupposition of the victim's identity (a closed population) as opposed to a typical mass disaster situation (an open population), which lacks this prior knowledge (1).

For this reason, Ubelaker and Jacobs' (9) thorough presentation of the utility of orthopedic devices in the identification process is a beneficial resource for investigators working in open-population contexts. However, the information provided in their article is outdated. In the past several years, orthopedic device manufacturers have undergone numerous company mergers and/or internal restructuring, thus necessitating the compilation of an updated list of manufacturers, their corporate identifier (logo), and their contact information, which this article provides.

From a forensic perspective, the growing prevalence of orthopedic devices in modern Americans requires understanding the

¹Department of Anthropology, The University of Tennessee, 250 South Stadium Hall, Knoxville, TN 37996-0720.

²Department of Natural and Behavioral Sciences, Pellissippi State Community College, Knoxville, TN.

³International Criminal Investigative Training Assistance Program (ICI-TAP-Colombia), Bogotá, Colombia.

*Presented in part at the 58th Annual Meeting of the American Academy of Forensic Sciences, February 20–25, 2006, in Seattle, WA.

Received 14 Oct. 2009; and in revised form 22 Jan. 2010; accepted 23 Jan. 2010.

circumstances leading to device implantation and how these devices can aid in the identification of an unknown decedent. The William M. Bass Donated Skeletal Collection serves as a unique example of the prevalence of implanted surgical devices in modern Americans. Surgical implants in the form of orthopedic devices are found in 84 individuals out of the 536 adult skeletons available for study, excluding open-heart surgery staples, vein or artery replacements, and other forms of implants (such as chemotherapy ports and pace-makers). The range of these devices is listed in Table 1.

The implantation of surgical devices results from musculoskeletal conditions including injury to bones, joints, muscle, ligaments, tendons, and osseous conditions, such as arthritis and osteoporosis (10). In fact, orthopedic complaints are among the top reasons for seeking medical care. Sprains and bone fractures account for half of all musculoskeletal disorders (11). In 2003, 56% of an estimated 56 million physician consultations were the direct result of traumatic injuries (11). While not all traumatic injuries require the implantation of a permanent fixation device, severe osseous injury remains the primary reason for device implantation. For example, at least 60 of the 84 individuals in the Bass Donated Collection with orthopedic devices have these as the by-product of a documented traumatic event.

Traumatic fixation devices typically consist of “single/multiple-component metallic bone fixation appliances and accessories” in the form of one or more metallic components and their metallic fasteners (12). Initially, orthopedic surgeons began using steel plates and screws for fixation early in the 20th century (13). Today, devices typically consist of a plate or a nail/plate combination made of alloys, such as cobalt–chromium–molybdenum, stainless

steel, and titanium (12). Fasteners, such as screws, nails, bolts, nuts, and washers, fix the plate in a specific location of the bone depending on the nature of the injury (12). For example, one common device in the Bass Donated Collection consists of a rod implanted through a bone’s medullary cavity and secured at either end to stabilize compound fractures.

Total or hemiarthroplasty accounts for the second most common reason for implanted devices besides fixation of traumatic injuries. The Bass Donated Collection has 18 individuals demonstrating arthroplastic surgery. Several of these individuals have multiple appliances, which total 35 identifiable components. Total arthroplasty involves the replacement of an entire joint complex. For example, a total hip replacement consists of the acetabulum and femoral head being replaced by plastic and/or metal components or a combination of the two. Hemiarthroplasty includes the partial replacement of a joint complex and can be unipolar or bipolar in form. For example, a partial knee replacement involving the tibia can consist of the replacement of only one or both condyles. Joint replacement parts (14) are typically constructed of metals (stainless steel, titanium, cobalt/chromium, etc.), polymers (silicone, polyethylene, etc.), and ceramics (cement). It is not uncommon to find a combination of materials in the construction of these devices or multiple different manufacturers within the same joint replacement, which can complicate the individuation process.

Another issue is that the design and production material of these devices may have not necessarily changed over the years (depending on the device), which makes length of time since injury difficult to determine. A University of Tennessee forensic case highlights the possible difficulty in tracking devices, owing to the static nature of certain device types through time. The completely skeletonized remains of an older man were recovered that included a right femur with multiple, large implanted plates and extensive osseous healing. As a presumptive identification existed as a result of the police investigation, the investigators were able to compare the description of the implant to the written medical records. This investigation revealed that the plate in question was implanted in the 1940s as the result of a severe automobile accident. While the manufacturer logo was visible, the plates were similar in appearance to plates recently manufactured. This illustrates the point that several devices have been engineered similarly for decades, which makes the identification of the manufacturer and, more crucially, the serial number, paramount to obtaining a successful outcome.

The Safe Medical Devices Act (SMDA) of 1990, administered through the Center for Devices and Radiological Health of the Food and Drug Administration (FDA), requires the tracking of certain medical devices (9). The SMDA requires manufacturers to track medical devices if failure of the device is likely to have adverse health consequences, if it is life-sustaining, and if it is permanently implantable (15). Guidelines for specific orthopedic devices can be found in the following sections of the FDA’s federal regulations: Title 21, Food and Drugs; Chapter 1, Food and Drug Administration Department of Health and Human Services; and subchapter H, Medical Devices (15). Effective from February 19, 1998, the tracking requirement changed under the FDA Modernization Act (FDAMA) of 1997, giving the FDA the discretion to track devices to the patient level and allowing patients to refuse the release of their information for tracking purposes (16). While orthopedic devices are currently not specifically listed as “Devices Subject to Tracking” under the FDAMA (Section 519(e)), they are permanently implanted; so, according to the SMDA, they should be subject to tracking.

Because the FDAMA and the SMDA seem contradictory in their requirements for orthopedic device tracking, we held numerous

TABLE 1—Variety and count of orthopedic devices in the William M. Bass Donated Skeletal Collection.

Type of Appliance	Location	Count
Glenoid fossa replacement	Scapula	1
Condyle replacement	Femur	4
	Tibia	4
Head replacement	Humerus	3
	Femur	10
Acetabular replacement	Os Coxa	3
	Plates	
	Mandible	1
	Humerus	2
	Radius	1
	Ulna	6
	Femur	7
	Tibia	3
	Fibula	7
Angled plates	Femur	8
Rods	Humerus	1
	Radius	1
Screws	Femur	6
	Tibia	5
	Cranium	4
	Scapula	1
	Humerus	2
	Radius	1
	Ulna	2
	Os Coxa	1
	Femur	3
	Tibia	11
	Phalanges	2
Chains	Cranium	4
	Mandible	1
Fixation devices	Vertebra	3
	Sternum	1
Wire	Vertebra	1
	Humerus	1
Total		111

conversations with representatives of orthopedic device-manufacturing companies and came to the conclusion that these devices are indeed subject to tracking under the SMDA. Most manufacturers have regulatory departments that track devices to the medical centers or physicians who purchase them. Typically, pertinent information from the orthopedic appliance (i.e., appliance type, manufacturer, lot/serial number) will be recorded at the time of surgery/implantation by the operating physician (17). Thus, through the SMDA, the FDA requires device manufacturers to have the ability to track implanted devices to patients through the purchasing physician/hospital in case of device flaws and/or failure.

Many problems have surfaced as a result of the vague wording and lack of standardization in the FDA guidelines for device tracking. The tracking of device requirement only pertains to permanently implanted devices, which generally eliminates screws and similar components, as these implants have the potential to be removed. Also, many of the plastic-based replacements are exempt from the SMDA requirements, because these components are not considered to be in the same category as the metal components. Furthermore, the FDAMA of 1997 attempted to alleviate the issues with the SMDA but, in actuality, made tracking by manufacturers optional for many appliances and left patient information accumulation up to the discretion of the patient.

The continual restructuring of the manufacturing sector has posed additional problems. The frequent reorganization of the manufacturing companies, whereby smaller companies are incorporated by larger conglomerates, can make tracking of specific devices extremely difficult. For example, while compiling the current manufacturer list, we discovered that a few of the companies that had manufactured devices found in individuals from the Bass Donated Collection no longer exist. Attempts to contact representatives who could answer questions about each defunct company and their records proved particularly complex, if not impossible. As an example of the potential difficulty with identifying the manufacturer, we confronted a situation involving a femoral joint replacement with the corporate identifier "EDRC" engraved on it. Upon speaking with the EDRC research group, we hit a dead end, as EDRC not only no longer makes devices and has not for a long time but appears to no longer have the records of any appliances once manufactured by them. In contrast, the larger, long-standing companies provide some of the best tracking possibilities, such as Synthes™ and Zimmer™. Both companies marked their implants with unique corporate identifiers (logo or name) and noted serial or production part numbers before the enactment of the SMDA. A younger company, Smith & Nephew™, is also very active in the tracking of appliances and understands its utility for forensic investigations.

As a response to the limitations and delays relating from the FDA's policies, the American Association of Orthopedic Surgeons (AAOS) instituted its own tracking system for joint replacements in 2004 (18). This tracking system allows orthopedic surgeons to follow-up with specific patients for research purposes (18). Even though the system was not specifically designed for forensic use, it provides an additional source of information from which to track a patient and possibly obtain a positive identification. Additionally, the field of bioengineering has established a system similar to that of the AAOS, which focuses on the postsurveillance of orthopedic devices at the hospital level, and is designed to track specific patients to ascertain long-term design integrity (19). Regardless of the tracking system used, the surgeons' notes will be the ultimate source of the identification because the serial number of the appliance, the part number, and the manufacturer information are in these records.

The increasing number of implanted arthroplastic and traumatic fixation devices requires full knowledge of how to use these for forensic investigations. This study provides the steps to identifying the types of orthopedic appliances, as well as manufacturer information, serial numbers, and part/lot numbers. In doing so, it provides a list of the most common orthopedic devices, U.S. manufacturers and their contact information, how to read the product information on an orthopedic appliance, and what these mean for the individuation process. Investigators should be able to initiate an investigation into unidentified individuals who have orthopedic devices once they have the knowledge of how to use the information contained in these implants.

Types of Orthopedic Appliances

The variety of orthopedic devices necessitates knowing the most common appliances found in skeletal remains. Most orthopedic devices in the Bass Donated Collection consist of, but are not limited to, screws, metal plates, and joint replacements (refer to Table 1). Several other appliances are present in the collection but are infrequent. Obtaining an identification from tracking an orthopedic device depends on both the type and proper description of an appliance. Some devices, like screws, are ineffective, while others, like joint replacements, are highly effective because of their unique morphology.

Screws are used in a majority of orthopedic surgical procedures, which can be a result of everything from reattachment of muscle to the fixation of fractures. The same type of screw can be found in several different skeletal elements. A single screw found near a muscle origin site is a common occurrence, as is depicted in Fig. 1, with the muscles of the shoulder and elbow typically affected. Screws tend to lack product information or are not tracked by manufacturers unless they belong to a specific piece of equipment. For example, only three individuals in the Bass Donated Collection have identifiable manufacturer information on their screws. Two of these individuals have intervertebral body fusion devices fixing several vertebrae together. The other individual has a unique chain-like plate securing the manubrium and body of the sternum, as can be seen in Fig. 2. The screws in all three situations had sequential serial numbers and the same part/lot numbers, indicating that they most likely came as a set with the fixation device.

Screws for orthopedic devices can be difficult to differentiate from common screws found in a hardware store. Many device manufacturers are starting to use hexagonal or squared screw heads to differentiate from the Phillips and flat-head screw used in



FIG. 1—The screw and washer in this proximal ulna is an example of a common implant to find throughout the skeleton.

construction materials, but the threading and size are still going to be identical (20). In fact, cases involving building/construction sites and/or sites with high fragmentation of human material may influence the ability to identify items, such as an orthopedic implant.

However, screws can still be useful in identifications. Access to and comparison of antemortem radiographs provide the best avenue for identification when dealing with screws. Screw placement in a device, its length, and orientation in a bone are vital to antemortem/postmortem radiograph comparisons. For example, a recent University of Tennessee forensic case involved using the combination of a surgical plate and screws implanted in the radius of the unknown skeleton to make the positive identification. However, a possible identification for the skeleton was already known, and the missing individual's family knew he had undergone surgery after suffering a fall. Upon acquisition of the medical records, the radiographs and physician notes confirmed the injury, the treatment, and even noted the manufacturer and serial number of the implanted device. The screws acted as substantiating evidence for the positive identification in this case. Thus, the family's prior knowledge of the major medical intervention was substantiated by the presence of the appliance and its comparison to the individual's medical records.

Metal plates, mostly stainless steel, account for the next largest group of surgical devices. These range from delicate, chain-like



FIG. 2—A sternum fixation device with product information visible on both the chain and the head of the screws.

devices to extremely robust devices running the length of a long bone. Small chain-like plates may be located in more fragile areas of the body, such as the maxillary and frontal regions (refer to Fig. 3). These devices are not traceable, because in composition, they are very similar to the malleable metal used in staples. Both are sold on spindles like sewing thread spools and are of a light-weight malleable metal alloy, which can be cut at any desired length. The company and product information are located on the spindle, rather than the metal, making it near impossible to use the device as a means to track an unknown skeleton. In this situation, similar to screws, the comparison of antemortem/postmortem radiographs and medical records is the best option.

Larger stainless steel metal plates represent the most straightforward way to identify unknown skeletal material when contending with open populations of decedents. Figure 4 depicts both an ulnar and radial implant of this type. These plates should bear some type of corporate logo, a part/lot number, and a serial number. In fact, several companies focus primarily on the production of plates and have widespread distributions of these, especially Synthes™. However, the issue in tracking plates is the continuing use of devices produced prior to the SMDA enactment because these plates may not have a serial number or the manufacturer may be unknown. Many surgeons have a stockpile of orthopedic devices purchased prior to newer pieces that are consistent with the SMDA regulations.

Joint replacements provide another valuable avenue for identification. These replacements are increasingly prevalent in orthopedic surgery, owing to both the increase in length of life of Americans and the obesity epidemic throughout the U.S. Hip and knee replacements account for most of the joint replacement devices in the Bass Donated Collection with 16 individuals having at least one device. According to the National Discharge Survey, more than 769,000 total hip or knee replacement surgeries occurred in the U.S. in 2005 (21). Knee replacements have become the leading

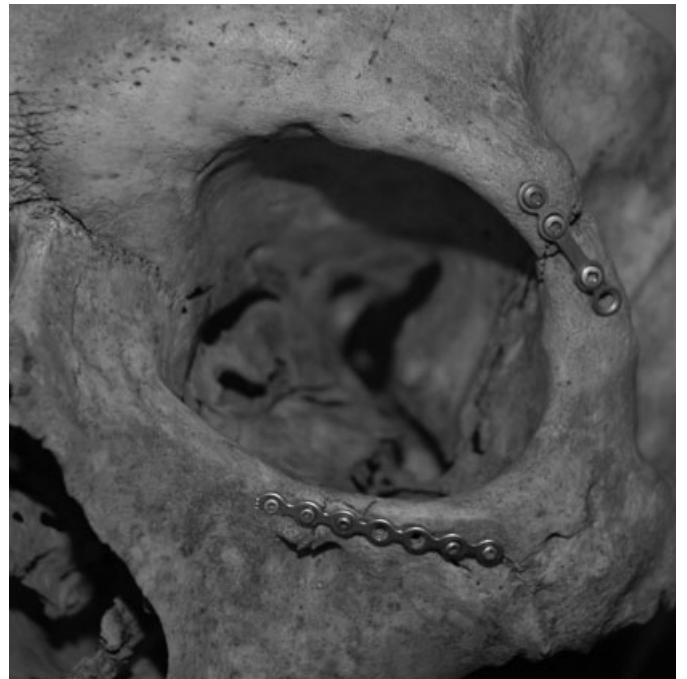


FIG. 3—An example of the small chain-like orthopedic devices found in the skeleton, which are more useful for the verification of medical intervention than for tracking purposes.



FIG. 4—A typical traumatic fixation plate as seen in the radius and ulna. Both plates have product information along the narrow side of the stainless steel plate.

arthroscopic surgery performed in the U.S., followed by total hip replacements. In 2005, 62% of knee replacements occurred in individuals aged 65 or older, which corresponds with the age distribution of individuals with appliances in the Bass Donated Collection. Total hip replacements accounted for 235,000 surgeries with 59% of these going to those individuals aged 65 or older (21). The high prevalence in older individuals results from surgeons' hesitation to perform orthopedic procedures on younger individuals unless it is absolutely necessary, because a replacement is not equivalent to the original morphology of bone and will need to be replaced again in younger individuals. When present in younger individuals, a preexisting medical condition, such as a sports injury, or congenital condition may exist in the medical records. Also, the increase in

frequency of arthroscopic implants in individuals over the age of 65 can assist with identification of the aged, owing to the difficulties in estimating age at death for older individuals as well as provide a way to substantiate other major conditions relatives or friends may remember about a missing individual.

Several researchers demonstrate the utility of the variety and uniqueness of orthopedic devices in making a positive identification (1,6–9). In most cases, the fact that a device is distinct and its anatomical placement provide excellent comparability for radiographs in a closed-population situation (22,23). When an open population exists, ascertaining a positive identification from radiograph comparisons becomes more difficult. Even if antemortem records do exist, it is nearly impossible to match up such records with the deceased when there are few clues as to even presumptive identification. Tracking a device from an unknown skeleton to a patient therefore becomes the primary goal in an open-population setting. The manufacturer and product information is just as important as being able to identify specific types of appliances in open-population situations, which necessitates the development of a comprehensive listing of manufacturers and the meaning of the associated product information.

Location of Manufacturer Information

Knowing the location of product information on specific appliances and its meaning can expedite the recovery of information necessary for tracking. The location of manufacturer and appliance-specific information varies depending on the manufacturer, type of appliance, and specific component. Ubelaker and Jacobs (9) highlight the large number of identifiable parts possible in a single device. For example, a partial hip replacement, in which just the femur is affected, can include a femoral stem and head, an acetabular shell, liner, and multiple screws (9).

Many small components do not have any identifiable markings, making it impossible to trace these components to a patient, as previously discussed. The vagueness in the U.S.'s federal regulations for tracking devices has led to most permanently implantable plastic components produced without corporate identifiers because most manufacturers understand the regulations as only pertaining to metal components. For example, those individuals with partial shoulder replacements in the Bass Donated Collection whereby the glenoid fossa of the scapula is replaced with a polyethylene component have no product information located anywhere on the device. This is also the case in knee replacements that involve the patella as is in the case in Fig. 5. In contrast to the plastic implants, corporate identifiers on the metal femoral stem and head and tibial plateau components are present and the easiest to locate. Logos on the distal femur and shoulder replacements are the most difficult to find because of the location of the identifier and secondary osseous responses. These appliances often have logos on the inner side of the appliances, which, when attached to the bone, obscures the logo from plain sight.

Screws will have the corporate identifier and part number, when present, located on the head of the screw. However, it is highly unusual that a serial number will be present. Also, femoral plates involving the neck typically do not have any information located on the fixation bolt. The metal plate itself should have a corporate identifier on the flat, widest part of the plate located between the holes for the screws. The part and serial numbers can be found on the main portion of the plate as well but are more commonly found on the side of the appliance. In a few instances in the Bass Donated Collection, the corporate identifier and product information were all located on the thin side of the appliance.

Joint replacements are not as consistent in terms of product information placement. Joint complexes tend to exhibit extensive osseous remodeling to a greater extent than implanted plates. The new bone growth obscures identifying numbers and must be destroyed to access the required information. Also, corporate identifiers and serial numbers are often found on the underside of an appliance, the side facing the bone. This is a common problem in femoral condyle replacements and tibial plateau components. However, arthroscopic implants are highly reliable in cremations or situations of extreme burning because the implant's unique shape remains intact enough for easy identification compared to plates and screws that can be confused with building materials.

Corporate identifiers on humeral head replacements are typically found in two different locations. The head components will have the product information, which includes the logo, serial number, and product descriptors, on the inside of the hollow shell of the head or on the side of the single, solid head component just above the edge. The stem, or piece attaching the head to the shaft of the bone, will have the product information located on its side. The stem's product information is rarely visible because it is placed in the medullary cavity of the long bone.

Hip replacement components are more complicated. Acetabular components usually do not have product information on the metal shell. The polyethylene inner part sometimes has product

information, but this is usually in the form of part descriptors, such as "25 mm," which describes the acetabular diameter. Additionally, newer hip replacements are being sold as a unit in which only one component of the multicomponent system has the product information. The increase in whole patented joint systems is especially true for appliances from Zimmer™ and Stryker™. In a total hip replacement, the femoral component consists of a small, solid ball for the head and stem for the neck. The stem has the product information on its long tapered portion. If the product information cannot be found on the slender tapered part of the stem, it may be located on the flatter neck portion or at the base (the junction between the neck and medullary portions). It becomes more difficult to find the necessary product information in these situations because of limited access to the actual appliance, owing to its anatomical placement. In other situations, all the product information is visible, including the alloy components, as is demonstrated in the femoral replacement seen in Fig. 6.

Partial hip replacements, involving just the femur, tend to have separate product information on the head and stem. The multiple components typically used for partial hip replacements increase the chances of more than one manufacturer for the different components, which is often the case. The actual product placement is quite similar to the total hip replacement systems. Instead of having the small, solid head, the head is a large hollow piece. This head component's product information will be located on the base of the head just above the edge or inside of the hollow head component.

Identifying information on knee replacement components is the most difficult to find. Product information that is not on the underside of a component typically is located on the lateral edge of the femoral condyle or the anterior portion of the tibial tray. The plastic pieces usually do not have any product information except part descriptors, such as "anterior," "posterior," or "TIB." Also, patellar replacements typically do not display any product information as these are polyethylene products that are not required to do so under the SMDA. With the production of whole, patented knee systems, like those produced for the hip, new products lack corporate identifiers on each separate piece. This is a common problem for total knee replacements that include patellar components.

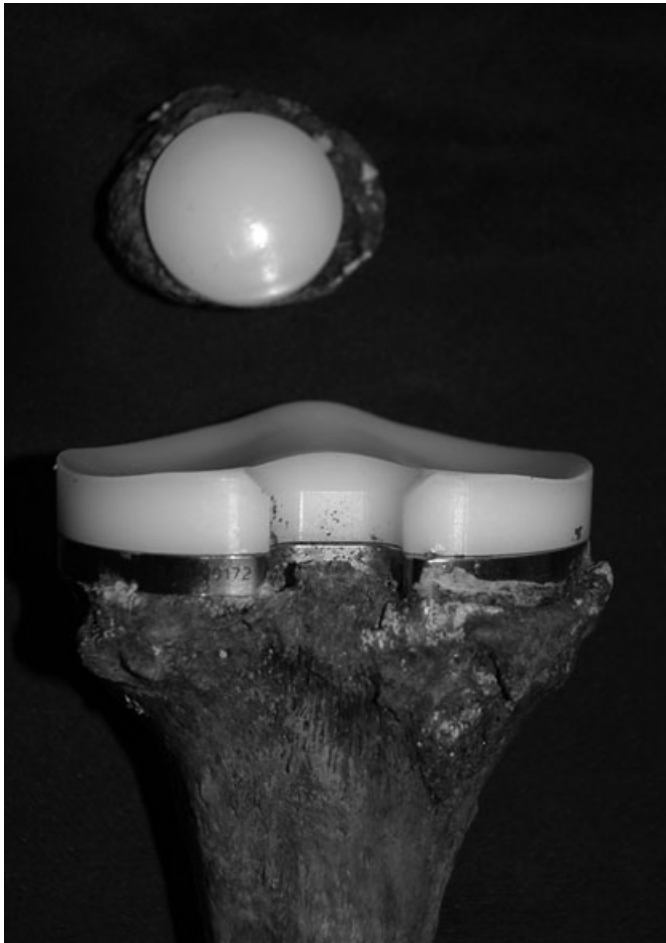


FIG. 5—A posterior view of a knee replacement with the tibia plateau and the patellar articular facets replaced. Note the plastic components of the knee and patella do not have any product information, while the metal base to the tibial implant does.



FIG. 6—An example of a femoral implant that clearly indicates the company logo, serial number, part/lot number, and other product information.

The variation in location of product information can make it difficult to find the necessary information for tracking purposes. Knowing the most common locations for specific components can aid in this endeavor. Once the product information is identified, the investigator needs to know what the different numbers mean and how to use them in the identification process.

Product Information

The product information found on a specific appliance translates into product descriptors, manufacturer name/logo, and serial numbers. This information leads to the company that produced the appliance and a means to associate it with a particular surgeon who implanted it into a patient. Following this chain, by properly identifying the type of appliance, manufacturer, and serial/part number, is an essential step in the identification process.

The most important feature includes the corporate identifier or logo, because it indicates the actual manufacturer of the device. Upon contacting the manufacturer, a representative can provide information on the hospital or surgeon which purchased the device. The serial number is the next most important aspect. An investigator must provide the serial number to the particular manufacturer, to allow the device to be tracked back to the purchaser. The serial number should have been recorded in the surgeon's notes at the time of implantation. In contrast, the part/lot numbers are not as specific in that they describe the physical dimensions of the object and/or when it was manufactured, and therefore, many different components may have the same part number. The part/lot number can still be helpful when dealing with a more universally used implant, however.

The corporate identifier is essential in the identification process when tracking an appliance to a particular patient. The logo or company identifier is indicative of which company produced the appliance, leading to more valuable information. A list of manufacturers would be useless unless an implanted device could be traced to the company that manufactured it. The first step in tracking an orthopedic device requires comparing the corporate logo with the current list of orthopedic device manufacturers. Figure 7 provides images of corporate logos found on several of the orthopedic device manufacturers found in the Bass Donated Collection, like the one visible in Fig. 6, augmented by additional common manufacturers. These logos represent manufacturers with appliances implanted in the U.S., but it should be noted that most companies have a worldwide distribution system, making the listing relevant to countries beyond the U.S. Table 2 provides the contact information for all of the manufacturers in Fig. 7 plus additional descriptors of companies for which logos are not included. The phone numbers provided in the table are current as of publication and belong to the specific department required to track devices. It is this number that should be contacted when seeking the purchaser of the device in question.

As noted however, the orthopedic industry has fluctuated in recent years with the disappearance, merging, and creation of new manufacturers. For example, Zimmer™ and Depuy Ace™ have recently acquired several other, smaller companies. These mergers complicate tracking a device, because the responsible departments are often eliminated or shuffled around during the acquisition process. While it may be more difficult to determine the manufacturer because a company is no longer in business, all manufacturers are required to keep information for appliances produced after 1993. Ideally, the larger companies still maintain information regarding device tracking for companies they have acquired which can be made available to the forensic investigator. This information is also incorporated in Table 2.

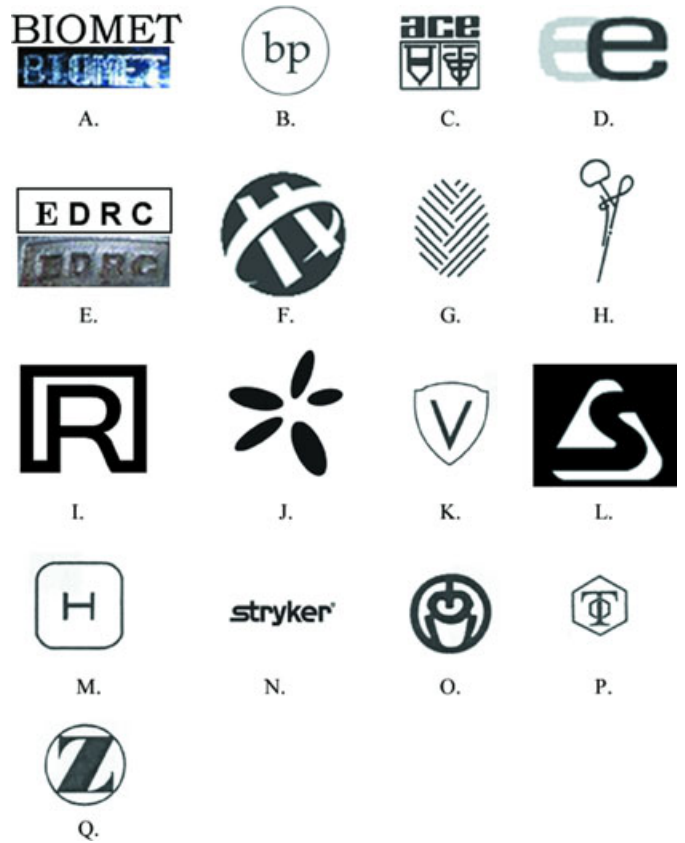


FIG. 7—Illustrations of manufacturer logos commonly found on orthopedic devices: A: Biomet; B: Biopro; C: DePuy Ace; D: Encore Medical Corporation; E: Engineering Design Research Center; F: Hayes Medical; G: Intermedics; H: Osteonics; I: Richards Orthopedics; J: Smith & Nephew; K, M, N: Stryker Howmedica Osteonics; L: StelKast Company; O: Synthes-Stratec (U.S.A.); P: Tornier; Q: Zimmer.

Furthermore, some orthopedic manufacturers' logos are more common in arthroscopic prostheses, like Zimmer™, while others are more prevalent in other areas of orthopedics, like Synthes™. It is helpful to know which manufacturers are known for making a specific device, especially when there is osseous remodeling present. If a corporate identifier is obfuscated, the knowledge of the most likely manufacturer can assist in trying to track the appliance when the serial number is observable. For example, Synthes™ is the top producer of surgical plates. In the Bass Donated Collection, half of all plates with visible logos were manufactured by Synthes™ (17 out of 37). On the other hand, Stryker™ is limited to mostly joint replacements. Also, certain manufacturers produce specialized devices specific to an injury or surgical specialty, like those used in the vertebral column. Overall, determining the manufacturer becomes difficult without knowing the corporate logos, because many manufacturers produce similar styles of a particular device and have similar construction materials.

The serial number is more difficult to identify and differentiate than the manufacturer and is often confused with part/lot numbers. Each company has specific configurations of numbers and letters, which comprise the serial number. The best way to identify the serial number is to look for a series of numbers without any punctuation or letters, e.g., "129599," located near the manufacturer logo. The other type of serial number includes letters and numbers, e.g., "A99V35A," but still does not include any type of punctuation. This form of serial number is often found away from the

TABLE 2—Orthopedic device manufacturer information.

Vendor	Phone	Web Address	Identifying Information
Abbott Spine	512-918-2700	http://www.abbottspine.com	Typeset "A"
Alphatec Spine	800-922-1356	http://www.alphatecspine.com	Infinity in a Globe
Biomet	800-348-9500	http://www.biomet.com	B; BIOMET; BMT, OEC, OEC in triangle (See Fig. 7A)
Biopro (6)	800-252-7707	http://www.bioproimplants.com	Biopro or BP in a circle (Fig. 7B)
Centerpulse	800-613-6131	see Zimmer	COUS
Corin Group	1285 659866	http://www.corin.co.uk	Stylized C
DePuy Ace	800-473-3789	http://www.depuyace.com	"ACE" over stylized crutch (see Fig. 7C)
DePuy Orthopaedics	800-336-8143	http://www.depuyorthopaedics.com	D followed by number
Encore Medical Corporation	800-456-8696	http://www.encoremed.com	Letter "e" with triangles or overlapping ee, see Fig. 2D
Engineering Design Research Center	412-268-3372	http://www.ices.cmu.edrc.html	Bold EDRC in a rectangle (see Fig. 7E)
Exactech	800-392-2832	http://www.exac.com	Stylized letter "e"—looks like Pacman, stylized screw head with bubbled letter Exactech
Hayes Medical	800-240-0500	http://www.hayesmed.com	Stylized "H" in a circle (see Fig. 7F)
Intermedics (6)	800-613-6131	see Zimmer	"IOI" or bold "Z" in a circle (Fig. 7G)
Johnson & Johnson	800-366-8143	see Depuy Ace	J&J
Link America Incorporated	800-932-0676	http://www.linkorthopaedics.com	LINK
Nuvasive	800-455-1476	http://www.nuvasive.com	Stylized Leaf
Ortho Development Corp	800-429-8339	http://www.odev.com	ODEV
Orthofix	800-535-4492	http://www.orthofix.com	"O" with overlapping "F"
Orthomet, Inc.	800-238-7117	see Wright Medical Technology	ORTHOMET
Orthopaedic Equipment Co.	800-348-9500	see Biomet	OEC; or "OEC" in a triangle
Osteoimplant Technology	800-456-8696	see Encore	OTI in a half circle
Osteonics	800-726-2725	see Stryker	Stylized femur (Fig. 7H)
Richards Orthopedics*	800-221-5700	see Smith & Nephew	"R" in a square (Fig. 7I)
Scient'X	407-571-2550	http://www.scientxusa.com	Stylized "X"
Smith & Nephew	800-821-5700	http://www.smith-nephew.com	Stylized flower (see Fig. 7J)
StelKast Company	888-273-1583	http://www.stelkast.com	"S" in a triangle (see Fig. 7L)
Stryker Howmedica Osteonics†	800-726-2725	see Stryker	"H" in a square, "V" in a shield (Fig. 7K,M,N)
Sulzer Medica	800-613-6131	see Zimmer	SULZER-MEDICA; SULZER; SOUS
Symmetry Medical		http://www.symmetrymedical.com	Stylized "S" with fanned ends
Synthes-Stratec (U.S.A.)	800-523-0322	http://www.synthes.com	Stylized pelvis (Fig. 7O)
Tornier, Inc.	888-867-6437	http://www.tornier-us.com	"T" in a hexagon (Fig. 7P)
Wright Medical Technology, Inc.	800-238-7117	http://www.wmt.com	WMT, Interlocking "V"s over a Circle
Zimmer	800-613-6131	http://www.zimmer.com	Bold "Z" in a circle (Fig. 7Q)

*Richards Orthopedics was bought by Smith & Nephew in 1986, at which point their logo was no longer used.

†Stryker and Howmedica merged in 2000, at which point the Howmedica logo was no longer used.

corporate identifier. The important feature of all serial numbers is that they typically are at least six characters in length. A few of the older appliances may have a five-character serial number. It is important to note here that serial numbers (and lot numbers) may not necessarily be unique to one particular device but be assigned to a group of appliances manufactured around the same time and sold in batches to hospitals and physicians around the U.S. and the world. Therefore, it is possible that several devices exist with the same serial and part/lot numbers.

The addition of punctuation distinguishes the serial number from the part/lot number. The two most common forms of punctuation are the period or dash. Synthes™ appliances have the best example for a period-based part and lot number. For example, the part and lot number "456.90" indicates the appliance is a femoral rod, as specified by "456", and "90" denotes the production number. The other common variety has a dash in place of the period, as demonstrated by "871-001," in which "871" specifies it is a screw and the "001" indicates it is in the first lot of this type of screw. A dash can also be found with a combination of numbers and letters, such as "1554-02C." Figure 6 provides an excellent example of the extent of product information that can be found on an orthopedic device.

Besides the production information, many appliances have further descriptors. These may include the material composition, the angle or overall dimensions of the device, or the size of the

replacement piece. These provide substantiating data to accompany the main product information but are not essential in the individualization process. The manufacturer information and the serial number are the essential pieces needed to track an appliance for identification purposes. A case example demonstrates how the various pieces of information found on an orthopedic device can be used to trace back to an individual.

Case Examples

To illustrate the utility of using orthopedic devices for establishing positive identifications in forensic anthropological contexts, an orthopedic implant from an identified individual was selected from the Bass Donated Collection at the University of Tennessee. The implant, located at the proximal femur, was chosen from an individual donated in 2003 and selected because the manufacturer's logo, serial number, and lot number were clearly visible on the implant during gross observation.

Following Ubelaker and Jacobs (9), we attempted to contact the manufacturer of the implant, Intermedics™ (see Fig. 1 for logo). As is the case with numerous orthopedic manufacturers, we quickly learned that Intermedics™ no longer exists, as buyouts and corporate mergers are common. As a result, we contacted Zimmer™, the manufacturer that acquired Intermedics™ and currently maintains associated Intermedics™ data. Personnel working in the Regulatory

Department at Zimmer™ were able to confirm that their company maintains an active registry of all Intermedics™ information.

Interestingly and of importance was the fact that personnel at Zimmer™ reiterated that both serial and lot numbers are not unique to a specific orthopedic appliance, as previously noted. Rather, these numbers identify manufactured batches of appliances that are sold individually to hospitals and surgical groups around the U.S. As a result, numerous copies of the same orthopedic device are likely to exist with identical serial and lot numbers.

In the example illustrated here, Zimmer™ was able to furnish us with a list of eight possible cases with the particular serial and lot number in question (Zimmer, Inc., provided no specific patient data in compliance with the Health Insurance Portability and Accountability Act [HIPAA] of 1996). We were provided with the list of hospitals that purchased the appliance, as well as the name of the surgeon and surgery date, if these data were available. Of the eight possibilities provided, two were from the same hospital in a region closest to the place of residence of the known decedent. Of these two, one name of a surgeon was available. We then contacted this surgeon with the serial and lot number from the implant in question. Unfortunately, the name in the surgeon's records did not match that of the identified decedent. This indicated to us, through a process of elimination, the match was most likely the one where no surgeon's name was available. While this was not an ideal outcome to our search, we were able to demonstrate that we could narrow down the field of possible candidates, through following the steps outlined in this study.

A recent presentation, however, provided an excellent example of how the device-tracking process can result in a positive outcome (24). In that case, an unknown mostly skeletonized individual was recovered in Franklin County, Missouri, that had extensive ante-mortem trauma with several fixation devices (24). The devices present were traced to Synthes™, which then provided a listing of the hospitals that received the devices. The combination of the fixation devices and the biological profile limited the potential matches to a few hospitals, which were then asked to provide medical records of the potential victims (24). As a result of the multi-agency cooperation in this case, the individual was able to be identified (24).

As both of these cases demonstrate, the tracking of an orthopedic device for individuation purposes works well for open-population situations or when there is no possible match in the local missing-person files.

Conclusions

The complexities involved with using orthopedic devices in forensic contexts have increased since the discussion was initiated by Ubelaker and Jacobs (9). We argue that forensic practitioners should understand these challenges and realize that while the presence of orthopedic data may still be of little use depending on the specific situation, it is nevertheless worthwhile to attempt tracking a device when other avenues have been exhausted. The examples presented here highlight the variability of orthopedic devices implanted into modern Americans and the myriad number of manufacturers responsible for producing them. We discovered that not all appliances have visible logos and that tracking devices back to an individual relies on the identification of the manufacturer, even though FDA regulations are ambiguous as to what needs to be tracked and by whom. In spite of the fact that it may be impossible to track some devices (owing to implantation prior to the implementation of federal regulations or obscured logos/serial numbers), the information presented here may assist

forensic professionals with obtaining presumptive or positive identifications.

Acknowledgments

The authors thank those individuals including the anonymous reviewers who provided valuable support and advice in the construction of this study. The orthopedic device manufacturers referenced in this study generously gave permission for the reproduction of their corporate logo and contact information. We extend special thanks to Erin Johnson for her assistance. This research would have been impossible without the generous donations to the William M. Bass Donated Skeletal Collection.

References

- Mundorff AZ, Vidoli G, Melinek J. Anthropological and radiographic comparison of vertebrae for identification of decomposed human remains. *J Forensic Sci* 2006;51(5):1002-4.
- Bennett JL, Benedix DC. Positive identification of cremains recovered from an automobile based on the presence of an internal fixation device. *J Forensic Sci* 1999;44(6):1296-8.
- Mundorff AZ, Shaler RC, Bieschke E, Mar-Cash E. Marrying anthropology and DNA: essential for solving complex commingling problems in cases of extreme fragmentation. In: Adams B, Byrd J, editors. *Recovery, analysis, and identification of commingled human remains*. Totowa, Canada: Humana Press, 2008;285-300.
- Mundorff AZ, Bartelink EJ, Mar-Cash E. DNA preservation of skeletal elements from the World Trade Center disaster: recommendations for mass fatality management. *J Forensic Sci* 2009;54(4):739-45.
- Sledzik PS, Dirkmaat D, Mann RW, Holland TD, Mundorff AZ, Adams BJ, et al. Disaster victim recovery and identification: forensic anthropology in the aftermath of September 11. In: Steadman DW, editor. *Hard evidence: case studies in forensic anthropology*, 2nd edn. Upper Saddle River, NJ: Prentice Hall, 2009;289-302.
- Murray KA, Rose JC. The analysis of cremains: a case study involving the inappropriate disposal of mortuary remains. *J Forensic Sci* 1993;38(1):98-103.
- Clarkson J, Schaefer M. Surgical intervention. In: Thompson T, Black S, editors. *Forensic human identification: an introduction*. Boca Raton, FL: CRC Press, 2007;127-46.
- Simpson EK, James RA, Eitzen DA, Byard RW. Role of orthopedic implants and bone morphology in the identification of human remains. *J Forensic Sci* 2007;52(2):442-8.
- Ubelaker DH, Jacobs CH. Identification of orthopedic device manufacturers. *J Forensic Sci* 1995;40(2):168-70.
- National Center for Health Statistics. *National ambulatory medical care survey*. Hyattsville, MD: National Center for Health Statistics, 2000.
- Praemer A, Furner S, Rice DP. *Musculoskeletal conditions in the United States*. Rosemont, IL: American Academy of Orthopaedic Surgeons, 1999.
- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=888.3080> (accessed on January 18, 2010).
- Lane WA. *The operative treatment of fractures*, 2nd edn. London, UK: The Medical Rutheday Co. Ltd, 1914.
- Hunter TB, Taljanovic M. Overview of medical devices. *Curr Probl Diagn Radiol* 2001;30:94-139.
- <http://www.fda.gov/MedicalDevices/default.htm>, CDRH-Center for Devices and Radiological Health, Food and Drug Administration (accessed on January 18, 2010).
- http://www.fda.gov/cdrh/devadvice/353.html#link_2, Office of Communication, Education and Radiation Programs Center for Devices and Radiological Health, Food and Drug Administration (accessed on January 18, 2010).
- Komar DA, Buikstra JE. *Forensic anthropology contemporary theory and practice*. New York, NY: Oxford University Press, 2008.
- Shaw J. "Substantially equivalent" the FDA, orthopedic device manufacturer, and you. *J Arthroplasty* 2005;20(1):1-3.
- Bioengineering. *Implant tracking up and running! Implant Technol Biomaterials Bull* 2005;4:2.

20. Precision Technology Supplies Ltd. Stainless steel metric mirco screws handbook, 4th edn. East Grinstead, UK: Precision Technology Supplies Ltd., 2007.
21. DeFrances CJ, Cullen KA, Kozak LJ. National Hospital Discharge Survey 2005 annual summary with detailed diagnosis and procedural data. National Center for Health Statistics. *Vital Health Stat* 2007;13(165): 1–209.
22. Taljanovic MS, Jones MD, Hunter TB. Joint arthroplasties and prostheses. *RadioGraphics* 2003;23:1295–314.
23. Taljanovic MS, Hunter TB, Miller MD, Sheppard JE. Orthopedic devices for the extremities and pelvis. *RadioGraphics* 2005; 25:859–70.
24. Haugen GM. Identification by the numbers: a case study in skeletal trauma examination and surgical implant tracking. Proceedings of the

60th Annual Meeting of the American Academy of Forensic Sciences; 2008 Feb 18–23; Washington DC. Colorado Springs, CO: American Academy of Forensic Sciences, 2008;304–5.

Additional information and reprint requests:

Rebecca J. Wilson, M.A.
Department of Anthropology
University of Tennessee
250 South Stadium Hall
Knoxville, TN 37996-0720
E-mail: rwilson8@utk.edu