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Advanced Radiological Imaging Techniques for Product Evaluation

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Non-Destructive Inspection of Evidence

In a product liability trial, as well as in intellectual property disputes, the central piece of evidence is usually a physical object or product. In either situation, the condition, as well as the size, shape, and material composition of the object must be preserved so that technical experts have the opportunity to examine said product and conduct analyses to support their opinions. Thus, preserving this evidence throughout the litigation is crucial, particularly because valuable, and often unique, information may only be obtained by an expert through a detailed examination of the product.[1]

Care should be taken to preserve the integrity and condition of evidence at every step, so that its condition is not altered during storage and shipping. The same care should be exercised during a technical evaluation, such that the act of inspecting the object itself does not result in spoliation of the evidence.[2] Therefore, the most critical step in the technical evaluation of a product is to extract as much information as possible in a non-destructive manner. The safest way to perform a non-destructive inspection is to utilize methods in which the object being studied does not come into contact with the analytical equipment used in the evaluation. Digital photography and optical microscopy offer a means through which to document a product being analyzed, and can provide semiquantitative data regarding size, shape, and physical features. However, these techniques do not offer continuity of scale. Rather one can either memorialize a product macroscopically with the former, or focus on examination of one particular microscopic zone using the latter.

Alternatively, technologies such as laser scanning, white light interferometry, optical profilometry, and scanning electron microscopy (SEM) can all capture data about the morphology and condition of a product non-destructively,[3] but are relegated to the study of the outer surfaces of the object. It is often desirable to examine the interior of a product or to

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1 Koesel MM, Turnbull TL. The Duty to Preserve Evidence. In: Gourash DF, ed. *Spoliation of Evidence: Sanctions and Remedies for Destruction of Evidence in Civil Litigation.* Third ed.: ABA Book Publishing; 2013.

2 Gruppie GR, Mouradian MO, Winder KA. Lose the evidence, lose your case: understanding and avoiding spoliation of evidence. *FDDC Quarterly*. 2012;63(1):27-34.

3 James BA. Medical Device Failure Analysis. In: Narayan RJ, ed. *Materials for Medical Devices.* Vol 23. Materials Park, OH: ASM International; 2012:343-344.

evaluate a product when it is contained or surrounded by another structure or materials. However, this is not always easy to do because, by doing so, the product of interest could be altered or destroyed and result in spoliation of the evidence. To that effect, plane radiographs and more recently X-ray computed tomography (CT), which use material-penetrating X-rays in combination with digital imaging techniques, can produce multiscale data, while simultaneously documenting the size, shape, condition, and features of the surfaces and the interior of a product, with superior resolution, and without loss or destruction of evidence.

Introduction to Two-Dimensional X-Ray Imaging

X-ray imaging was originally discovered in 1895 by Wilhelm Conrad Roentgen and has since become a ubiquitously used medical imaging technique.[4] This same technique has been adapted to industrial and laboratory applications to allow for the non-destructive visualization of the internal structures of objects. X-ray imaging involves projecting the image of an object into a surface, similar to projecting a shadow puppet onto a wall. In the case of a shadow puppet, a hand is placed between a light source and the wall, resulting in the projection of a magnified shadow of that hand onto the wall. X-ray imaging uses the same concept, except instead of a visible light source, X-ray radiation is used to create the projected image of the object.

Figure 1A is a simplified schematic of an X-ray imaging set-up. There are three main components, the X-ray source, the sample, and the detector. Inside the X-ray source, a filament is heated to release electrons that bombard a flat tungsten target, causing the release of energy in the form of X-rays.[5] The resulting X-ray beam then travels toward the detector and passes through a sample that is positioned between the source and the detector, resulting in a projected image of the sample that can be electronically recorded.[6] The distance between the source, sample, and detector can be changed in order to control the amount of magnification of the projected image. By significantly magnifying the projected image, it is possible to observe features on the micrometer-scale.

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[4] Gedeon A. *Science and technology in medicine: an illustrated account based on ninety-nine landmark publications from five centuries.* Springer Science & Business Media; 2006.

[5] Zink FE. X-ray tubes. *Radiographics.* 1997;17(5):1259-1268.

[6] Allisy-Roberts P, Williams J. Chapter 3 - Imaging with X-rays. In: Allisy-Roberts P, Williams J, eds. *Farr's Physics for Medical Imaging (Second Edition)*: W.B. Saunders; 2008:49-64.

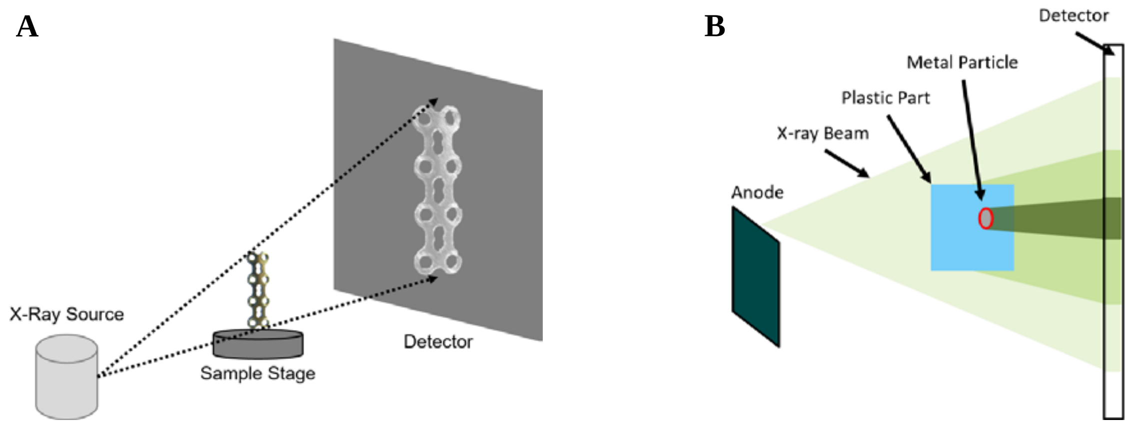

Figure 1. *(A) Schematic of an X-ray imaging set-up, including the x-ray source, the sample to be imaged, and the detector. (B) Schematic of attenuation of the X-ray beam as it passes through different density parts within the sample.*

As the X-ray beam passes through the sample, the X-rays are absorbed differently depending on the thickness and density of different parts of the sample.[7] For example, Figure 1B is a schematic of an X-ray beam passing through a plastic sheet that contains an embedded metal particle. Due to the much greater density of the metal particle compared to the plastic sheet, it will absorb more energy from the X-ray beam, and the projection of the metal particle will appear as a darker spot in the projection. X-ray images are produced in greyscale, with the brighter areas representing less dense or thinner parts of the sample and darker areas representing denser or thicker parts of the sample. It is important to note, however, that the greyscale values of X-ray images and CT scans are often inverted so that the denser or thicker components show up brighter and are therefore easier to see.

While X-ray imaging is a quick and relatively simple technique for the non-destructive visualization of the internal structure of an object, it only provides two-dimensional projections of a three-dimensional object. Similar to when a shadow is cast on a wall, the projection of a three-dimensional object into a two-dimensional image may result in a loss of perspective and proportion. Also, it may not be possible to fully understand the three-dimensional interactions of the components, and some features of the object may not be visible when the object is imaged in a certain orientation. For example, Figure 2 shows two different X-ray images of the same drone motor taken at different orientations. Depending on the orientation of the object with respect to the X-ray beam and detector, different features are clear, while other features are obscured. In cases where three-dimensional imaging becomes important, computed tomography imaging may be a better option than two-dimensional X-ray imaging.

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[7] Allisy-Roberts P, Williams J. Chapter 3 - Imaging with X-rays. In: Allisy-Roberts P, Williams J, eds. *Farr's Physics for Medical Imaging (Second Edition)*: W.B. Saunders; 2008:49-64.

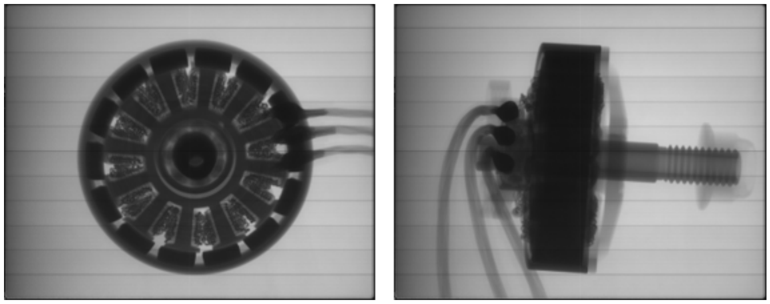

Figure 2. *X-ray images of a drone motor taken at two different orientations.*

Introduction to Computed Tomography (CT)

Many of the issues associated with two-dimensional X-ray imaging can be solved via the use of Computed Tomography (CT) scanning. Known in the medical community as a CAT (computed *axial* tomography) scan, a CT scan consists of hundreds of 2D X-ray images collected from 360 degrees around the object and processed via computer algorithms to create a virtual three-dimensional object. The resulting 3D image can be manipulated and sliced in a virtual environment for examination and analysis. By analyzing the radiographs collected from all around the object, the virtual object – often referred to as a "volume" – bypasses the perspective and proportion limitations of X-ray imaging, even allowing for accurate measurements down to the scale of the scan resolution – usually reported in voxels (a voxel is the 3D equivalent of a pixel).

It is not hard to imagine how CT can be a very useful tool to support litigation efforts. Allowing for fine scale visualization of internal structures, CT can be used to better understand a piece of critical evidence without needing a court order to conduct destructive analyses. CT can also be used to obtain a three-dimensional record of an object prior to proceeding with destructive testing or examination. A great analogy is leveraging CT to evaluate sensitive evidence found in matryoshkas, commonly known as Russian nesting dolls (Figure 3). CT not only allows for the visualization of each doll, but also their relative positions with respect to each other, the presence of internal defects, and even the grain of the wood. Under adversarial conditions, opening of each layer/doll would require an individual court order, requiring months of court time and inspections as opposed to a few hours to collect the CT scan data.

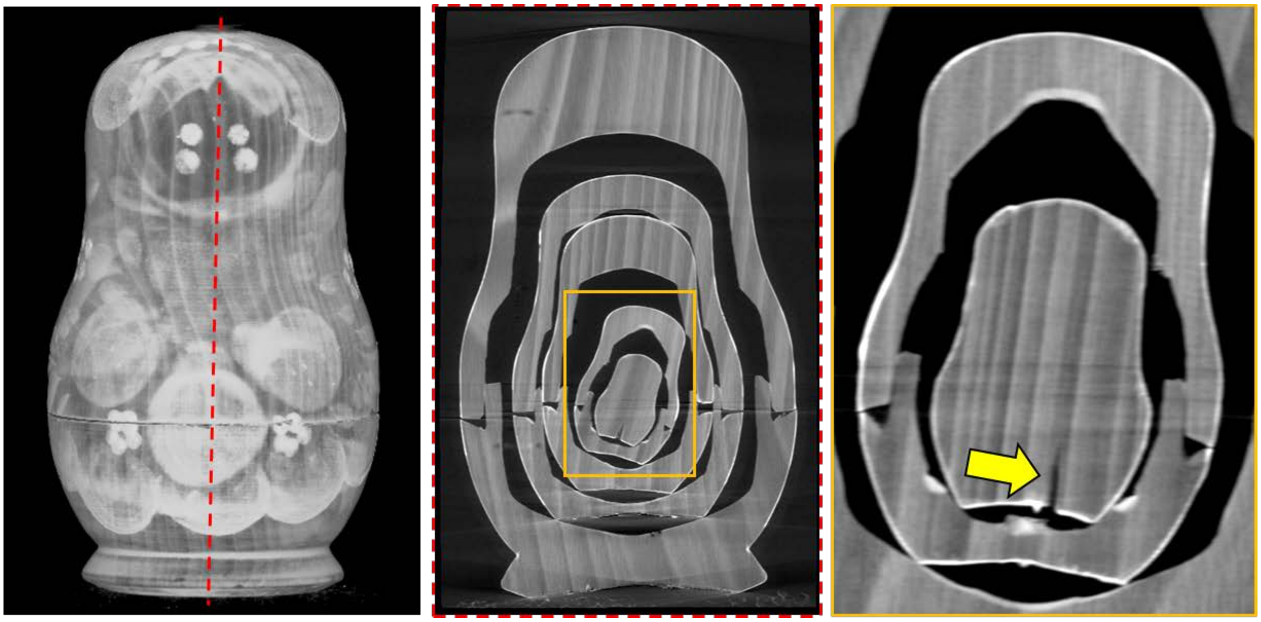

Figure 3. CT 3D rendering and virtual cross sections of a Russian nesting doll. Misalignment of the inner dolls (middle image) and a fracture in the wood of the innermost doll (right image, indicated by the yellow arrow) can be seen in the images.

Computed Tomography Applications

The high-resolution, spatially complete multiscale data set generated through a CT scan can prove useful in multiple areas of litigation.[8] For example, the digital data from a CT scan can be reconstructed mathematically in three dimensions to create a computer generated solid model in the ".stl" format. This solid model can be used as the input for additive manufacturing equipment, such as 3D printing, for turning the computer model into a solid, physical demonstrative. This physical model can then be used in court to educate the judge and jury, clarify complex technical concepts, or provide context regarding how a particular product was manufactured, handled, transported, and used or abused based on the markings, shape, features, or other indicators of its operation during its useful life.

In addition, due to its high resolution, the data captured via a CT scan provides technical experts the ability to accurately and precisely measure features and quantify potential wear or damage of the scanned part. This is done by comparing measurements obtained through the three-dimensional CT scan, and using computer aided design and analysis tools to overlay and compare three-dimensional CT scan data to the dimensions on the original design drawings and 3D models, or to the scan of an exemplar object.[9] This comparison can indicate whether the part being inspected was manufactured to its design specifications, or if the wear or damage that may

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8 du Plessis A, le Roux SG, Guelpa A. Comparison of medical and industrial X-ray computed tomography for non-destructive testing. *Case Studies in Nondestructive Testing and Evaluation.* 2016;6:17-25.

9 Shah P, Racasan R, Bills P. Comparison of different additive manufacturing methods using computed tomography. *Case Studies in Nondestructive Testing and Evaluation.* 2016;6:69–78.

be apparent is consistent with its intended use and service environment. This ability is especially critical in intellectual property cases, when the determination of whether a particular product falls within the stated claims of a patent is critical to success.

Last but not least, the ability to non-destructively assess an object via X-ray imaging and CT scanning can be used to guide subsequent destructive steps of the investigation. Even if an object needs to be modified for further investigation, previous evaluation via X-ray or CT allows for a targeted approach, minimizing disruption to the object of interest.

Case Example: Investigation of an Electric Cooktop Fire

Two-dimensional X-ray imaging and CT are used extensively in fire investigations to assist in determining the cause of the fire. In the aftermath of a fire, it is often difficult to identify objects among the ash and debris. X-ray imaging and CT both allow for the clear visualization of objects involved in the fire without destroying evidence. As an example, Figure 4A shows a pile of debris after a fire. Without needing to separate or remove the debris, a CT scan was able to reveal the presence of an electric cooktop element (Figure 4B). The CT scan was further used to identify the manufacturer, part number, and specifications that were stamped into the metal of the cooktop element (Figure 5). In addition to the identification of objects at the scene of a fire, X-ray imaging and CT can be used to examine products for any indication that the product may have played a role in starting the fire. For example, in Figure 5, the cross-section view of the cooktop element coils can be examined for any signs of damage, such as cracking or chipping of the coating.

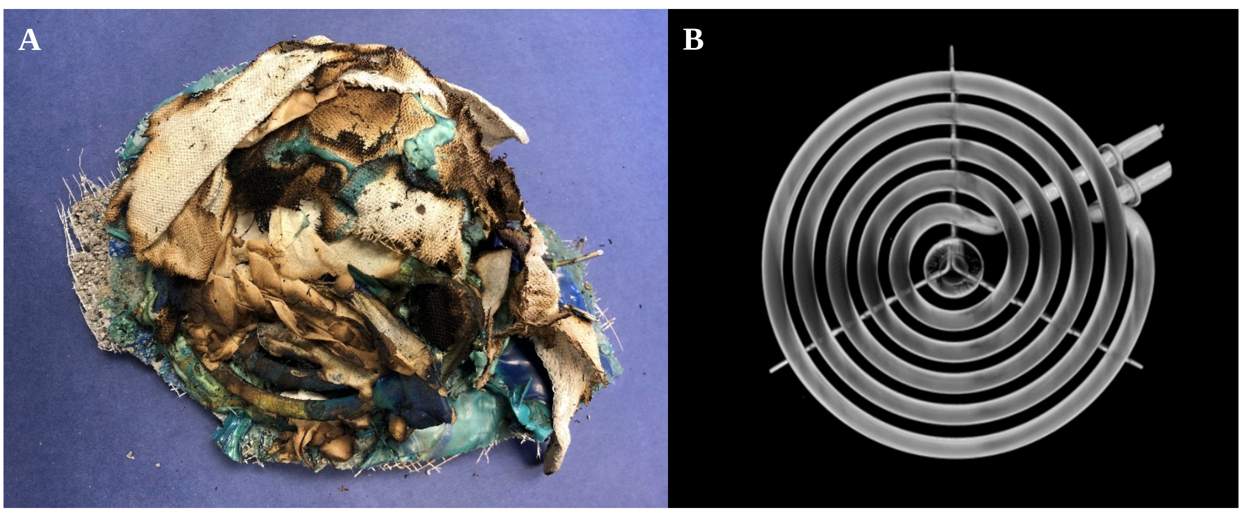

Figure 4. *(A) Pile of debris following a fire. (B) A CT scan of the pile of debris revealed an electric cooktop element that was underneath the debris.*

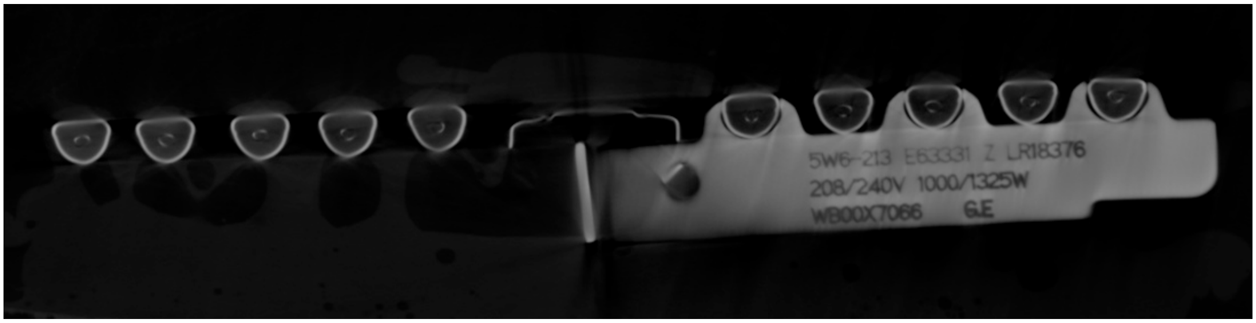

Figure 5. *Two-dimensional slice from the CT scan of the cooktop element showing the cross section of the coils and the product information stamped into the metal.*

Case Example: Consumer Electronics Product Evaluations

Consumer electronics, also known as home electronics, refer to any electronic devices (analog or digital) designed for the individual use of an end user on a daily basis. From complex toys with actuating parts (Figure 6), to programmable thermostats and battery-containing cellphones, consumer electronics are almost too varied for general claims to be made about them. The two things all consumer electronic products have in common are a complex arrangement of circuits, often located in a circuit board, and the possibility of human injury or property loss upon malfunction.

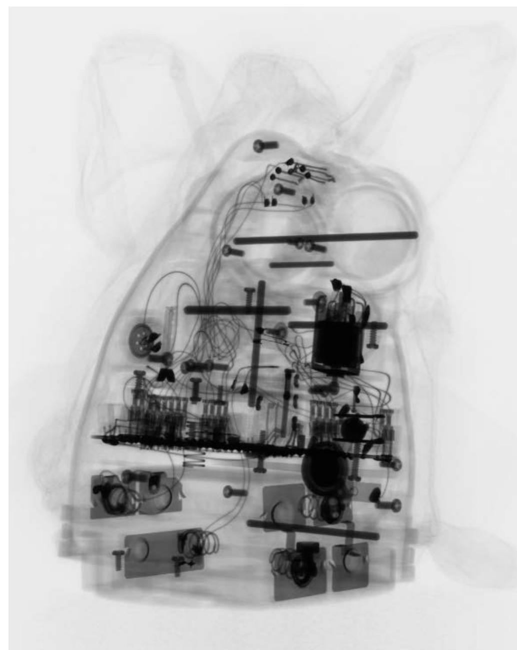

Figure 6. X-ray image of an electronic, robotic toy (Furby).

Allowing for visualization of the internal components without damaging the exterior of a device, X-ray imaging is a very powerful tool for the evaluation of any type of failed consumer electronic device. X-ray imaging can be utilized to check for missing or misplaced components, and the findings can have important consequences for understanding the failure and assigning responsibility. For example, a missing component inside of a pristine device could indicate a manufacturing error, while a misplaced component (like a loose screw inside of a device) could indicate user tampering.

The use of CT scanning can provide even more information in consumer electronic investigations. The ability to visualize components in three dimensions can allow the user to pinpoint potential failure root causes, including misaligned components – such as a misaligned gyroscope in a drone – or manufacturing issues –such as voids in the solder connecting different electronic components on a circuit board (Figure 7). Furthermore, the ability to obtain measurements of the internal components via CT can be crucial to understanding whether a failure is due to a device not meeting industry specifications. The Institute of Electrical and Electronics Engineers (IEEE) has produced numerous standards for the components utilized in consumer electronics (USB ports, capacitors, fuses, transformers, wires, etc.), often specifying dimensions and clearances. CT can be utilized to provide numerical values that can be checked against these standards without damaging the sample, which in some cases could result in deformation of the very measurements to be examined.

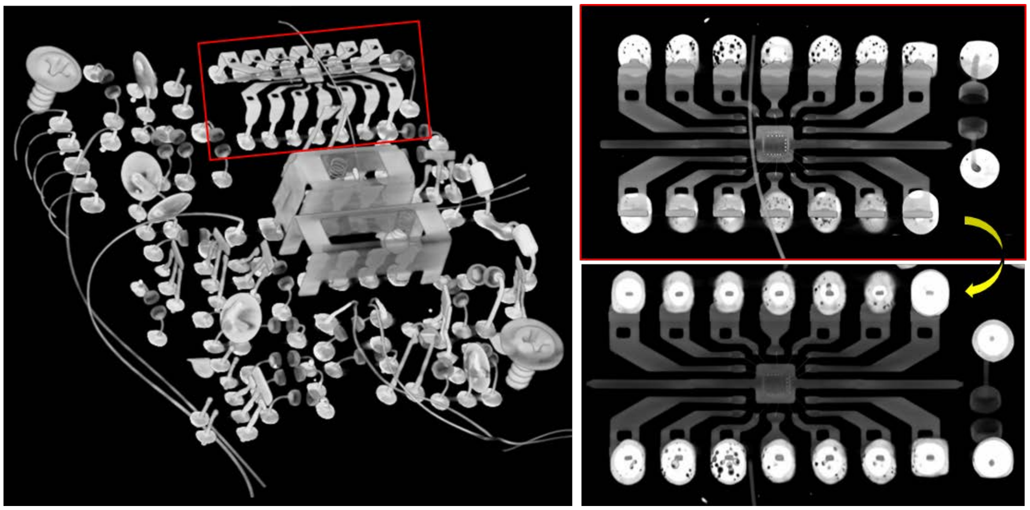

Figure 7. CT 3D renderings of a circuit board. Images to the right exhibit magnified views of the logic component and voids in the solder connecting it to the circuit board.

Case Example: Fracture of Modular Total Hip Replacement Devices

Total hip arthroplasty (THA) for the treatment of hip arthritis is considered one of the most successful orthopaedic interventions and has a history going back over 100 years.[10] In the early 1960's, Sir John Charnley developed a THA device that has served as the basis for the design of all modern THA devices. The Charnley hip is a monolithic or monoblock design, because the femoral components (stem, neck, and head) are all one piece. However, over the last several decades, increased modularity of THA devices has been widely adopted, since it allows surgeons to independently select different sizes and angles of the components to more closely restore the patient's native biomechanics.[11,12,13,14,15] These modular components are joined using taper junctions to build the femoral portion of the THA device. While these modular devices offer

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10 Knight SR, Aujla R, Biswas SP. Total Hip Arthroplasty-over 100 years of operative history. *Orthopedic reviews.* 2011;3(2).

11 Bobyn JD, Tanzer M, Krygier JJ, Dujovne AR, Brooks CE. Concerns with modularity in total hip arthroplasty. *Clinical orthopaedics and related research.* 1994(298):27-36.

12 Ellman MB, Levine BR. Fracture of the modular femoral neck component in total hip arthroplasty. *The Journal of arthroplasty.* 2013;28(1):196. e191-196. e195.

13 Gilbert J, Mali S, Sivan S. Corrosion of modular tapers in total joint replacements: a critical assessment of design, materials, surface structure, mechanics, electrochemistry, and biology. *Modularity and Tapers in Total Joint Replacement Devices*: ASTM International; 2015.

14 Grupp TM, Weik T, Bloemer W, Knaebel H-P. Modular titanium alloy neck adapter failures in hip replacement-failure mode analysis and influence of implant material. *BMC musculoskeletal disorders.* 2010;11(1):3.

15 Wright CG, Sporer S, Urban R, Jacobs J. Fracture of a modular femoral neck after total hip arthroplasty: a case report. *The Journal of Bone and Joint Surgery American volume.* 2010;92(6):1518.

many benefits, they also have drawbacks such as micromotion, fretting (wear of contacting surfaces), and corrosion within the modular taper junctions. In some patients, this fretting corrosion can lead to fracture of the device at the modular junction (Figure 8).

Figure 8. Retrieved modular THA device that has fractured at one of the modular taper junctions.

As part of the inspection of these fractured devices, it is important to consider the role of patient and surgical factors in addition to the design and manufacturing of the device. One surgical factor that plays a vital role in the function of these modular devices is the cleanliness and proper assembly of the taper junctions.[16,17,18,19] Examination of the taper junctions using CT scanning allows the internal, contacting surfaces of such junctions to be inspected without destroying the device.

Figure 9A shows an exemplar modular THA device, with the modular sleeve component outlined in the orange box. Figure 9B and C are two-dimensional slices of the CT scan, showing that there is a gap between the sleeve and stem components of the device caused by a contaminant within the taper junction (outlined by the orange boxes). This contaminant was subsequently identified to be fragments of bone, which are likely contaminants within the taper junctions of THA devices due to the cutting and reaming of the patient's bone that is performed during the surgery. The presence of this contaminant, which created the gap between the sleeve and stem components, is likely to increase stresses, micromotion, fretting, and corrosion, and could ultimately lead to fracture of the device. Therefore, the use of CT scanning to non-destructively discover contaminants and improper assembly of taper junctions plays a critical role in identifying the cause of fracture in modular THA devices.

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[16] Grupp TM, Weik T, Bloemer W, Knaebel H-P. Modular titanium alloy neck adapter failures in hip replacement-failure mode analysis and influence of implant material. *BMC musculoskeletal disorders.* 2010;11(1):3.

[17] Pennock AT, Schmidt AH, Bourgeault CA. Morse-type tapers: factors that may influence taper strength during total hip arthroplasty. *The Journal of arthroplasty.* 2002;17(6):773-778.

[18] Bobyn JD, Tanzer M, Krygier JJ, Dujovne AR, Brooks CE. Concerns with modularity in total hip arthroplasty. *Clinical orthopaedics and related research.* 1994(298):27-36.

[19] Lavernia CJ, Baerga L, Barrack RL, et al. The effects of blood and fat on Morse taper disassembly forces. *American journal of orthopedics (Belle Mead, NJ).* 2009;38(4):187-190.

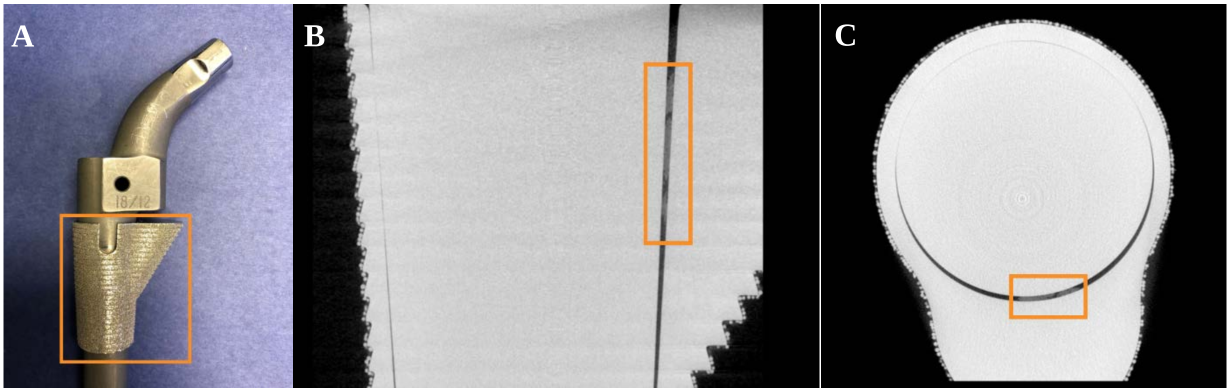

Figure 9. *(A) Exemplar THA device with a modular sleeve (indicated by the orange box) on the stem portion of the device. (B and C) Two-dimensional slices of the CT data in two different planes showing a gap between the stem and modular sleeve and the presence of a contaminant (outlined in the orange boxes) in the modular junction.*

Case Example: Assessment of Battery Quality and Failures

A battery is, in its simplest definition, a container in which chemical energy can be converted into electricity and used as a source of power.[20] They come in many shapes, sizes, and chemistries, powering anything from small radios to electric buses. Batteries can be classified in two large groups: rechargeable and non-rechargeable. Non-rechargeable batteries (also known as primary batteries) are a 13-billion-dollar industry that includes the well-known alkaline batteries that are used in everyday household items such as remote controls.[21] As their name implies, these batteries have a single use and only hold their maximum chemical energy at the moment of manufacturing. On the other hand, the chemistries and design of rechargeable batteries (also known as secondary batteries) also allow for electricity to be converted into chemical energy, allowing for multiple cycles of charge and discharge throughout the lifetime of the battery. As of 2017, rechargeable batteries corresponded to a 75-billion-dollar industry.[22] Although the rechargeable battery market is still dominated by lead acid batteries, it is quickly shifting towards a faster and more powerful type of rechargeable battery chemistry: lithium-ion.

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20 Oxford English Dictionary, accessed December 13, 2018, https://en.oxforddictionaries.com/definition/battery

21 Mike Sanders, Avicenne Energy, “The Rechargeable Battery Market and Main Trends 2016 – 2025,” accessed December 3, 2018, http://www.avicenne.com/pdf/The%20Rechargeable%20Battery%20Market%20and%20Main%20Trends%202016-2025_C%20Pillot_M%20Sanders_September%202017.pdf

22 Michael Sanders, “Avicenne Energy: Avicenne Background,” March 2018

First introduced into the market by Sony 27 years ago (1991), lithium-ion batteries have become ubiquitous in our modern life. They already are, or are becoming, an integral part of our productivity tools (laptops, phones, smart-watches), recreation tools (speakers, camping tools, toys, vaping devices), home appliances (power tools, snow-blowers, lawnmowers), and even our vehicles (cars, buses, electric bikes, electric scooters). As a matter of fact, nowadays it is even possible for a consumer to purchase stand-alone lithium-ion batteries. However, this convenience comes at a cost when it comes to battery failures. Although lithium-ion batteries can fail graciously (i.e. not causing damage to themselves or their surroundings), there is also the possibility for a critical failure in which the chemical energy stored in the battery is released all at once. This can generate internal temperatures in excess of 2000 °F inside the battery and over 800 °F at the surface of the battery, often accompanied by flames and/or explosions. Through a combination of probability and production variability, the growing lithium-ion battery market is constantly increasing the probability of critical battery failures, which in turn increases the probability of injury or loss of property. As an example of the latter, in 2016, there were at least 98 incidents of fires and/or explosions caused by e-cigarettes alone.[23]

In addition to the ability to non-destructively assess thermally damaged remnants (see the fire investigation case example above), both X-ray imaging and CT scanning are uniquely equipped to assist with battery-related investigations. For example, X-ray imaging can be leveraged to determine the identity and origin of a failed lithium-ion battery (Figure 10): Different manufacturers include unique features in their batteries, such as number of vents, welding patterns of current collecting tabs, or the presence of a center pin. On the other hand, CT is invaluable in failure analysis for identifying the root cause: The ability to obtain accurate measurements can be used to visualize and investigate damage caused by a user (Figure 11) or a cell manufacturing defect. For example, CT enables the ability to differentiate material compositions that could detect contaminants introduced into the cell during production (Figure 12).

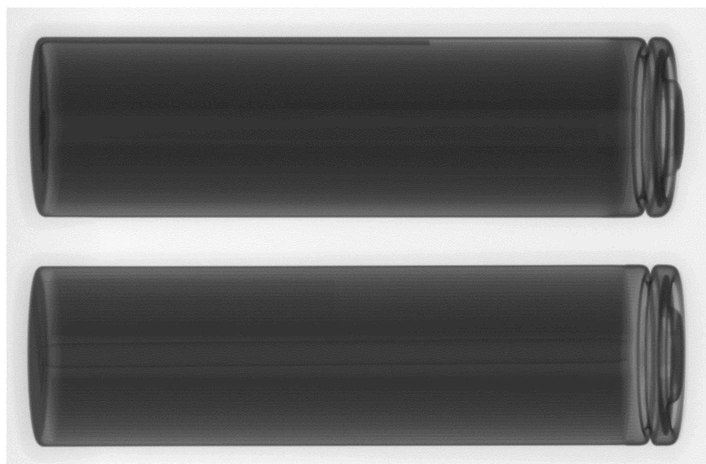

Figure 10. X-ray imaging of two lithium-ion batteries. Differences in the internal components (center pin) and external components (cell cap) allow for identification and differentiation of cell manufacturers.

[23] FEMA, "Electronic Cigarette Fires and Explosions in the United States 2009 – 2016," July 2017, accessed December 3, 2018, https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf

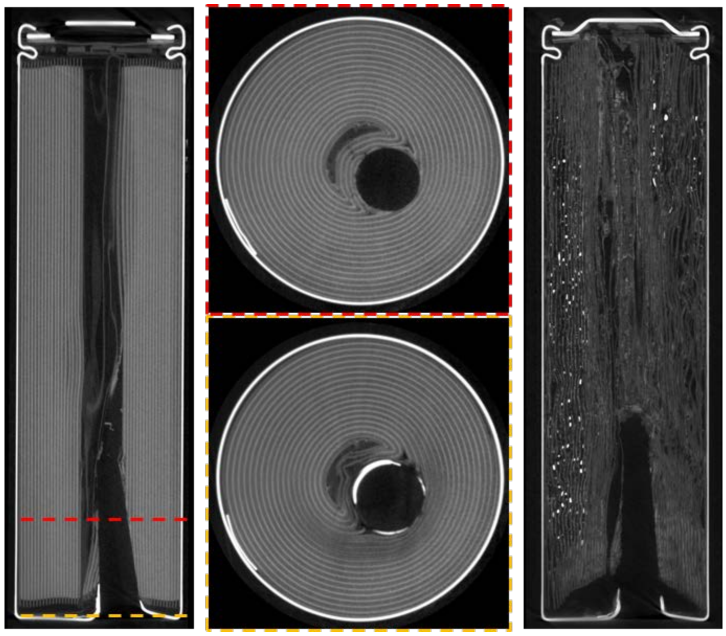

Figure 11. *Virtual cross sections of two batteries after nail penetration testing. The left and center images, corresponding to a battery that did not suffer a thermal runaway event, allow for the identification of the nail diameter. The right image corresponds to a battery that experienced a thermal runaway event after nail penetration, as evidence from the bright spots indicative of melted / resolidified copper from the negative electrode.*

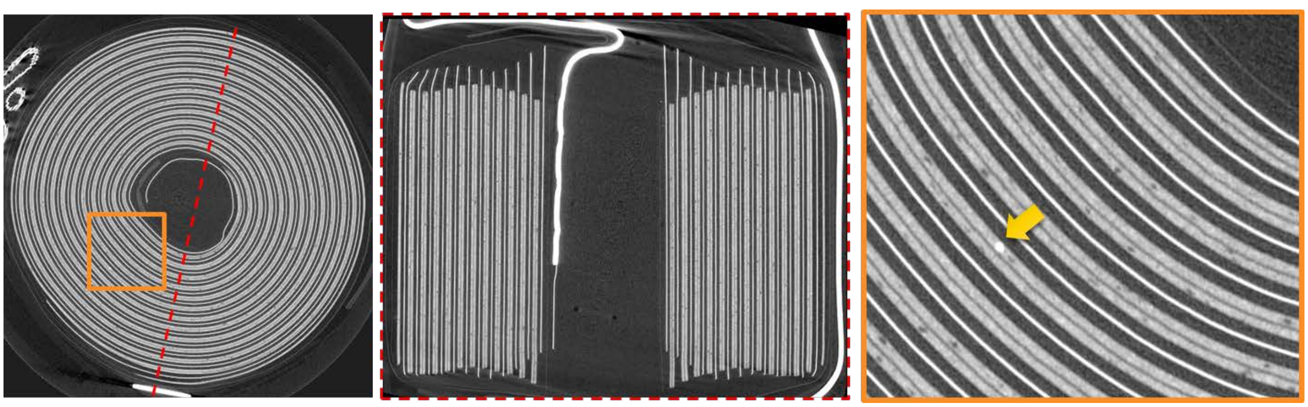

Figure 12. *Virtual cross sections of a headphone battery. CT allows for the visualization of irregular electrode overlap and cell contaminants (yellow arrow), both of which can be attributed to improper manufacturing practices.*