Number Nine in a Series

Imaging Techniques for Vertebral Assessment on DXA Devices:

Advantages of the Single-energy, Breath-hold Technique

Review

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The clinical utility of vertebral fracture assessment in osteoporosis evaluation is widely acknowledged. It has been shown that an existing spine fracture is associated with a doubling of hip fracture risk and a four- to five-fold increase in additional spine fracture risk.[1-8] In a typical clinical setting, 20–25% of post-menopausal women will have vertebral fractures, the vast majority of which are asymptomatic.[9-12] Studies have shown *(Figure 1)* that 15-20% of patients with normal or osteopenic BMD (as classified by WHO criteria, using spine and hip BMD) have existing, asymptomatic spine fractures.[13] These patients, who make up about 30% of patients who have osteoporosis, will not receive appropriate care without vertebral assessment.

The consequences of overlooked vertebral fractures are serious and immediate. Prospective studies have found that *within one year* of a vertebral fracture, one in five women will fracture again *(Figure 2)*.[14] The potential impact of vertebral assessment on this high-risk population cannot be underestimated, particularly in light of the available effective therapeutic agents proven to reduce the rate of vertebral fractures in high-risk populations.

Vertebral fractures have traditionally been assessed radiographically, through visual evaluation of AP and lateral views of the thoracic and the lumbar spine. Recently validated by clinical studies, vertebral assessment has become available on state-of-the-art fan-beam Dual Energy X-Ray Absorptiometry (DXA) bone densitometry systems. Vertebral assessment on DXA systems is clinically attractive due to the importance of existing fractures in osteoporosis evaluation and the practical limitations (radiation dose, cost, inconvenience) that inhibit the regular use of radiographic assessment. The following white paper reviews imaging techniques for vertebral assessment,

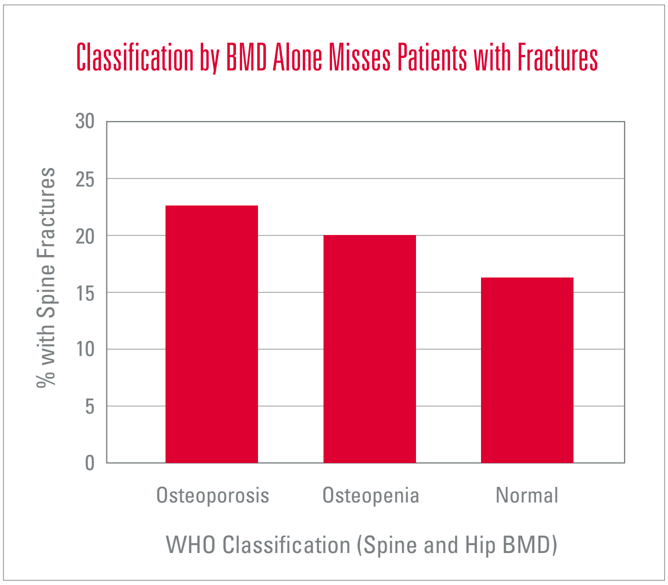

Figure 1. A significant percentage of females classified as "Normal" or "Osteopenic" by spine and hip DXA have existing asymptomatic vertebral fractures.[13] Instant Vertebral Assessment (IVA) capabilities featured on the Hologic Delphi QRD Series bone densitometer allow point-of-care vertebral assessment for proper evaluation and management.

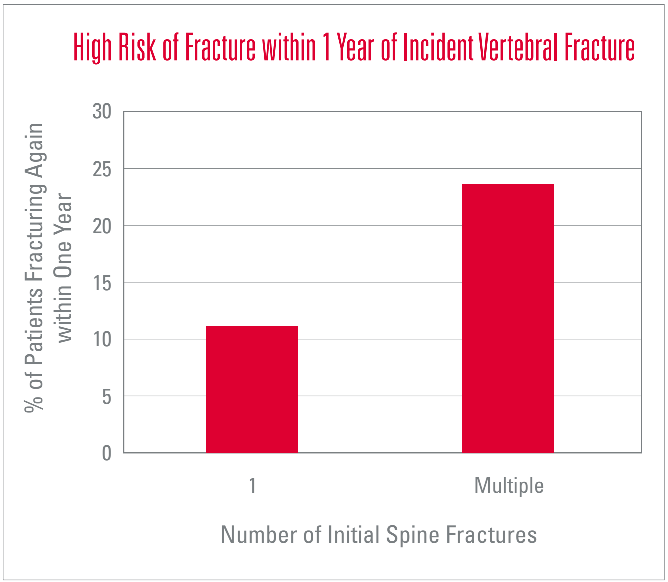

Figure 2. Risk of fracture is substantial in the year following vertebral fracture.[14] Overall, 20% of women will fracture again within one year of an incident fracture and risk increases with number of initial fractures.

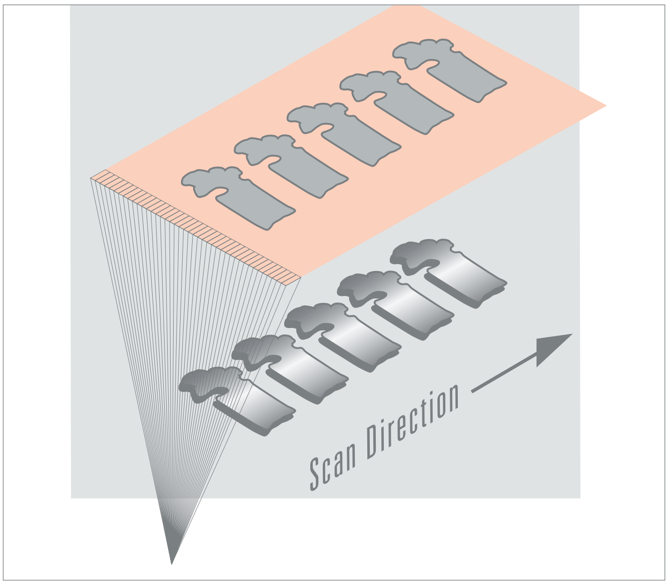

Figure 3. CT and fan-beam DXA share a similar imaging geometry and obtain spine images through linear gantry motion along the length of the patient.

with an emphasis on the technical differences between true fan-beam acquisition and limited-angle, fan-beam (rectilinear) acquisition.

Radiographic Techniques

Radiographic techniques for vertebral assessment are well established.[15,16] High-resolution, single-energy images of the spine are obtained using a cone-beam geometry and are visually interpreted following standardized criteria.[17] AP views of the thoracic and lumbar spine are obtained with the patient in either a supine or standing position. Lateral views of the thoracic and lumbar spine are acquired with the patient in a decubitus position. A breath-hold technique is commonly employed in the lumbar spine in order to reduce the effects of diaphragm motion, which can obscure vertebrae in the lower thorax and upper lumbar region.

Table 1. Radiographic assessment of the spine: summary of imaging technique parameters.

Parameter	Radiographic Technique
Imaging method	Single energy
Imaging geometry	Cone beam
Breath-hold technique	Commonly used for lumbar region
Views acquired	AP and lateral
Regions evaluated	Thoracic and lumbar spine
Evaluation method	Visual reading

Fan-beam Imaging of the Spine

Fan-beam imaging of the spine has been available utilizing CT scout views for over 20 years. The high-resolution imaging capabilities of a typical CT system are provided by a linear array of solid state detectors and a large-angle, fan-beam scanning geometry. In this imaging geometry, the x-ray fan beam and linear detector array are aligned perpendicular to the length of the patient, allowing simultaneous acquisition of data across the patient's width. By moving the detector gantry linearly along the length of the patient's spine, high-resolution, single-energy images are obtained in seconds. On commercial CT systems, these scout-view images are utilized for precise placement of the scanner gantry for full three-dimensional CT imaging. The deleterious effects of scatter radiation on image contrast are minimized by the CT imaging geometry, which places the patient at a substantial distance from the detector array.

State-of-the-art DXA bone densitometry systems share numerous technological similarities to commercial CT systems, employing a fan-beam imaging geometry and utilizing a multi-element solid-state detector array *(Figure 3)*.

Benefits of a CT-like, Fan-beam Imaging Geometry

- **Single-energy imaging:** A true CT-like fan-beam imaging geometry makes high-resolution, single-energy imaging possible *(Figure 4)*. Single-energy imaging is the widely accepted standard and is necessary for accurate evaluation and physician acceptance. True fan-beam imaging requires only linear motion of the scanner gantry along the length of the patient, allowing imaging with low radiation dose (< 10 mRem) and rapid acquisition times (10 seconds for the entire

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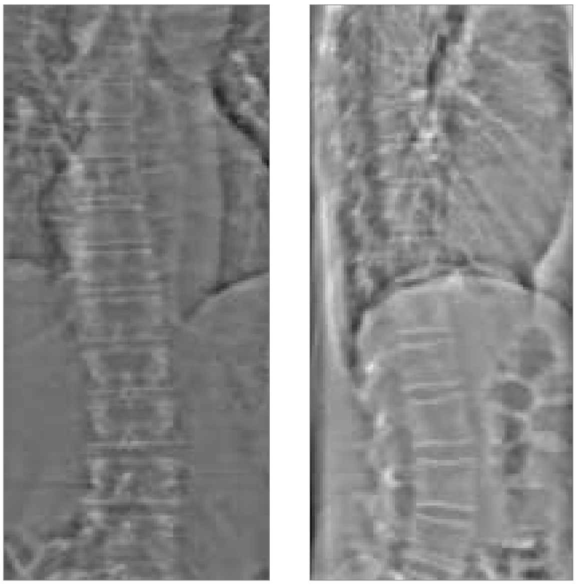

Figure 4. The single-energy, breath-hold imaging technique provides high-quality images for vertebral assessment. Standard radiographic protocols include AP (left) and lateral (right) spine images.

spine). Breathing and patient motion artifacts are eliminated by short acquisition times, allowing imaging during suspended respiration. Single-energy imaging is not only the standard for vertebral imaging but also for all other radiographic tests.

- **Faster procedure times:** Single-energy imaging minimizes procedure time by eliminating the unnecessary acquisition of a second image. Unlike dual-energy techniques, where imaging times are more than doubled for thicker patients, single-energy image acquisition times are independent of patient thickness.

Single-energy imaging minimizes procedure time by eliminating the unnecessary acquisition of a second image.

- **Low radiation dose:** Single-energy imaging allows substantial dose reduction compared to dual-energy techniques, where both high-energy and low-energy images are acquired for quantitative evaluation of bone density. The elimination of the unnecessary second image also minimizes patient radiation exposure. Compared to single-energy techniques, dual-energy subtraction techniques suffer from poorer signal-to-noise characteristics, requiring even further increases in dose and procedure times to obtain adequate images. This dose disparity increases exponentially with patient thickness and is particularly problematic in the lateral projection, where thickness is greatest.

Single-energy imaging allows substantial dose reduction compared to dual-energy techniques.

- **No requirement for anti-scatter grids:** Imaging geometries where the patient is in close proximity to the image receptor (e.g., radiography, mammography) require anti-scatter grids to minimize the degradation of image contrast. Anti-scatter grids typically absorb 50% of the incident radiation, requiring doubling of patient dose and procedure times for adequate imaging. Some fan-beam DXA systems may be subject to this requirement, if the system design places the patient in close proximity to the detector array. For example, the small distance between the tabletop and the detector array of the Lunar Prodigy™ may require a grid for lateral spine imaging. This is borne out by the experience of Lunar's previous system, the Expert. The consequences of scatter radiation required Lunar to install an anti-scatter grid in the Expert, which was subsequently renamed Expert-XL.
- **Improved image resolution through magnification:** Magnification techniques are routinely used in radiological imaging to improve image resolution. Magnification mammography, for example, utilizes the increased spatial resolution obtained by magnification to evaluate micro-calcifications and fine structure (spiculations) surrounding suspect masses. Similarly, magnification increases the resolution of spine images obtained in a CT-like, fan-beam geometry. True fan-beam systems take advantage of the benefits of magnification (improved resolution, reduced scatter) to provide superior images *(Figure 4)* with reduced radiation dose and procedure times.

Clinical Validation of True Fan-beam Spine Imaging

The effectiveness of fan-beam spine imaging for the assessment of vertebral deformities has been validated by clinical studies published in peer reviewed journals.[18-20] In these studies, visual readings of Hologic single-energy fan-beam spine images were compared to a radiologist's reading of films for the same patients. The studies found that agreement between the blinded reading of the fan-beam spine images and radiographs was as good as between different radiologists reading the same films.

Limitations of Limited-angle (Rectilinear) Fan-beam Imaging Geometry

- **Dual-energy imaging is required:** A limited-angle, fan-beam scanning geometry precludes single-energy image acquisition. Limited-angle systems, like older pencil-beam DXA systems, are forced to scan in a rectilinear pattern to obtain a full two-dimensional image *(Figure 5)*. If single-energy imaging were attempted with a rectilinear scanning system, patient motion due to breathing between successive detector passes over the patient will result in substantial artifacts due to mis-registration of anatomical structures.

A limited-angle, fan-beam scanning geometry precludes single-energy image acquisition.

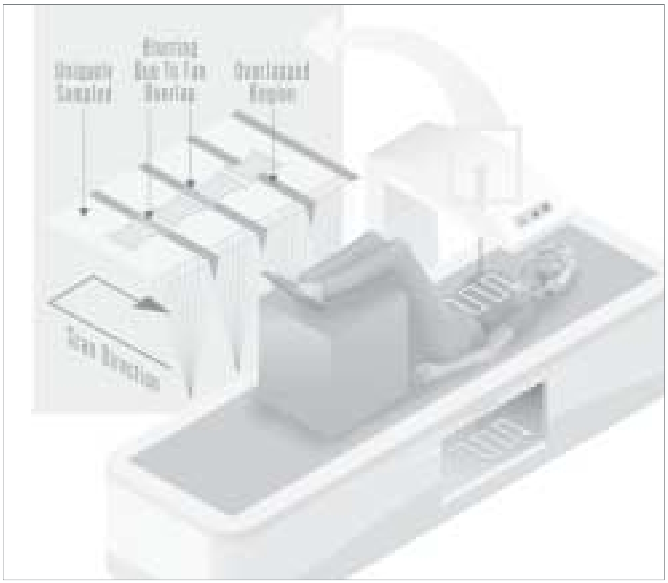

Figure 5. Limited-angle fan-beam systems are required to move in a rectilinear pattern to produce a two-dimensional image of the spine. Slow scan times lead to breathing artifacts and patient motion, making single-energy imaging impossible.

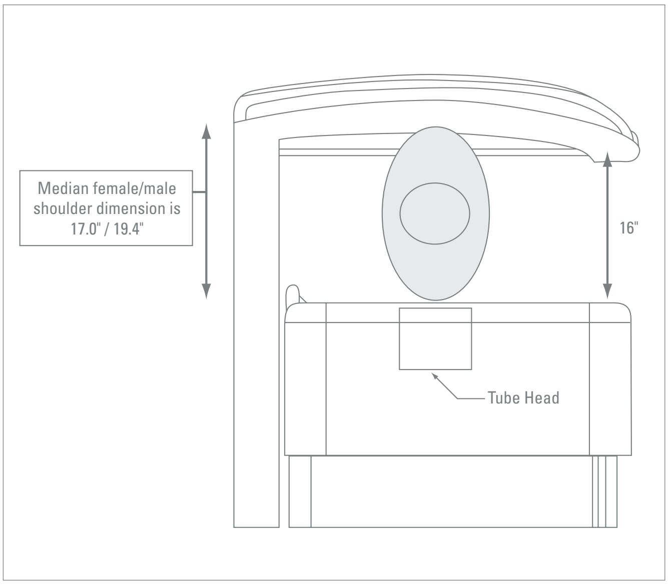

Figure 6. Patient clearance (16 inches, 41 cm) is inadequate for lateral positioning on Prodigy.[23] Less than 15% of females, and less than 1% of males, can fit their shoulders under Prodigy's C-arm in the lateral decubitus imaging position.[25]

Mis-registration artifacts due to breathing obscures or distorts vertebral bodies, making accurate evaluation of fracture status impossible. Patient motion during scanning, a common problem for elderly patients, particularly in the decubitus position, results in artifacts and distortions in rectilinear imaging. With the extended scan times required for dual-energy recti-linear imaging, patient motion is a common problem, leading to erroneous alterations in vertebral shapes. Fan-beam imaging requires only linear motion of the scanner gantry along the length of the patient, allowing rapid image acquisition during suspended respiration.

- **Noisy dual-energy images are inferior to single-energy images:** Dual-energy imaging techniques inherently suffer from poor signal-to-noise characteristics compared to single-energy techniques. This fundamental limitation arises from the very nature of the technique, which requires the subtraction of a "low" energy image from a "high" energy image. The subtracted "difference image" suffers from the noise contributions from each of the two precursor images. Image processing, often used to reduce image noise in dual-energy techniques, can degrade image resolution and further restrict image quality. Virtually all high-quality imaging techniques utilize single energy, while dual-energy techniques are typically utilized for quantitative measurements (such as BMD assessment).

Dual-energy imaging techniques inherently suffer from poor signal-to-noise characteristics compared to single-energy techniques.

- **Unnecessary radiation exposure:** Dual-energy imaging, which is required for slower, rectilinear scanning ystems, subjects the patient to substantial unnecessary radiation dose compared to single-energy techniques, in which only a single-energy image is acquired. For true fan-beam systems, the unnecessary second energy image is elimi-nated, minimizing patient radiation exposure. Because dual-energy subtraction tech-niques suffer from poor signal-to-noise characteristics, an additional dose is required to obtain images comparable to single-energy images. This dose disparity increases exponentially with patient thickness and is particularly problematic in the lateral projection, where thickness is highest. Even in the AP projection, Prodigy's dual-energy dose is increased by a factor of nine for thicker patients.[21]

Because dual-energy subtraction techniques suffer from poor signal-to-noise characteristics, an additional dose is required to obtain images comparable to single-energy images.

- **Unnecessarily longer procedure times:** Dual-energy imaging, required by limited-angle systems, unneces-sarily lengthens procedure times for three important reasons:
  1. Rectilinear scanning is necessarily slower than linear fan-beam scanning.
  2. The need to acquire data at two energies slows acquisition.
  3. For dual-energy techniques, imaging times must be lengthened for thicker patients in order to maintain proper signal-to-noise characteristics in the image. Prodigy requires 90 seconds for scanning just the lumbar portion (6" length) of the spine in the lateral projection,[22] indicating 4-5 minutes will likely be required for the entire spine (18" length). Single-energy image acquisition times are indepen-

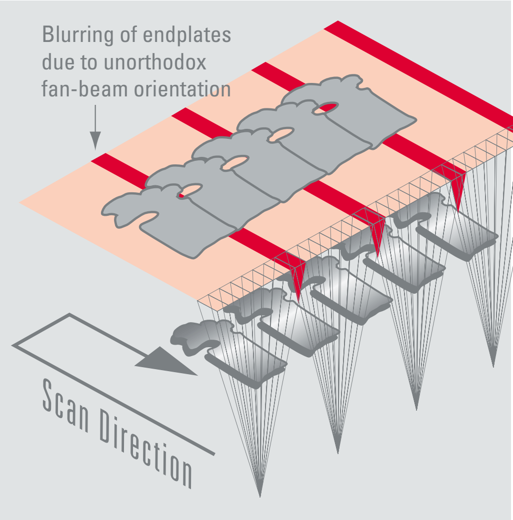

Figure 7. Unorthodox fan-beam orientation used by limited-angle fan-beam systems like Prodigy causes blurring of vertebral endplates, compromising interpretation.

dent of patient thickness.

- **Anti-scatter grids are typically necessary for systems with small patient-to-image receptor distances:** Imaging geometries in which the patient is in close proximity to the image receptor (e.g. radiography, mammography) typically require anti-scatter grids to minimize the degradation of image contrast. Anti-scatter grids absorb approximately 50% of the incident radiation, requiring doubling of patient dose and procedure times for comparable image quality. The design of the Lunar Prodigy, with a small table top-to-image receptor distance (16 inches/41 cm),[23] requires that the patient (if they can fit) will be in close proximity to the detector.

Design Limitations of Limited-Angle Fan-beam Systems

Unlike true fan-beam systems, which employ CT-like imaging geometries, most rectilinear systems were designed for low cost rather than for imaging. As a result, numerous limitations are inherent in system design, which prevent the simple addition of imaging capabilities. These compromises in design, a likely consequence of cost reduction constraints, have the effect of precluding fast, high-resolution, single-energy imaging. Some examples of design limitations of the Lunar Prodigy are:

1. **A small number of detectors.** Prodigy's 16-element detector array[24] accommodates only a limited-angle fan beam and is the system's fundamental design constraint. Because the small-angle fan beam cannot image across the patient's body, Prodigy is forced to orient the fan beam along the length of the patient, an unorthodox imaging geometry *(Figure 5)*. This orientation necessitates rectilinear scanning, as opposed to the standard linear scanning allowed by a more conventional CT-like geometry. Rectilinear scanning is fundamentally too time consuming to allow imaging of the spine in a breath-hold, making traditional single-energy imaging impossible. Thus, the selection of a 16-element detector array forces Prodigy to use slower, non-standard, dual-energy methods.

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2. **Small (16 inches) table top to receptor distance.** Similarly, the use of only 16 detectors requires a short focal spot-to-detector distance because beam divergence increases with distance and would require more detectors. Prodigy's design allows only 16 inches (41 cm) clearance between the tabletop and the C-arm *(Figure 6)*. This distance is smaller than the waist or shoulders of many patients, making full lateral spine imaging impossible without system modification.

According to published anthropometric data, less than 15% of females (and less than 1% of males) have shoulders that will fit under Prodigy's C-arm.

According to published anthropometric data,[25] less than 15% of females (and less than 1% of males) have shoulders that will fit under Prodigy's C-arm, precluding full spine imaging. Fully 20% of females and 10% of males have hip dimensions larger than 16 inches and will not be able to be imaged, even in the lumbar region. Allowing for safe clearance, the Prodigy Operator's Manual[23] shows an even more stringent 15 inches (38 cm) useable table-to-C-arm distance. Lengthening this distance raises numerous design issues, including lengthening of the detector to accommodate the larger beam size at the new position. An anti-scatter grid will also likely be required.

3. **Lack of magnification limits image resolution.** True fan-beam imaging geometries, like that used by Hologic's Delphi™ QDR® system, take advantage of magnification to improve image resolution. Systems without magnification suffer from poorer image resolution, compromising image quality and interpretation.

4. **Blurring of vertebral endplates due to beam geometry.** The alignment of Prodigy's limited-angle fan-beam along the length of the patient's body results in blurring of vertebral endplates *(Figure 7)*, compromising image interpretation. True fan-beam systems have no blurring in this direction, due to the extremely fine collimation of the beam.

5. **Lack of true single-energy x-ray generation capability.** Systems designed for imaging have dedicated single-energy imaging modes. Simple rectilinear bone

densitometers have only standard dual-energy x-ray generation capabilities. Prodigy's fixed K-edge beam filter cannot be removed from the beam, producing "split" (hi/lo) energy spectra at all times. In contrast, programmable, pulsed x-ray generators can generate optimized single-energy spectra.

6. **Need for tube cooling.** Slow dual-energy scanning of the entire spine may exceed Prodigy's tube load rating. Prodigy requires a 10-minute cool-down period[26] after the tube heat load is exceeded. A standard patient evaluation protocol, consisting of AP spine BMD, hip BMD, and AP and lateral spine imaging, may require a 10-minute cool-down. AP and lateral images of the lumbar and thoracic spine *(Figure 4)*, the standard for radiological evaluation, are important for accurate interpretation. The need for AP images is particularly acute for scoliotic patients, where two views are needed for proper interpretation.

On Prodigy, a standard patient evaluation protocol, consisting of AP spine BMD, hip BMD, and AP and lateral spine imaging, may require a 10-minute cool-down.

Table 2. Advantages of True Fan-beam Imaging vs. Limited-angle, Fan-beam Imaging

Hologic Delphi (True Fan Beam)	Lunar Prodigy (Limited-angle Fan Beam)
128 detectors	16 detectors
CT-like imaging geometry, with high-resolution detector array	Not available
Multiple collimators for optimized imaging	Not available
Settings for optimized imaging: programmable x-ray controller supports multiple kVp, mA	Not available
Patient fits comfortably under C-arm	16 inches (41 cm) table-to-C-arm distance will not accommodate most patients
Single or dual-energy imaging	Dual energy only
Linear scanning	Rectilinear scanning
Fast, 10-second imaging	Slow, 3-minute scan
Breath-hold imaging	Too slow for breath-hold
No breathing artifacts	Breathing artifacts
Low-noise, high-resolution images	Noisy, low-resolution images
Very low dose (<10mR)	Likely higher dose due to dual-energy approach
Improved resolution through magnification	No magnification
IVA reimbursement as a separate procedure due to peer-reviewed clinical studies showing comparable performance	No peer-reviewed clinical studies showing comparable performance vs. radiographs
Full patient exam without tube cool-down (AP BMD, hip BMD, AP & lateral spine imaging)	10-minute tube cool-down may be required for full exam

Conclusions

The advantages of a true fan-beam imaging geometry *(Table 2)* are well documented and have important implications for vertebral imaging. Hologic's Delphi system employs this well established CT-like imaging geometry, allowing fast, low-dose, high-resolution imaging of the spine. Delphi's design, which utilizes multiple x-ray collimators and a programmable x-ray controller, provides maximum flexibility for imaging applications.

In contrast, limited-angle fan-beam systems suffer from inherent design compromises that preclude single-energy imaging and require rectilinear dual-energy imaging with long scan times and high radiation dose. Due to its small number of detectors (16), Lunar's Prodigy system is limited to rectilinear, dual-energy scanning and a table top-to-C-arm distance that is too small for lateral positioning of patients.

The importance of clinical vertebral fracture assessment in osteoporosis evaluation is widely acknowledged. Clinical guidelines, including those of the National Osteoporosis Foundation (NOF), the International Osteoporosis Foundation (IOF), and the World Health Organization (WHO), indicate that existing vertebral fractures are the key risk factor, along with reduced BMD, in assessing fracture risk.[27-29]

Numerous studies have shown that an existing spine fracture is associated with a doubling of hip fracture risk and a four- to five-fold increase in spine fracture risk. In a typical clinical setting, 20-25% of postmenopausal women will have vertebral fractures, the vast majority of which are asymptomatic. Additional studies have shown that 15-20% of patients with normal or osteopenic BMD (as classified by WHO criteria at the spine and hip) have existing, asymptomatic spine fractures. These patients, who make up about 30% of patients who have osteoporosis, will not receive appropriate care without vertebral assessment.

Delphi's unique IVA technology, which allows point-of-care integration of BMD testing and vertebral assessment, represents an important step forward in osteoporosis evaluation. Through the use of a CT-like true fan-beam imaging geometry, Delphi is able to image the full spine in just 10 seconds, permitting high-quality, single-energy image acquisition, without breathing artifacts. Clinical studies have documented that Delphi's images are comparable to radiographs for vertebral assessment and superior to older rectilinear scanning approaches. Delphi's rapid, low-dose imaging procedure, combined with its standard BMD measurement capabilities, thus provides integrated, point-of-care assessment of the two key risk factors for osteoporotic fractures: existing fractures and low BMD.

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