

# Strong Bones or Heavy Bones? Let's Find Out.

By Cynthia A. Pearson

For more than 20 years, midlife and older women have been targeted with advertising and marketing messages that equate strong bones with heavy (dense) bones. That's oversimplified.

In the old days (way back in the 1970s) fragile bones were diagnosed based on what happened to the body that the bones supported. Was an older person's spine hunched? Did someone fracture their hip when they leaned over to make the bed? Those were dramatic signs of weak bones. And back then, there wasn't much that could be done for an older person who had already suffered one of the painful and disabling effects of fragile bones.

Researchers knew that fragile bones looked much different than healthy bones — think of the difference between piece of lace and a cotton t-shirt — but extracting pieces of bone for analysis wasn't a popular strategy for finding out if someone's bones were weakening.

Then, scientists figured out how to use a form of X-ray technology to determine how heavy or dense certain bones are. This technology, dual energy x-ray absorptiometry (called DXA), wasn't as accurate as looking at actual bones, but it was a heck of a lot more convenient for women. Eventually, studies showed that knowing how heavy people's bones were (their DXA score) helped predict whether they would experience a fragility fracture. Kinda. Sorta.

In the meantime, several new developments occurred: Aging Baby Boomers wanted to be physically active well into their 80s; the pharmaceutical industry secured the right to market prescription drugs directly to consumers; and, chemists invented bisphosphonates, drugs that

burrow into living bone and prevent further loss of density. These factors (a willing audience, an open pathway to communicate with that audience, and a new product) turbocharged the oversimplified message that “dense bones equal strong bones” and, conversely, that “low bone density equals weak bones.” And, moreover, that all weak bones are dangerous.

What happened next? Bone density screening machines started popping up everywhere funded, in large part, by the same companies that were selling bisphosphonates. Doctors got free DXA machines, women's groups got “educational grants” to promote screening, and celebrities were paid to pose for bisphosphonate ads. Perhaps worst of all, drug company money flowed through professional societies and guideline-setting entities to create a new definition of light-weight bones: osteopenia. There really was no such thing as an “osteopenic” bone; this is just a fancy way of saying that a middle-aged or older woman's bones weighed less than the bones of a young adult (the actual reference group for DXA screening was college

students in San Diego, almost all of whom were white).

Osteopenia identified through DXA screening led to millions of healthy women being given bisphosphonates in their 50s and being told to keep taking the drug indefinitely. Just one problem... taking a drug that burrows into one's bones actually prevents those bones from being able to repair themselves. As a result, long-term bisphosphonates users are vulnerable to damaged jaws after oral surgery and unprovoked fracture of the thigh bone, something that had previously been incredibly rare. I still remember sitting in the audience at an FDA advisory committee meeting in July 2011, listening as one woman after another explained how she got a DXA scan because she thought finding out her bone-density score would help her stay healthy but, instead, it led to a dangerous fracture with lasting consequences for her quality of life.

The FDA was listening that day, too, and soon revised its prior approval of bisphosphonates and limited use to no more than five years in most cases. Also in 2011, the U.S. Preventive

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Services Task Force issued guidelines for DXA screening that led to insurers cutting off coverage for most people under age 65. Less DXA screening led to fewer bisphosphonate prescriptions. Stricter FDA guidelines (technically called “the label”) led to less long-term use. And now, 10 years later, the harm caused by the overuse of bisphosphonates is much less common.

But DXA screening persists. By itself, it’s still not a great screening tool. A few years ago however, European researchers developed a software program that analyzes DXA images in a manner that gives some information about bone strength. It’s called the Trabecular Bone Score (TBS). When doctors tell women “Your bones are full of holes, like a piece of lace”, they’re referring to the trabecular bone. Although “trabecular” means “spongy,” trabecular bone is sturdy stuff, composed of microscopic structures that provide strength and resilience. The TBS software program examines the DXA images to determine whether the healthy microscopic structures have been eroded, and sorts the results into low-, medium-, high- and very-high-risk categories.

TBS has been approved by the FDA to be used as part of a DXA examination. It was approved in 2016 via the Substantial Equivalence [501(k)] pathway, as are nearly all medical devices.<sup>1</sup> (Bonus fact: the FDA considers software programs to be medical devices.) Clinical trials to prove that a new device (or in this case, the new software) actually performs well in humans are not required for Substantial Equivalence approval. And, as far as the NWHN is concerned, Substantial Equivalence

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approval alone isn’t enough to convince us that the new product is ready for widespread use. So, until recently, the NWHN hadn’t done our trademark deep dive into TBS’ evidence.

In response to questions from members — including Joanne Fagerstrom and Shelly Zeichner who invited me to speak at a Bone Health Workshop in October 2020 — the NWHN took that deep dive into the TBS studies. There are about 20 studies, so far. The first demonstrated that, without knowing a woman’s history of fracture, TBS software did a pretty good job identifying women with weaker bones. With that promising early evidence in hand, researchers started doing long-term prospective observational studies. There are six studies in as many countries, all using the same general approach: women had DXA exams, TBS scores were calculated, and the women were followed for five to eight years.<sup>2</sup> The study results showed that the initial DXA plus TBS score did a better job of predicting who would have a fragility fracture compared to DXA results alone. Success! It seems like we finally have our first reasonably good screening tool for bone strength. One especially helpful aspect of a TBS

score is that it enables clinicians to personalize a woman’s DXA results: she may have a “bad” DXA but still have strong bones, and vice versa.

The NWHN’s bottom line: Don’t get a DXA test before age 65, unless you have extra risk factors such as long-term steroid use; don’t get a DXA **just** to get TBS; and, if you’re getting ready for a DXA exam, definitely ask if the facility uses the TBS software. ❖

#### REFERENCES

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2. Harvey NC, Gluer CC, Binkley N, et al., “Trabecular bone score (TBS) as a new complementary approach for osteoporosis evaluation in clinical practice,” *Bone*, 2015; 78: 216-224.



Cynthia Pearson is the former Executive Director of the NWHN. She has especially vivid memories of spending her birthday trying to convince an FDA advisory committee to tell patients that DXA screens at midlife couldn’t predict fracture risk in old age.