



Reveals Cortical & Trabecular Bone

From 2D DXA

3D-SHAPER MEDICAL PUBLICATIONS BOOKLET

APR 2023

3D-SHAPER Technology

DXA is a quick, painless and low-radiation dose imaging modality that provides 2D measurements of bone density. DXA does not however provide clinicians with a way to analyse and visualise bone in 3D to assess local fragilities in the cortical and trabecular compartments, nor can it effectively assess the efficacy of selected therapies longitudinally.

This is possible using Quantitative Computed Tomography (QCT), however QCT is significantly more expensive and time consuming, and exposes patients to much larger radiation doses. It is therefore not commonly used for this purpose.

But what if you could obtain 3D QCT-like results, from a standard 2D DXA image?

That means no extra radiation, no long scan time, and no hefty price tag!

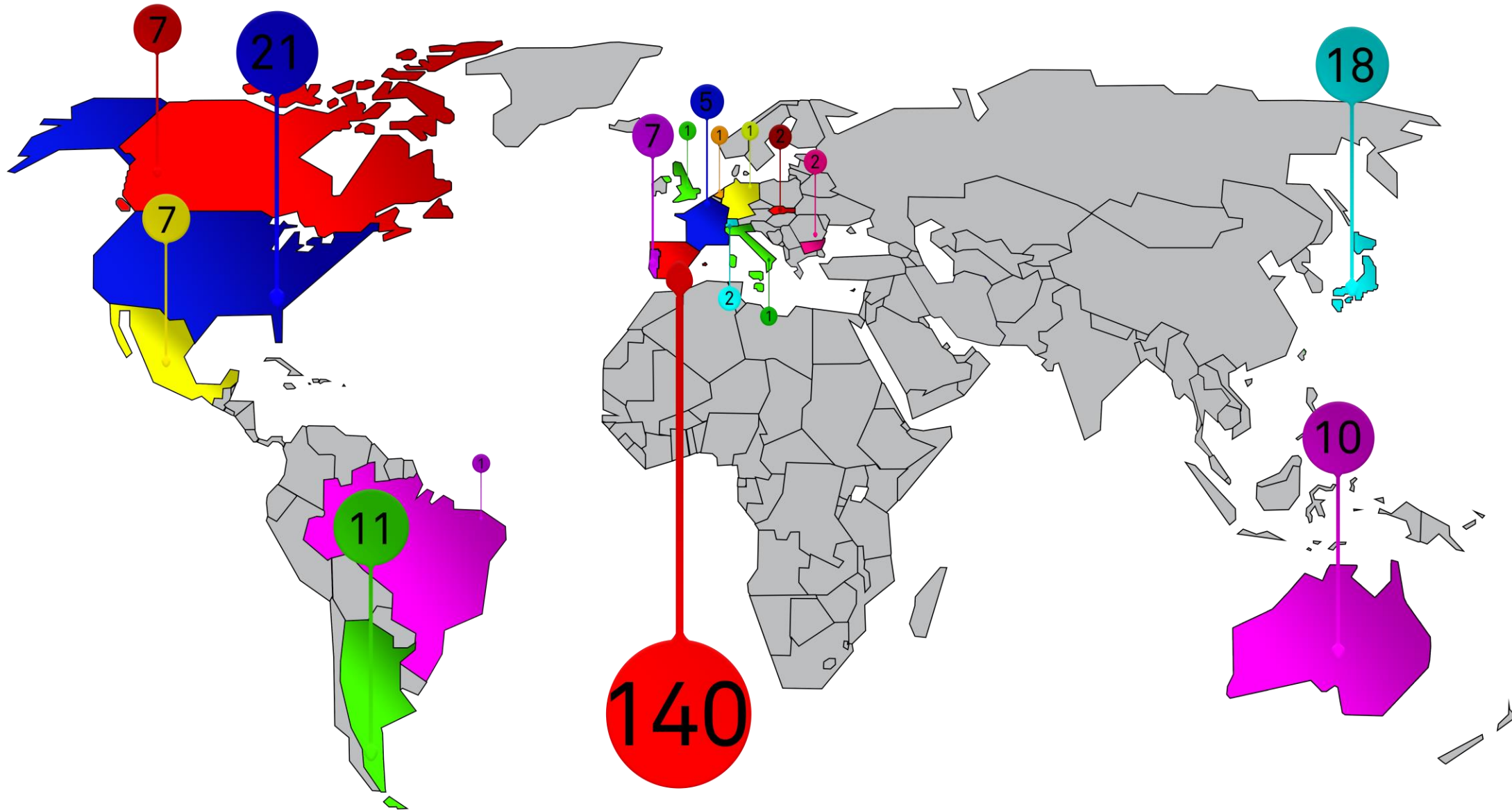
Well, that's where 3D-Shaper comes in. 3D-Shaper uses advanced technology to transform a standard 2D DXA image into a patient-specific 3D QCT-like model, providing you with a fast, safe and cost-effective solution for visualising and assessing local changes in a patient's Cortical and Trabecular bone.

Why is this important? Visualising compartments separately allows clinicians to assess the bone density in specific regions of the bone, and therefore identify where there are potential local fragilities. As therapies affect bone regions differently depending on their mode of action, 3D-Shaper enables clinicians to be highly selective when choosing to prescribe a therapy, whilst simultaneously providing evidence-based rationale to support decision making. Subsequent follow-ups will then allow for rapid monitoring and analysis of a therapy's effectiveness over time.

The following compilation of papers and posters represents the latest research into 3D-Shaper's software solution.



3D-SHAPER studies per country



A total of 237 studies*, 17 countries and 4 continents have used 3D-SHAPER technology

*Includes: Journal Publications, Conference Abstracts, Posters and Oral presentations



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Featured Studies

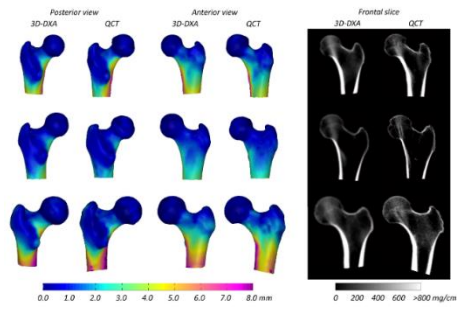

Technical & Validation


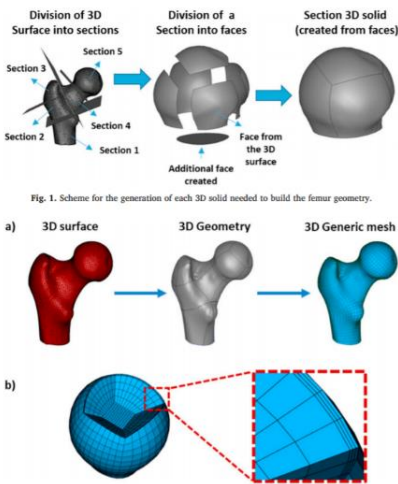

3D-Shaper’s technology is being used worldwide to assess changes in the cortical, trabecular and integral bone compartments from a standard 2D DXA image. But how do we know this technique works? How accurate is it? And how valid are the results that are output from the software?

Well, it turns out that 3D-Shaper’s statical modelling method is a highly accurate alternative to QCT and has achieved statistically significant correlations when compared against QCT imaging.

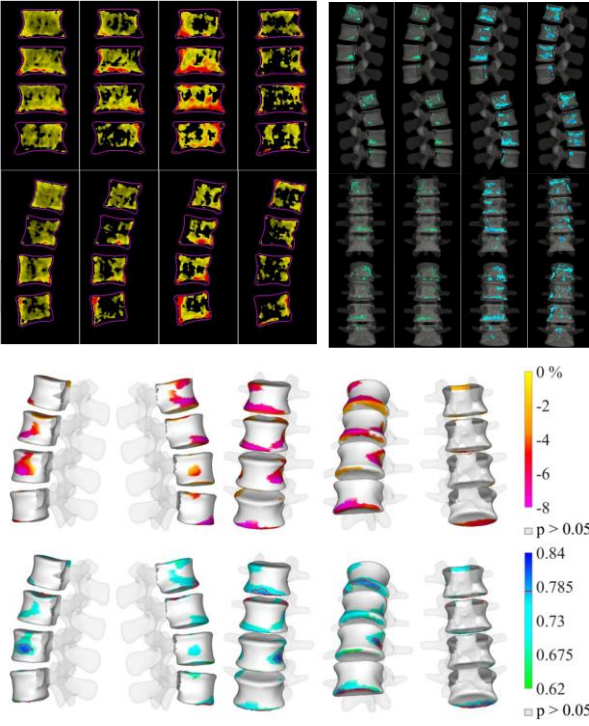

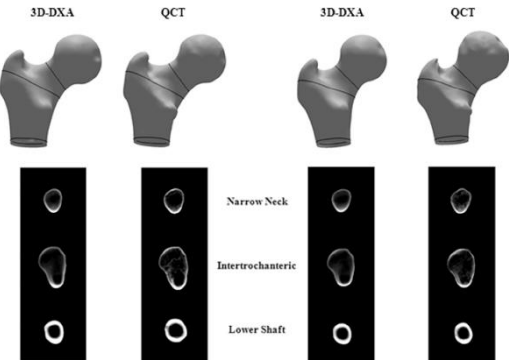

This section outlines some of the key studies highlighting the *accuracy* and *validity* of the 3D-Shaper technology.

To date, there have been a total of **55** studies across **7** countries related to ‘*Technical & Validation*’:

KEY PUBLICATION				
STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>3D-DXA: Assessing the femoral shape the trabecular macrostructure and the cortex in 3D from DXA images.</p> <p>[2017]</p> <p>Available here</p>	<p>157 subjects;</p> <ul style="list-style-type: none"> • 57 males • 100 females • Normal/Osteopenic/ Osteoporotic 	<p>3D-DXA technology is an accurate method to measure bone density distribution (cortical and trabecular compartments) from routine hip DXA scan, without adding scan/ radiation dose to the patient.</p>	 <p>Correlation coefficients*: integral vBMD: 0.95, trabecular vBMD: 0.86; cortical vBMD: 0.93; Mean cortical thickness: 0.91</p> <p>*Calculated with first version without calibration between DXA models. Values recalculated with version 2.7.4: from 0.91 to 0.93</p>	 <p>Spain</p> <p>Humbert L, Martelli Y, Fonollà R, Steghöfer M, Di Gregorio S, Malouf J, Romera J, Del Río Barquero LM.</p>

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<p>3D Analysis of Cortical and Trabecular Bone from Hip DXA: Precision and Trend Assessment Interval in Postmenopausal Women.</p> <p>[2019]</p> <p>Available here</p>	<p>60 Subjects Precision Study:</p> <ul style="list-style-type: none"> 48 Male 12 Female Over 50 <p>53 Subjects Longitudinal Study:</p> <ul style="list-style-type: none"> 53 Female 	<p>Trend Assessment Intervals in postmenopausal women were similar to those measured for aBMD measurements. DXA-derived 3D measurements could potentially provide additional indicators to improve patient monitoring in clinical practices.</p>	<table border="1" data-bbox="724 398 1279 539"> <thead> <tr> <th></th> <th>Baseline</th> <th>Annual change</th> <th>p-value</th> <th>TAI (years)</th> </tr> </thead> <tbody> <tr> <td colspan="5">DXA measurements</td> </tr> <tr> <td>Neck aBMD (g/cm³)</td> <td>0.857 ± 0.088</td> <td>-0.0057</td> <td>0.035</td> <td>2.8</td> </tr> <tr> <td>Total femur aBMD (g/cm³)</td> <td>0.901 ± 0.104</td> <td>-0.0059</td> <td><0.001</td> <td>2.7</td> </tr> <tr> <td colspan="5">3D measurements</td> </tr> <tr> <td>Integral vBMD (mg/cm³)</td> <td>293 ± 47</td> <td>-1.95</td> <td><0.001</td> <td>2.9</td> </tr> <tr> <td>Trabecular vBMD (mg/cm³)</td> <td>142 ± 33</td> <td>-2.34</td> <td><0.001</td> <td>2.6</td> </tr> <tr> <td>Cortical sBMD (mg/cm³)</td> <td>151 ± 21</td> <td>-1.10</td> <td>0.006</td> <td>3.5</td> </tr> </tbody> </table> <p>Least significant changes were 10.39 and 8.72 mg/cm³ for integral volumetric BMD, 9.64 and 9.59 mg/cm³ for trabecular volumetric BMD and 6.25 and 5.99 mg/cm² for cortical surface BMD.</p> <p>Trend assessment intervals in postmenopausal women were 2.9 years (integral volumetric BMD), 2.6 years (trabecular volumetric BMD) and 3.5 years (cortical surface BMD) As a comparison, trend assessment intervals for aBMD were 2.8 years at neck, and 2.7 years at total femur.</p>		Baseline	Annual change	p-value	TAI (years)	DXA measurements					Neck aBMD (g/cm ³)	0.857 ± 0.088	-0.0057	0.035	2.8	Total femur aBMD (g/cm ³)	0.901 ± 0.104	-0.0059	<0.001	2.7	3D measurements					Integral vBMD (mg/cm ³)	293 ± 47	-1.95	<0.001	2.9	Trabecular vBMD (mg/cm ³)	142 ± 33	-2.34	<0.001	2.6	Cortical sBMD (mg/cm ³)	151 ± 21	-1.10	0.006	3.5	 <p>Spain</p> <p>Humbert L, Winzenrieth R, Di Gregorio S, Thomas T, Vico L, Malouf J, del Río L.</p>
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<p>3D patient-specific finite element models of the proximal femur based on DXA towards the classification of fracture and non-fracture cases.</p> <p>[2019]</p> <p>Available here</p>	<p>111 Subject 2 groups:</p> <ul style="list-style-type: none"> 62 fracture cases 49 non-fracture control 	<p>3D FE models derived from DXA scans might significantly improve the prediction of hip fracture risk; providing a new insight for clinicians to use FE simulations in clinical practice for osteoporosis management.</p>	 <p>Fig. 1. Scheme for the generation of each 3D solid needed to build the femur geometry.</p> <p>a) 3D surface → 3D Geometry → 3D Generic mesh</p> <p>b) Detailed view of the 3D Generic mesh</p> <ul style="list-style-type: none"> The major principal stress was better discriminator (AUC > 0.80) than the volumetric BMD (AUC ≤ 0.70). High discrimination capacity was achieved when the analysis was performed by bone type, zone of fracture and gender/sex. Outcomes suggested that the trabecular bone is critical for fracture discrimination. 	 <p>Spain</p> <p>Ruiz Wills C, Olivares AL, Tassani S, Ceresa M, Zimmer V, González Ballester MA, Del Río LM, Humbert L, Noailly J.</p>																																								



STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Discrimination of osteoporosis-related vertebral fractures by DXA-derived and 3D measurements: a retrospective case-control study.</p> <p>[2019]</p> <p>Available here</p>	<p>74 postmenopausal women:</p> <ul style="list-style-type: none"> • 37 with incident vertebral fractures and • 37 age-matched controls without any type of fracture 	<p>Trabecular vBMD was the measurement that best discriminates between fracture and control groups: AUC of 0.733 against 0.682 for aBMD.</p> <p>This study showed the ability of cortical and trabecular measurements from DXA-derived 3D models to discriminate between fracture and control groups.</p>	 <p>Images showing: Average trabecular vBMD changes and AUC map, and average differences in cortical sBMD and AUC map.</p>	 <p>Spain</p> <p>López Picazo M, Humbert L, Di Gregorio S, González Ballester MA, Del Río Barquero LM.</p>
<p>Structural Parameters of the Proximal Femur by 3-Dimensional Dual-Energy X-ray Absorptiometry Software: Comparison With Quantitative Computed Tomography.</p> <p>[2018]</p> <p>Available here</p>	<p>60 subjects with DXA and QCT</p>	<p>Our study demonstrated that accurate estimates of structural parameters for the femur can be obtained from 3D-DXA models. This provides clinicians with 3D indexes related to the femoral strength from routine anteroposterior DXA scans, which could potentially improve osteoporosis management and fracture prevention.</p>	 <p>Correlation coefficients were:</p> <ul style="list-style-type: none"> • 0.86 for the femoral neck axis length • 0.71 for the femoral neck shaft angle. • From 0.86 to 0.96 for the cross-sectional parameters • From 0.84 to 0.97 for the volumetric structural parameters 	 <p>Spain</p> <p>Clotet J, Martelli Y, Di Gregorio S, Del Río Barquero LM, Humbert L.</p>

Association with Fracture

DXA, known for its ability to assess areal Bone Mineral Density and provide clinicians with a T-Score to support the subsequent diagnosis of Osteoporosis, low BMD or normal BMD. This information is widely used, amongst other factors, to help indicate a person’s risk of sustaining a fracture.


3D-Shaper takes this one step further by exploring the bone in full 3D and proving clinicians with quantitative, patient-specific measurements for Cortical, Trabecular and Integral bone.

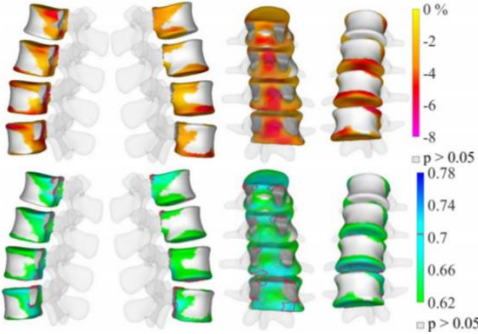

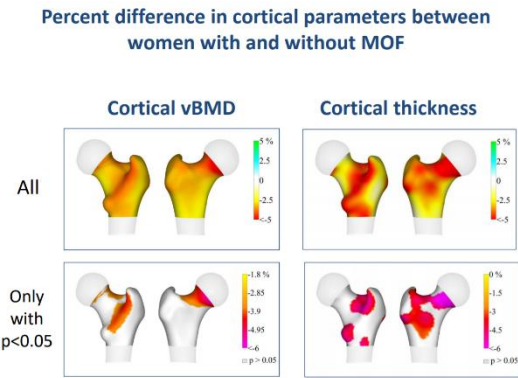

But how are these values associated with fracture? What clinical significance can they provide?

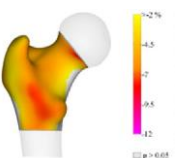
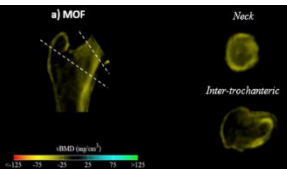

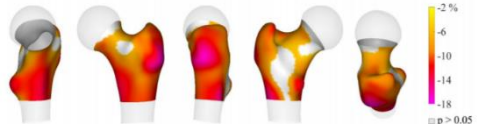
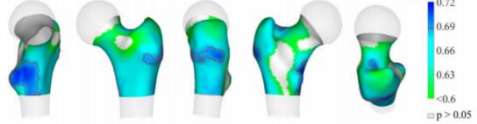

This section outlines a few key studies that have researched exactly this, identifying how 3D-Shaper can *support clinical decision making* and identify patients at risk.

To date, there have been a total of **38** studies across **5** countries related to ‘Association with Fracture’:

KEY PUBLICATION

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS																																																																																																																						
<p>Predictive ability of novel volumetric and geometric indices derived from dual-energy X-ray absorptiometric images of the proximal femur for hip fracture compared with conventional areal bone mineral density: the Japanese Population-based Osteoporosis (JPOS) Cohort Study.</p> <p>[2021]</p> <p>Available here</p>	<p>1331 Women</p> <p>Age 40–79 years at baseline</p> <p>Baseline survey & at least one follow-up survey over 20 years</p>	<p>vBMD obtained from 3D modeling using routinely obtained hip DXA images significantly improved hip fracture risk prediction over conventional Femoral Neck aBMD, but not Total Hip aBMD.</p>	<table border="1"> <thead> <tr> <th rowspan="2">Predictor</th> <th colspan="2">Unadjusted</th> <th colspan="2">Age-adjusted</th> <th colspan="2">Multivariate-adjusted^A</th> </tr> <tr> <th>HR</th> <th>(95% CI)</th> <th>HR</th> <th>(95% CI)</th> <th>HR</th> <th>(95% CI)</th> </tr> </thead> <tbody> <tr> <td colspan="7">aBMD</td> </tr> <tr> <td>FN-aBMD</td> <td>3.33</td> <td>(2.54, 4.39)</td> <td>1.8</td> <td>(1.29, 2.52)</td> <td>-</td> <td>-</td> </tr> <tr> <td>TH-aBMD</td> <td>3.34</td> <td>(2.64, 4.26)</td> <td>2.02</td> <td>(1.49, 2.74)</td> <td>-</td> <td>-</td> </tr> <tr> <td colspan="7">Volumetric indices</td> </tr> <tr> <td>TH-TvBMD</td> <td>5.03</td> <td>(3.58, 7.04)</td> <td>2.90</td> <td>(1.92, 4.37)</td> <td>3.17</td> <td>(1.75, 5.75)</td> </tr> <tr> <td>FN-TvBMD</td> <td>5.18</td> <td>(3.64, 7.41)</td> <td>2.92</td> <td>(1.89, 4.48)</td> <td>3.55</td> <td>(1.74, 7.25)</td> </tr> <tr> <td>IT-TvBMD</td> <td>4.44</td> <td>(3.28, 6.02)</td> <td>2.68</td> <td>(1.86, 3.86)</td> <td>3.11</td> <td>(1.82, 5.29)</td> </tr> <tr> <td>IT-CvBMD</td> <td>3.03</td> <td>(2.31, 3.98)</td> <td>1.75</td> <td>(1.27, 2.40)</td> <td>1.55</td> <td>(1.03, 2.31)</td> </tr> <tr> <td>TH-CsBMD</td> <td>3.32</td> <td>(2.53, 4.37)</td> <td>1.91</td> <td>(1.38, 2.63)</td> <td>1.85</td> <td>(1.11, 3.07)</td> </tr> <tr> <td>IT-CsBMD</td> <td>3.41</td> <td>(2.56, 4.55)</td> <td>1.91</td> <td>(1.37, 2.66)</td> <td>1.81</td> <td>(1.06, 3.09)</td> </tr> <tr> <td colspan="7">Geometric indices</td> </tr> <tr> <td>FN-CSA</td> <td>4.08</td> <td>(2.99, 5.59)</td> <td>2.23</td> <td>(1.54, 3.22)</td> <td>2.38</td> <td>(1.19, 4.76)</td> </tr> <tr> <td>IT-CSA</td> <td>4.27</td> <td>(3.14, 5.81)</td> <td>2.45</td> <td>(1.69, 3.55)</td> <td>3.13</td> <td>(1.68, 5.81)</td> </tr> <tr> <td>IT Z</td> <td>3.45</td> <td>(2.58, 4.59)</td> <td>1.99</td> <td>(1.44, 2.74)</td> <td>1.85</td> <td>(1.21, 2.82)</td> </tr> <tr> <td>IT BR^C</td> <td>2.47</td> <td>(2.07, 2.95)</td> <td>1.68</td> <td>(1.35, 2.08)</td> <td>1.61</td> <td>(1.19, 2.18)</td> </tr> </tbody> </table> <ul style="list-style-type: none"> A significantly larger AUC of trabecular volumetric BMD (vBMD) at the total hip (AUC = 0.741), femoral neck (AUC = 0.748), and intertrochanter (AUC = 0.738) and significant NRI (0.177, 0.149, and 0.195, respectively) were observed compared with FN-aBMD (AUC = 0.701), but not TH-aBMD. 	Predictor	Unadjusted		Age-adjusted		Multivariate-adjusted ^A		HR	(95% CI)	HR	(95% CI)	HR	(95% CI)	aBMD							FN-aBMD	3.33	(2.54, 4.39)	1.8	(1.29, 2.52)	-	-	TH-aBMD	3.34	(2.64, 4.26)	2.02	(1.49, 2.74)	-	-	Volumetric indices							TH-TvBMD	5.03	(3.58, 7.04)	2.90	(1.92, 4.37)	3.17	(1.75, 5.75)	FN-TvBMD	5.18	(3.64, 7.41)	2.92	(1.89, 4.48)	3.55	(1.74, 7.25)	IT-TvBMD	4.44	(3.28, 6.02)	2.68	(1.86, 3.86)	3.11	(1.82, 5.29)	IT-CvBMD	3.03	(2.31, 3.98)	1.75	(1.27, 2.40)	1.55	(1.03, 2.31)	TH-CsBMD	3.32	(2.53, 4.37)	1.91	(1.38, 2.63)	1.85	(1.11, 3.07)	IT-CsBMD	3.41	(2.56, 4.55)	1.91	(1.37, 2.66)	1.81	(1.06, 3.09)	Geometric indices							FN-CSA	4.08	(2.99, 5.59)	2.23	(1.54, 3.22)	2.38	(1.19, 4.76)	IT-CSA	4.27	(3.14, 5.81)	2.45	(1.69, 3.55)	3.13	(1.68, 5.81)	IT Z	3.45	(2.58, 4.59)	1.99	(1.44, 2.74)	1.85	(1.21, 2.82)	IT BR ^C	2.47	(2.07, 2.95)	1.68	(1.35, 2.08)	1.61	(1.19, 2.18)	 <p>Japan</p> <p>Iki M, Winzenrieth R, Tamaki J, Sato Y, Dongmei N, Kajita E, Kouda K, Yura A, Tachiki T, Kamiya K, Kagamimori S.</p>
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<p>Association between osteoporotic femoral neck fractures and DXA-derived 3D measurements at lumbar spine: a case-control study.</p> <p>[2020]</p> <p>Available here</p>	<p>61 women with transcervical hip fractures</p> <p>61 age-matched women without any type of fracture</p>	<p>This study showed the association of DXA-derived measurements at lumbar spine with transcervical hip fractures. A strong association between vBMD at the posterior vertebral elements and transcervical hip fractures was observed, probably because of global deterioration of the cortical bone</p>	 <ul style="list-style-type: none"> Integral vBMD, cortical vBMD, cortical sBMD, and cortical thickness were the DXA-derived 3D measurements at lumbar spine that showed the stronger association with transcervical hip fractures The highest AUC (0.726) and OR (2.610) at the lumbar spine were found for integral vBMD at the posterior vertebral elements. Significantly, lower AUC (0.617) and OR (1.607) were found for trabecular vBMD at the vertebral body. 	 <p>Spain</p> <p>López Picazo M, Humbert L, Winzenrieth R, Di Gregorio S, González Ballester MA, Del Río Barquero LM.</p>
<p>DXA-based 3D mapping of hip cortical thinning correlates with incident fractures in postmenopausal women from the GERICO cohort.</p> <p>[2019]</p> <p>Available here</p>	<p>796 Postmenopausal women at baseline.</p> <p>Follow-up 5.7 ± 1.5 yrs.</p> <p>100 women (13%) with lowtrauma clinical fracture, 44 with MOF</p>	<p>DXA-based 3D modeling parameters are associated with all types and major osteoporotic fractures</p> <p>The associations of trabecular vBMD with fractures are of greater magnitude than those of the cortical parameters.</p>	<p>Percent difference in cortical parameters between women with and without MOF</p>  <ul style="list-style-type: none"> Predicting incidence of low-trauma fractures: Risk increased by 23-40% Prediction of MOF: Risk increased by 36-63% 	 <p>Switzerland</p> <p>Biver E, Hars M, Winzenrieth R, Rizzoli R, Ferrari S.</p>

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Cortical and trabecular bone of patients with prevalent major osteoporotic fracture: a case-control study using DXA-based 3D modelling.</p> <p>[2018]</p> <p>Available here</p>	<p>1,848 women from 50, including 105 fractured individuals (MOF)</p>	<p>The authors concluded that the trabecular volumetric BMD is the strongest parameter to discriminate fractured from non-fractured individual, and that assessing 3D bone parameters could be useful for fracture discrimination in clinical practice</p>	  <p>Spine aBMD, Total Femur aBMD and all 3D measurements significantly lower in fractured subjects (fx);</p> <p>Adjusted for age: only TF aBMD & trabecular vBMD remain significant discriminating factors for fx adjusted for age and weight, trabecular vBMD remains the only significant discriminator of fx</p>	 <p>USA</p> <p>Winzenrieth R, Humbert L, Leib E.</p>
<p>DXA-Based 3D Analysis of the Cortical and Trabecular Bone of Hip Fracture Postmenopausal Women: A Case-Control Study.</p> <p>[2018]</p> <p>Available here</p>	<ul style="list-style-type: none"> 64 hip fracture post-menopausal women 64 controls 	<p>This case-control study showed the association of DXA-derived 3D measurements with hip fracture. Hip fracture group had lower cortical sBMD and trabecular vBMD, compared to controls</p>	 <p>Figure 1: Differences in cortical sBMD at each vertex of the femoral surface between subjects included in the hip fracture group and controls. Non-significant differences (unpaired two-sample t-test) in the total femur region are left in grey.</p>  <p>Figure 2: AUC calculated using cortical sBMD at each vertex of the femoral surface of the subjects included in the hip fracture group and controls. Regions where the differences in cortical sBMD were not significant (unpaired two-sample t-test) at the total femur region of interest are left in grey. Regions showing AUC higher than the 90th percentile (i.e. AUC > 0.687) are colored in red. Maximum AUC was 0.725.</p> <ul style="list-style-type: none"> Total hip aBMD of hip fracture group as measured by DXA was 10.7% lower compared to control group. Differences in vBMD were more pronounced in the trabecular compartment (-23.3%) than in the cortex (-8.2%). Differences in the cortex more pronounced at the medial aspect of the shaft, the lateral aspect of the greater trochanter, and the superolateral aspect of the neck. 	 <p>Spain</p> <p>Humbert L, Bagué A, Di Gregorio S, Winzenrieth R, Sevillano X, González Ballester MÁ, Del Rio L.</p>

Treatment Monitoring

The effect of various pharmacological agents on bone health and density is well known regarding the specific impact to Bone Mineral Density as assessed with DXA, and many with specific regional changes as assessed by QCT. But QCT is not routinely used clinically as it's expensive, time consuming and exposes patients to large doses of radiation. In research, the problems with QCT are the same: exposing patients to large radiation doses, higher research costs and difficult image acquisition.

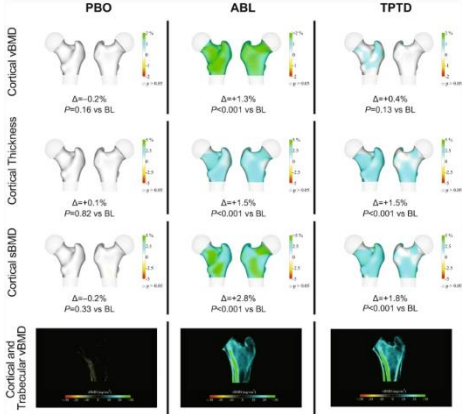

Using 3D-Shaper, researchers and clinicians now have the ability to review the impact of specific therapies on each bone compartment, without the need for QCT or alternative imaging methods;

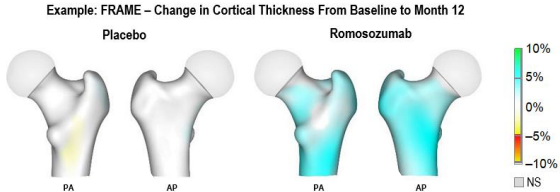
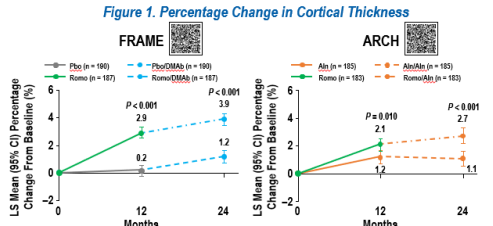
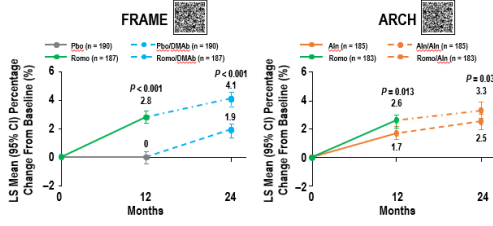
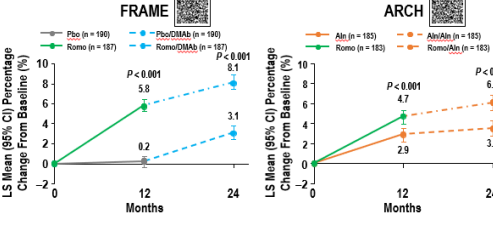

3D-Shaper completely simplifies the longitudinal monitoring of patients.

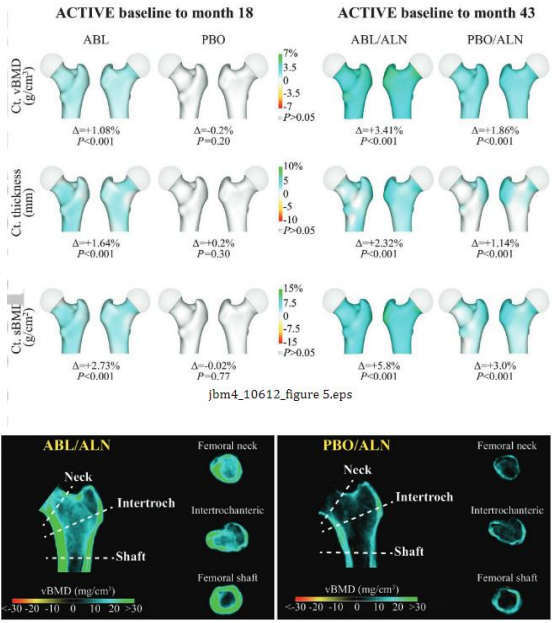

Below are some of the recent highlights and key projects using 3D-Shaper for this purpose.

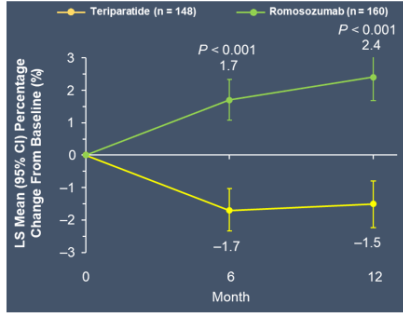
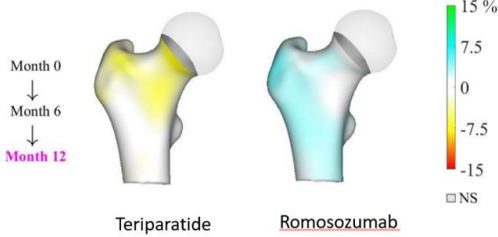
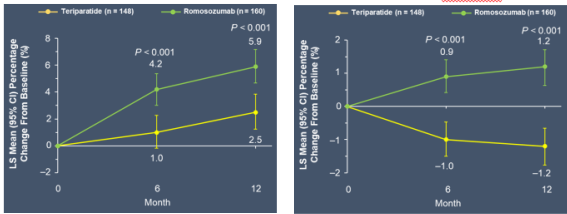
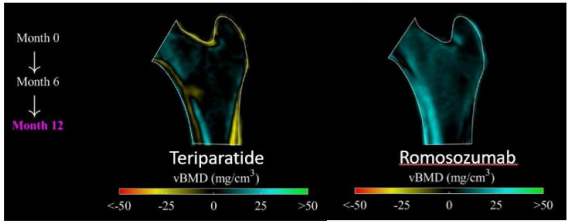

To date, there have been a total of **50** studies across **6** countries related to 'Treatment Monitoring'

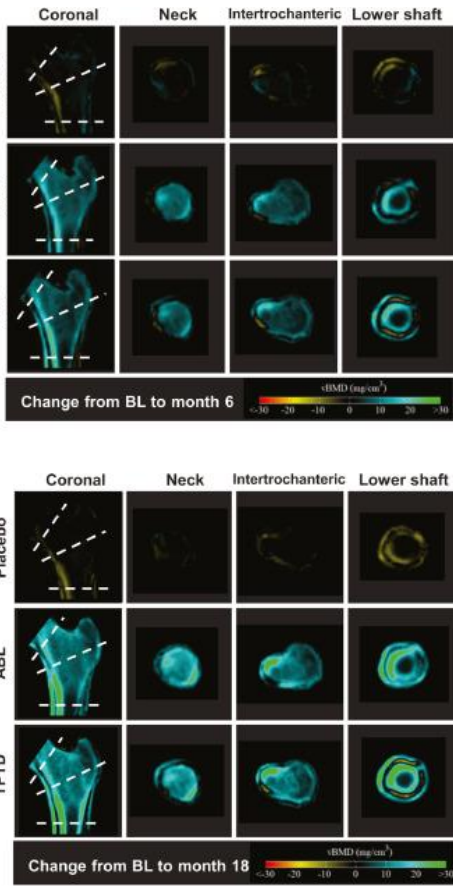

KEY PUBLICATION

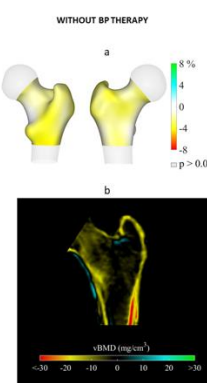
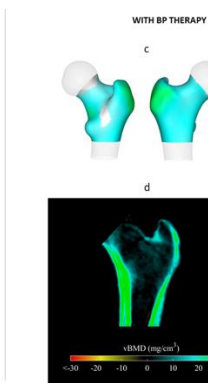

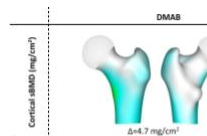
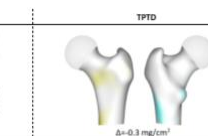

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Differential effects of abaloparatide and teriparatide on hip cortical volumetric BMD by DXA-based 3D modeling.</p> <p>[2021]</p> <p>Available here</p>	<p>750 patients</p> <p>3 treatment arms:</p> <ul style="list-style-type: none"> • 250 ABL • 250 TPTD • 250 Placebo 	<p>Similar significant increases in trabecular volumetric BMD (vBMD, + 9%) and cortical thickness (+ 1.5%) were observed with ABL and TPTD by 3D-DXA at 18 months. In contrast, only ABL significantly increased cortical vBMD versus baseline (+ 1.3%), and changes in both cortical vBMD and cortical surface BMD were significantly greater with ABL versus TPTD.</p>	 <p>Spatial changes in 3D-DXA cortical endpoints and cross-sectional representations of spatial changes in vBMD at month 18.</p> <p>Increases in cortical sBMD, cortical vBMD, and cortical thickness are presented in blue-green colors while decreases are presented in yellow-red colors.</p>	 <p>USA</p> <p>Winzenrieth R, Ominsky MS, Wang Y, Humbert L, Weiss RJ.</p>

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Cortical and Trabecular Bone improvements with Romosozumab followed by Denosumab or Alendronate assessed using 3D Modeling from DXA images.</p> <p>[2022]</p> <p>Abstract not currently Available</p>	<p>377 patients in FRAME</p> <ul style="list-style-type: none"> 190 women PBO 187 women ROMO <p>368 patients in ARCH</p> <ul style="list-style-type: none"> 185 women ALN 183 women ROMO 	<p>3D-SHAPER analysis provides an alternative to QCT to estimate changes in cortical and trabecular parameters from standard DXA images.</p> <p>Results from the 3D-SHAPER analysis of FRAME and ARCH complement extensive evidence demonstrating that treatment with ROMO results in substantial gains in hip cortical and trabecular bone compartments within 1 year, and that transition to an antiresorptive can maintain or augment those gains.</p> <p>Supports evidence that patients at high risk for fracture may benefit from treatment with romosozumab first, followed by an antiresorptive.</p>	<p>Example: FRAME – Change in Cortical Thickness From Baseline to Month 12</p>  <p>Figure 1. Percentage Change in Cortical Thickness</p>  <p>Figure 2. Percentage Change in Cortical vBMD</p>  <p>Figure 3. Percentage Change in Cortical sBMD</p>  <p>Figure 4. Percentage Change in Trabecular vBMD</p> <p>At month 12, treatment with ROMO vs PBO in FRAME and ROMO vs ALN in ARCH resulted in significantly greater increases with ROMO in cortical thickness, cortical vBMD, cortical sBMD, and trabecular vBMD.</p> <p>At month 24, cumulative gains in these parameters remained significantly greater in ROMO-DMAB and ROMO-ALN switch groups when compared against ROMO-PBO and ALN-ALN groups.</p>	 <p>USA</p> <p>M. Lewiecki, D. Betah, L. Humbert, C. Libanati, M. Oates, Y. Shi, R. Winzenrieth, S. Ferrari, F. Omura.</p>

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Proximal Femur Responses to Sequential Therapy with Abaloparatide Followed by Alendronate in Postmenopausal Women with Osteoporosis by 3D Modeling of Hip DXA.</p> <p>[2022]</p> <p>Available here</p>	<p>406 patients</p> <p>2 treatment arms:</p> <ul style="list-style-type: none"> • 204 ABL/ALN • 202 PBO/ALN 	<p>These results, which are among the first to describe skeletal responses to alendronate after treatment with a PTHR1 agonist that is currently approved for the treatment of PMO, indicate significant improvements in aBMD, Ct.vBMD, and Tb.vBMD of the total hip and hip subregions with ABL/ALN versus PBO/ALN.</p> <p>For most 2D-DXA and 3D-DXA parameters, particularly the cortical measures, alendronate effects were relatively similar whether alendronate was administered after abaloparatide or after placebo.</p> <p>These results support the use of abaloparatide as the initial treatment in sequential therapy with alendronate in women with PMO at very high fracture risk.</p>	 <p>ACTIVE baseline to month 18</p> <p>ACTIVE baseline to month 43</p> <p>ABL PBO ABL/ALN PBO/ALN</p> <p>Ct.vBMD (g/cm³): Δ=+1.08% (P<0.001) vs Δ=-0.2% (P=0.20) at 18m; Δ=+3.41% (P<0.001) vs Δ=+1.86% (P<0.001) at 43m.</p> <p>Ct.thickness (mm): Δ=+1.64% (P<0.001) vs Δ=+0.2% (P=0.30) at 18m; Δ=+2.32% (P<0.001) vs Δ=+1.14% (P<0.001) at 43m.</p> <p>Tb.vBMD (g/cm³): Δ=+2.73% (P<0.001) vs Δ=-0.02% (P=0.77) at 18m; Δ=+5.8% (P<0.001) vs Δ=+3.0% (P<0.001) at 43m.</p> <p>Subregion vBMD (mg/cm³): Neck, Intertroch, Intertrochanteric, Femoral shaft.</p> <p>Strength indices in the ABL/ALN group improved in all subregions versus baseline (all P<0.0001) and versus PBO/ALN (all P<0.02).</p> <p>In the ABL/ALN group, collagen type I N-terminal propeptide (PINP) levels at the time of alendronate initiation correlated with subsequent percent changes in all 3D-DXA parameters with 24 months of alendronate therapy.</p>	 <p>USA</p> <p>R.Winzenrieth, P.Kostenuik J.I.Boxberger, Y.Wang, L.Humbert</p>

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Comparison of Romosozumab and Teriparatide effects on Cortical and Trabecular bone using 3D Modeling from DXA images in Postmenopausal women transitioning from Bisphosphonate Therapy.</p> <p>[2022]</p> <p>Abstract not currently Available</p>	<p>Women from the STRUCTURE phase 3 clinical trial.</p> <p>308 Postmenopausal women</p> <p>2 treatment arms:</p> <ul style="list-style-type: none"> • 148 TPTD • 160 ROMO 	<p>Use of DXA-based 3D modeling by 3D-SHAPER analysis allowed advanced assessment of the cortical and trabecular bone changes using standard hip DXA scans.</p> <p>3D-SHAPER analysis provides an alternative to QCT to derive useful cortical and trabecular parameters from standard DXA images</p>	<div style="text-align: center;"> <p>Cortical sBMD</p>  <p>Distribution of changes</p>  <p>Teriparatide Romosozumab</p> </div> <div style="text-align: center;"> <p>Trabecular vBMD Cortical vBMD</p>  <p>Distribution of changes</p>  <p>Teriparatide Romosozumab</p> <p>vBMD (mg/cm³) vBMD (mg/cm³)</p> </div> <p>Results obtained by DXA-based 3D modeling were consistent with results obtained by QCT in STRUCTURE for cortical vBMD but not for trabecular vBMD.</p> <p>Both DXA-based 3D modeling and QCT showed increases in cortical vBMD with romosozumab and loss with teriparatide, with the difference between the two treatments reaching statistical significance for both methods.</p> <p>Both DXA-based 3D modeling and QCT showed greater increases in trabecular vBMD with romosozumab vs teriparatide; however, gains were statistically greater with DXA-based 3D modeling, but not with QCT.</p>	<div style="text-align: center;">  <p>USA</p> </div> <p>M. Lewiecki, D. Betah, L. Humbert, C. Libanati, M. Oates, Y. Shi, R. Winzenrieth, S. Ferrari, F. Omura.</p>

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Abaloparatide Effects on Cortical Volumetric BMD and Estimated Strength Indices of Hip Subregions by 3D-DXA in Women with Postmenopausal Osteoporosis.</p> <p>[2021]</p> <p>Available here</p>	<p>750 patients</p> <p>3 treatment arms:</p> <ul style="list-style-type: none"> • 250 ABL • 250 TPTD • 250 Placebo 	<p>3D-DXA show that 6 and 18 mo of ABL or TPTD similarly increased Tb.vBMD at the femoral neck, trochanter, and femoral shaft vs baseline and PBO, whereas the ABL group showed greater increases in Ct.vBMD vs TPTD and PBO at mo 18 for all 3 hip subregions of interest.</p> <p>Cortical thickness of the femoral neck, intertrochanteric, and shaft regions was similarly increased with ABL and TPTD, and Ct.sBMD of the femoral neck and intertrochanteric subregions showed greater increases at mo 18 with ABL than TPTD.</p>	 <p>Change from BL to month 6</p> <p>Change from BL to month 18</p> <p>Cross-sectional views depicting average vBMD changes at months 6 and 18 for each group. Data reflect absolute vBMD changes from baseline. Blue/green represents increased vBMD, yellow/orange represents decreased vBMD, black represents no change.</p> <p>Central compartments (FN & intertrochanteric slices) are noticeably bluer at mo 6 & 18 in ABL and TPTD examples vs PBO (consistent with observed treatment effects of ABL and TPTD on Tb.vBMD).</p> <p>The outermost peripheral aspects of the FN & shaft appear blue and green in ABL & TPTD groups, especially at mo 18 (consistent with observed increases from baseline in Ct.vBMD).</p> <p>Yellow rings are evident within the femoral shaft of the ABL & TPTD groups at mo 6 (may reflect reductions in vBMD of the deep cortex). Reduced vBMD remains evident at mo 18 with TPTD but not with ABL.</p>	 <p>USA</p> <p>R.Winzenrieth, L.Humbert, J.I.Boxberger, R.J.Weiss, Y.Wang, P.Kostenuik</p>

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS																									
<p>Trabecular and cortical bone health in postmenopausal women receiving aromatase inhibitors for early breast cancer treatment: The B-ABLE prospective cohort study.</p> <p>[2019]</p> <p>Available here</p>	<p>464 women</p> <p>366 with bisphosphonates (BP+)</p> <p>98 without bisph. (BP-)</p> <p>bone evaluation by DXA at baseline, 12 and 24 months</p>	<p>This study highlights the possibility to better manage patients with early breast cancer in terms of bone assessment, monitoring, and treatment recommendation.</p>	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>WITHOUT BP THERAPY</p>  </div> <div style="text-align: center;"> <p>WITH BP THERAPY</p>  </div> </div> <ul style="list-style-type: none"> AI impaired both trabecular and cortical compartments in BP- subjects while BP compensate for the deleterious AI effects on bone; Consistently with aBMD at spine, BP- had a more marked decrease of the trabecular compartment at femur; <p>3D analysis showed that BP protective treatment stops to overcome the negative effect of AI on trabecular bone after 12 months, suggesting a possible decrease of the trabecular bone after 24 months of AI.</p>	 <p>Spain</p> <p>Nogués X, Rodríguez R, Rodríguez-Sanz M, Winzenrieth R, Humbert L, Pineda-Moncusí M, Servitja S, García-Giralto N, Martos T, Tusquets I, Martínez-García M, Rodríguez Morera R, A Dies Perez, Albanell J.</p>																									
<p>Effects of osteoporosis drug treatments on cortical and trabecular bone in the femur using DXA-based 3D modelling.</p> <p>[2018]</p> <p>Available here</p>	<p>155 subjects;</p> <ul style="list-style-type: none"> 16 males <p>139 females</p>	<p>This study highlights the possibility and added value to monitor TTT effects through a 3D analysis, as TTTs have different effects at the cortical and trabecular compartments. Such analysis required, until now, the use of QCT (cost+radiation ↗) and is now possible from DXA</p>	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th></th> <th>NAIVE</th> <th>AL</th> <th>DMAB</th> <th>TPTD</th> </tr> </thead> <tbody> <tr> <td>Trabecular vBMD (mg/cm³)</td> <td>-</td> <td>+</td> <td>++</td> <td>++</td> </tr> <tr> <td>Cortical sBMD (mg/cm²)</td> <td>-</td> <td>+</td> <td>++</td> <td>=</td> </tr> <tr> <td>Cth (mm)</td> <td>=</td> <td>=</td> <td>+</td> <td>+</td> </tr> <tr> <td>Cortical vBMD (mg/cm³)</td> <td>=</td> <td>+</td> <td>+</td> <td>-</td> </tr> </tbody> </table> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;"> <p>DMAB</p>  <p>Δ+7 mg/cm³</p> </div> <div style="text-align: center;"> <p>TPTD</p>  <p>Δ+0.3 mg/cm³</p> </div> </div>		NAIVE	AL	DMAB	TPTD	Trabecular vBMD (mg/cm ³)	-	+	++	++	Cortical sBMD (mg/cm ²)	-	+	++	=	Cth (mm)	=	=	+	+	Cortical vBMD (mg/cm ³)	=	+	+	-	 <p>Spain</p> <p>Winzenrieth R, Humbert L, Di Gregorio S, Bonel E, García M, Del Rio LM</p>
	NAIVE	AL	DMAB	TPTD																									
Trabecular vBMD (mg/cm ³)	-	+	++	++																									
Cortical sBMD (mg/cm ²)	-	+	++	=																									
Cth (mm)	=	=	+	+																									
Cortical vBMD (mg/cm ³)	=	+	+	-																									

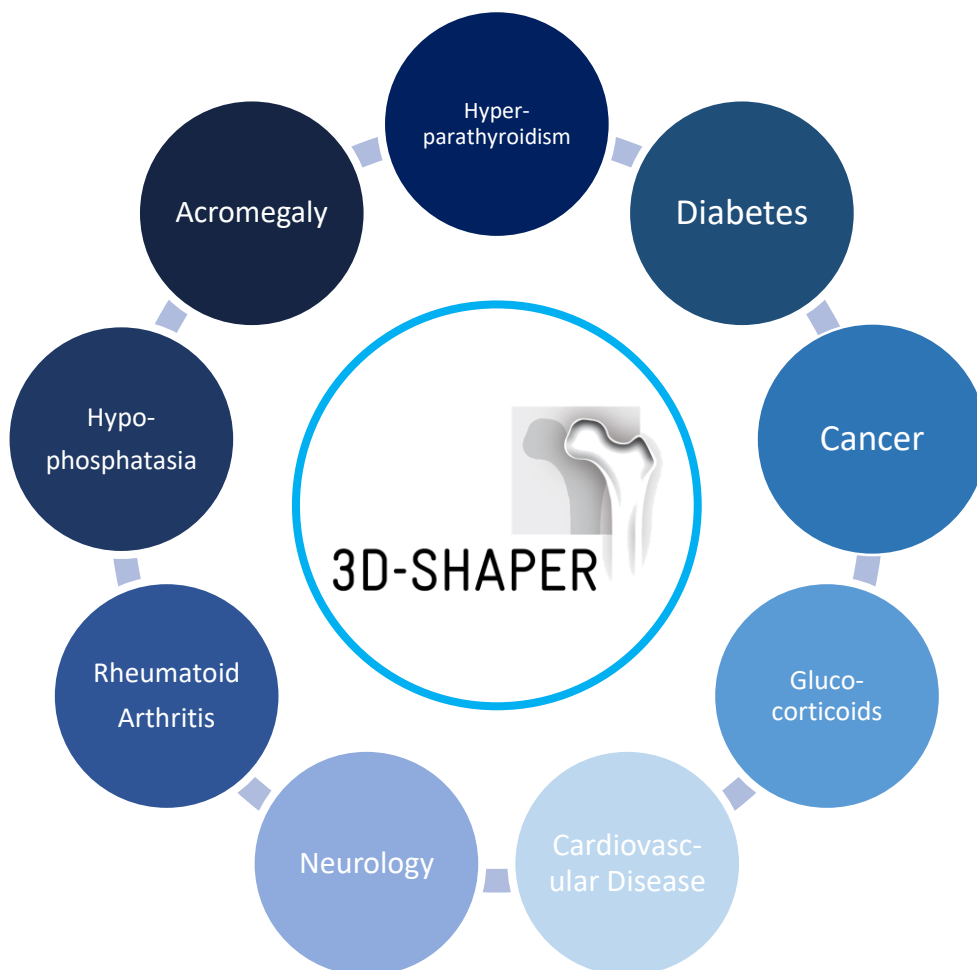
Secondary Osteoporosis

Secondary Osteoporosis is defined as low bone mass with microarchitectural alterations in bone leading to fragility fractures in the presence of an underlying disease or medication. This topic has been attracting a lot of attention globally and researchers have been doing a fantastic job looking into how these diseases/ medications are impacting bone density and what we can do to limit and stop them.

3D-Shaper has been playing a pivotal role by providing researchers with a tool to explore their data in a way only previously possible with QCT. Now, with a standard 2D-DXA image, researchers can *visualise bone impact in full 3D*, *assess local fragilities* and *monitor* how each bone compartment is impacted over time.

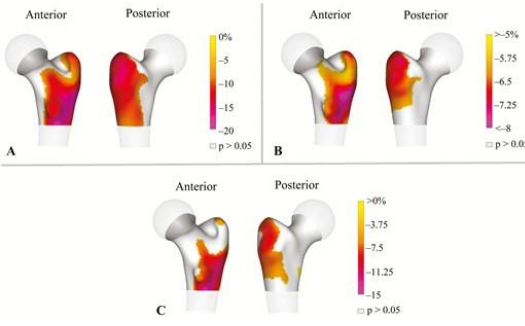

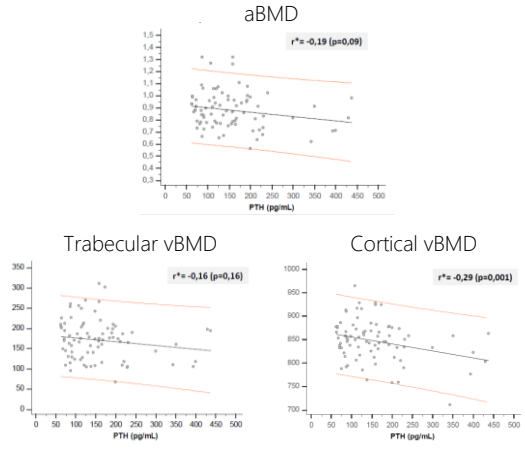
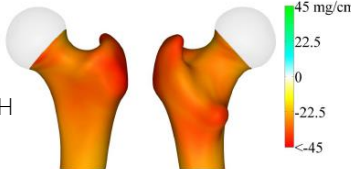
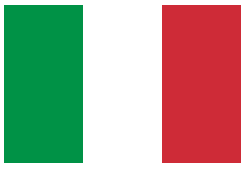
Below outlines a few key studies exploring the effects of secondary osteoporosis.

To date, there have been a total of **76** studies across **13** countries related to '*Secondary Osteoporosis*

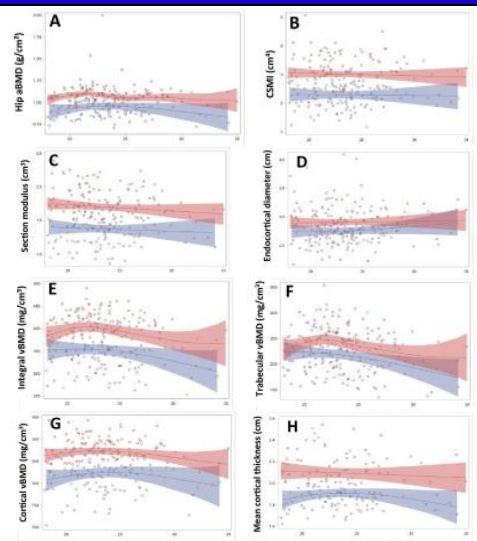
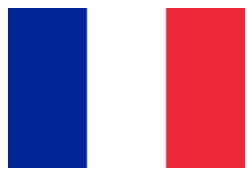





Hyperparathyroidism

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS																																																																																								
<p>Analysis of Bone Impairment by 3D DXA Hip Measures in Patients With Primary Hyperparathyroidism: A Pilot Study.</p> <p>[2020]</p> <p>Available here</p>	<p>80 adults (59.5 ± 9.1 yrs)</p> <ul style="list-style-type: none"> 40 with PHPT 40 age- and sex-matched healthy controls. 	<p>The trabecular bone is relatively preserved while cortical bone is largely affected.</p> <p>Patients with PHPT and diagnosed with osteoporosis or osteopenia had significantly lower cortical vBMD compared with those who had normal bone values.</p> <p>3D-DXA findings are consistent with those reported in studies using HRpQCT.</p>	 <p>Table 2. Mean-Adjusted (by Age, Sex, and Body Mass Index) Differences in Areal Bone Mineral Density (aBMD) and 3D-DXA Parameters Between the Study Groups</p> <table border="1" data-bbox="742 683 1268 884"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">Primary Hyperparathyroidism (n = 40)</th> <th colspan="2">Controls (n = 40)</th> <th rowspan="2">P</th> <th rowspan="2">Effect Size^a</th> </tr> <tr> <th>Mean</th> <th>95% CI</th> <th>Mean</th> <th>95% CI</th> </tr> </thead> <tbody> <tr> <td>aBMD (g/cm²)</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Femoral neck</td> <td>0.695</td> <td>0.664 – 0.726</td> <td>0.747</td> <td>0.716 – 0.778</td> <td>0.023</td> <td>0.51</td> </tr> <tr> <td>Trochanter</td> <td>0.610</td> <td>0.585 – 0.635</td> <td>0.672</td> <td>0.647 – 0.697</td> <td>0.001</td> <td>0.75</td> </tr> <tr> <td>Shaft</td> <td>0.989</td> <td>0.950 – 1.028</td> <td>1.105</td> <td>1.066 – 1.144</td> <td><0.001</td> <td>0.91</td> </tr> <tr> <td>Total hip</td> <td>0.838</td> <td>0.807 – 0.869</td> <td>0.940</td> <td>0.909 – 0.971</td> <td><0.001</td> <td>1.01</td> </tr> <tr> <td>3D-DXA</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Cortical aBMD (mg/cm²)</td> <td>147.24</td> <td>141.30 – 153.18</td> <td>159.71</td> <td>153.77 – 165.65</td> <td>0.005</td> <td>0.65</td> </tr> <tr> <td>Trabecular vBMD (mg/cm³)</td> <td>161.81</td> <td>152.21 – 174.41</td> <td>175.32</td> <td>165.72 – 184.92</td> <td>0.055</td> <td>0.44</td> </tr> <tr> <td>Cortical vBMD (mg/cm³)</td> <td>794.11</td> <td>774.69 – 813.53</td> <td>823.84</td> <td>804.42 – 843.26</td> <td>0.037</td> <td>0.47</td> </tr> <tr> <td>Integral vBMD (mg/cm³)</td> <td>291.41</td> <td>276.94 – 305.87</td> <td>315.77</td> <td>301.30 – 330.23</td> <td>0.022</td> <td>0.52</td> </tr> <tr> <td>Cortical thickness (mm)</td> <td>1.85</td> <td>1.81 – 1.90</td> <td>1.93</td> <td>1.89 – 1.97</td> <td>0.011</td> <td>0.63</td> </tr> </tbody> </table> <p>PHPT have lower aBMD at the hip sites and reduced cortical 3D parameters compared with an age- and sex-matched healthy control group. In addition, the vBMD of the trabecular compartment seems to be affected, although to a lesser extent.</p>		Primary Hyperparathyroidism (n = 40)		Controls (n = 40)		P	Effect Size ^a	Mean	95% CI	Mean	95% CI	aBMD (g/cm ²)							Femoral neck	0.695	0.664 – 0.726	0.747	0.716 – 0.778	0.023	0.51	Trochanter	0.610	0.585 – 0.635	0.672	0.647 – 0.697	0.001	0.75	Shaft	0.989	0.950 – 1.028	1.105	1.066 – 1.144	<0.001	0.91	Total hip	0.838	0.807 – 0.869	0.940	0.909 – 0.971	<0.001	1.01	3D-DXA							Cortical aBMD (mg/cm ²)	147.24	141.30 – 153.18	159.71	153.77 – 165.65	0.005	0.65	Trabecular vBMD (mg/cm ³)	161.81	152.21 – 174.41	175.32	165.72 – 184.92	0.055	0.44	Cortical vBMD (mg/cm ³)	794.11	774.69 – 813.53	823.84	804.42 – 843.26	0.037	0.47	Integral vBMD (mg/cm ³)	291.41	276.94 – 305.87	315.77	301.30 – 330.23	0.022	0.52	Cortical thickness (mm)	1.85	1.81 – 1.90	1.93	1.89 – 1.97	0.011	0.63	 <p>Spain</p> <p>Gracia-Marco, L. García-Fontana, B. Ubago-Guisado, E. Vlachopoulos, D. García-Martín, A. Muñoz-Torres, M.</p>
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<p>Primary Hyperparathyroidism (PHPT) impaired 3D cortical density at femur as assessed from 2D DXA</p> <p>[2017]</p> <p>Abstract not currently Available</p>	<p>81 adults (59.4 ± 13.5 yrs) with PHPT.</p>	<p>Negative effect of PTH level on the Cortical vBMD and mean Cortical Thickness.</p> <p>No effects were observed in the Trabecular compartment.</p>	 <p>Differences in cortical vBMD between subjects from PTH level 1st quartile and 4th quartile</p> 	 <p>Italy</p> <p>Guglielmi, G. Winzenrieth, R. Battista, C. Scillitani, A.</p>																																																																																								

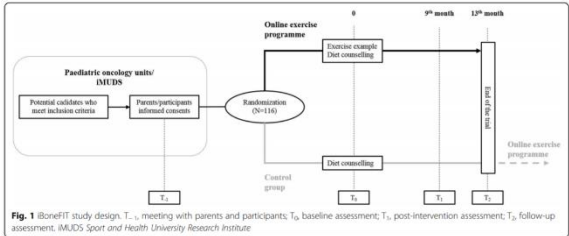

Obesity

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Modification of bone mineral density, bone geometry and volumetric BMD in young women with obesity.</p> <p>[2021]</p> <p>Available here</p>	<p>220 adolescent and young women from 18 to 35 years old</p> <ul style="list-style-type: none"> 128 patients with obesity 92 age-matched (± 6 months) normal-weight controls 	<p>Young women with obesity presented higher aBMD, better hip geometry and greater strength compared with normal-weight controls.</p> <p>Cortical and trabecular compartments measured by 3D-SHAPER® were favourably and concomitantly modified.</p>	 <p>Subjects with obesity presented significantly higher aBMD at all bone sites.</p> <p>Bone size & strength estimates were higher at all femoral subregions in young women with obesity.</p> <p>vBMD was higher in subjects with obesity, but the difference between groups was greater for cortical vBMD compared with trabecular vBMD</p>	 <p>France</p> <p>Maimoun L, Renard E, Humbert L, Aouinti S, Mura T, Boudousq V, Lefebvre P, Mahadea K, Philibert P, de Santa-Barbara P, Avignon A, Guillaume S, Sultan A, Nocca D, Mariano-Goulart D.</p>

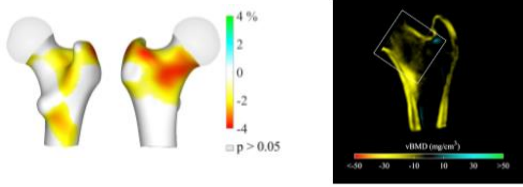
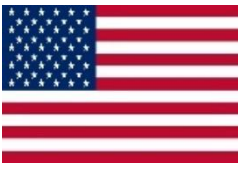
Diabetes

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Relationship Between Insulin Resistance (HOMA-IR), Trabecular Bone Score (TBS), and Three-Dimensional Dual-Energy X-ray Absorptiometry (3D-DXA) in Non-Diabetic Postmenopausal Women.</p> <p>[2020]</p> <p>Available here</p>	<p>381 postmenopausal women</p>	<p>In non-diabetic postmenopausal women there was a direct relationship between insulin resistance and vBMD, whose effect is directly related to greater weight.</p> <p>This might be explained by the formation of advanced glycosylation products (AGEs) in the bone matrix, which reduces bone deformation capacity and resistance, as well as increases fragility.</p>	<p>Women located in quartile 4 (Q4) of HOMA-IR had higher values of volumetric bone mineral density (vBMD) but not TBS.</p> <p>The increase was higher in the trabecular compartment (16.4%) than in the cortical compartment (6.4%). Similar results were obtained for insulin.</p>	 <p>Spain</p> <p>Campillo-Sánchez F, Usategui-Martín R, Ruiz-de Temiño A, Gil J, Ruiz-Mambrilla M, Fernández-Gómez JM, Dueñas-Laita A, Pérez-Castrillón JL.</p>

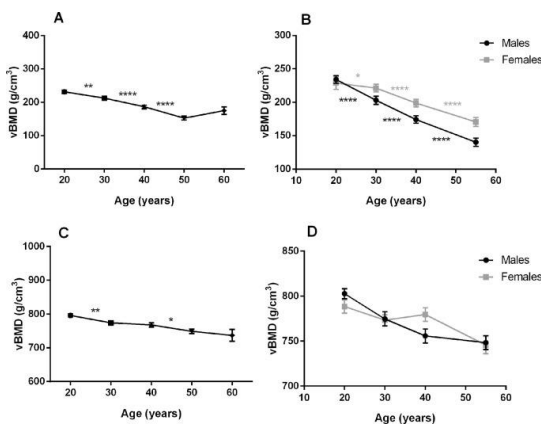

Cancer

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS																																																																																														
<p>The effect of an online exercise programme on bone health in paediatric cancer survivors (iBoneFIT): study protocol of a multi-centre randomized controlled trial.</p> <p>[2020]</p> <p>Available here</p>	<p>116 Subjects</p> <ul style="list-style-type: none"> Aged 6 to 18 Intervention (n=58) Control (n=58) 	<p>This article describes the design, rationale and methods of a study intended to test the effect of a rigorous online exercise programme on bone health in paediatric cancer survivors. If successful, the iBoneFIT study will contribute to decrease chronic health conditions in this population and will have a positive impact in the society.</p>	 <p>Fig. 1 iBoneFIT study design. T₀, meeting with parents and participants; T₀, baseline assessment; T₁, post-intervention assessment; T₂, follow-up assessment. MJDJS Sport and Health University Research Institute</p> <p>Table 3 iBoneFIT study exercise programme periodisation</p> <table border="1"> <thead> <tr> <th>Phase</th> <th>Warm up*</th> <th>Exercise^b</th> <th>Level</th> <th>Repetitions</th> <th>Sets a day (Rest^c)</th> <th>Sessions a Week</th> <th>Squats/Jumps a Week</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td rowspan="2">RAMP</td> <td rowspan="2">BM-based Squat</td> <td>1 (1-4 wk)</td> <td>15</td> <td>3</td> <td>4</td> <td>180</td> </tr> <tr> <td>2 (5-8 wk)</td> <td>20</td> <td>4</td> <td>4</td> <td>320</td> </tr> <tr> <td colspan="8">Total phase 1 (8 wk)</td> </tr> <tr> <td rowspan="3">2</td> <td rowspan="3">RAMP</td> <td rowspan="3">SJ</td> <td>1 (9-12 wk)</td> <td>10</td> <td>3</td> <td>3</td> <td>90</td> </tr> <tr> <td>2 (13-16 wk)</td> <td>15</td> <td>3</td> <td>4</td> <td>180</td> </tr> <tr> <td>3 (17-20 wk)</td> <td>20</td> <td>4</td> <td>4</td> <td>320</td> </tr> <tr> <td colspan="8">Total phase 2 (12 wk)</td> </tr> <tr> <td rowspan="4">3</td> <td rowspan="4">RAMP</td> <td rowspan="4">CMJ</td> <td>1 (21-24 wk)</td> <td>10</td> <td>3</td> <td>3</td> <td>90</td> </tr> <tr> <td>2 (25-28 wk)</td> <td>12</td> <td>3</td> <td>4</td> <td>144</td> </tr> <tr> <td>3 (29-32 wk)</td> <td>15</td> <td>3</td> <td>4</td> <td>180</td> </tr> <tr> <td>4 (33-36 wk)</td> <td>20</td> <td>4</td> <td>4</td> <td>320</td> </tr> <tr> <td colspan="8">Total phase 3 (16 wk)</td> </tr> <tr> <td colspan="7">Total intervention (36 wk)</td> <td>7296</td> </tr> </tbody> </table> <p><small>RAMP raise, activate, mobilise and potentiate, BM body mass, SJ squat jump, CMJ countermovement jump ^aWarm up will be focused on dynamic exercises with progressive intensity enhancing optimal core body temperature, motor unit excitability, kinesthetic awareness and ranges of motion ^bEach exercise will be suggested to be performed at the pace of the personal trainer managing the session, if not, a self-paced performance will be recommended ^cPhase 1 rest=45 s Phases 2 and 3 rest=1 min</small></p>	Phase	Warm up*	Exercise ^b	Level	Repetitions	Sets a day (Rest ^c)	Sessions a Week	Squats/Jumps a Week	1	RAMP	BM-based Squat	1 (1-4 wk)	15	3	4	180	2 (5-8 wk)	20	4	4	320	Total phase 1 (8 wk)								2	RAMP	SJ	1 (9-12 wk)	10	3	3	90	2 (13-16 wk)	15	3	4	180	3 (17-20 wk)	20	4	4	320	Total phase 2 (12 wk)								3	RAMP	CMJ	1 (21-24 wk)	10	3	3	90	2 (25-28 wk)	12	3	4	144	3 (29-32 wk)	15	3	4	180	4 (33-36 wk)	20	4	4	320	Total phase 3 (16 wk)								Total intervention (36 wk)							7296	 <p>Spain</p> <p>Gil-Cosano JJ, Ubago-Guisado E, Sánchez MJ, Ortega-Acosta MJ, Mateos ME, Benito-Bernal AI, Llorente-Cantarero FJ, Ortega FB, Ruiz JR, Labayen I, Martínez-Vizcaino V, Vlachopoulos D, Arroyo-Morales M, Muñoz-Torres M, Pascual-Gázquez JF, Vicho-González MC, Gracia-Marco L.</p>
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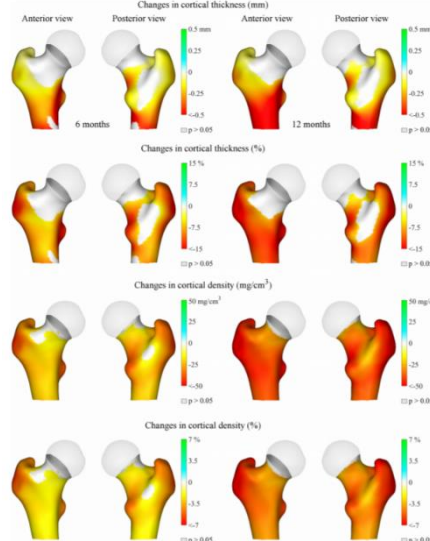

Glucocorticoids

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Daily low dose of glucocorticoids induces trabecular and cortical bones impairment at the femur: a 3D analysis using DXA-based modelling.</p> <p>[2018]</p> <p>Available here</p>	<p>402 patients (females and males) treated with low dose of GC (>5mg/d for >3 months); Versus 1,087 gender-, age- and BMI-matched controls</p>	<p>An impairment of both cortical and trabecular bone is observed in patients treated with GC, even with low dose, with:</p> <ul style="list-style-type: none"> Effect on the cortical bone at the total femur Effect on the trabecular bone localized at the femoral neck 	 <ul style="list-style-type: none"> On 2D: significantly lower aBMD at total femur in GC (while no significant difference at lumbar spine) On 3D: significantly lower cortical surface BMD at total femur & lower trabecular volumetric BMD localized at the femoral neck <p>In a sub-analysis of fractured subjects, lower cortical sBMD and trabecular vBMD observed at the total femur, and significantly lower in GC-treated Fx vs GC-treated without fx.</p>	 <p>USA</p> <p>Manasanch Berengué A, Winzenrieth R, Humbert L, Leib E.</p>

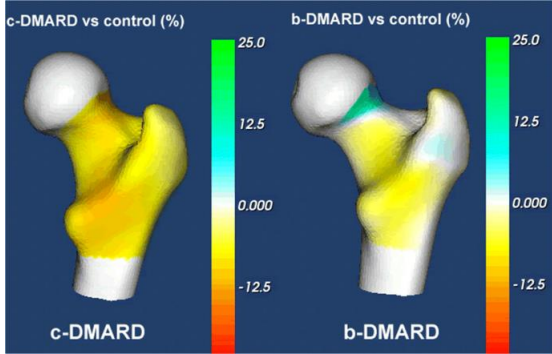

Down Syndrome

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Volumetric BMD by 3D-DXA and Trabecular Bone Score in Adults With Down Syndrome.</p> <p>[2021]</p> <p>Available here</p>	<p>297 Adult subjects with Down Syndrome. Males & Females</p>	<p>Trabecular vBMD at total hip and femoral neck was lower in males than in females.</p> <p>Trabecular and cortical vBMD decreased with age, but age decline in trabecular vBMD was more pronounced in males.</p> <p>Both 3D-DXA & TBS could be used as complementary tools to areal BMD</p>		 <p>Spain</p> <p>Costa R, Real de Asúa D, Gullón A, De Miguel R, Bautista A, García Emilia Roy C, García-Vadillo J, Suárez C, Moldenhauer F, Castañeda S.</p>


Spinal Cord Injury

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Analysis of the evolution of cortical and trabecular bone compartments in the proximal femur after spinal cord injury by 3D-DXA.</p> <p>[2018]</p> <p>Available here</p>	<p>16 Subjects</p> <ul style="list-style-type: none"> • Male • SCI <3 months since injury • Without anti-osteoporotic treatment 	<p>Marked trabecular and cortical bone loss was observed at the proximal femur short-term after SCI. 3D-DXA measured vBMD evolution at both femoral compartments and cortical thinning, providing better knowledge of their differential contributory role to bone strength and probably of the effect of therapy in these patients.</p>	 <p>vBMD</p> <p>significantly decreased at integral, trabecular, and cortical compartments at 6 months, with a further decrease at 12 months. Resulting in an overall decrease of - 16.6, - 21.9, and - 5.0%, respectively.</p> <p>Cortical thickness also decreased at 6 and 12 with the maximal decrease being observed during the first 6 months.</p>	 <p>Spain</p> <p>Gifre L, Humbert L, Muxi A, del Rio L, Vidal J, Portell E, Monegal A, Guañabens N, Peris P.</p>

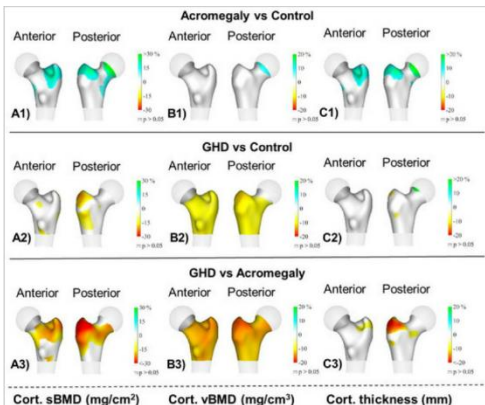


Rheumatoid Arthritis

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Trabecular and cortical bone involvement in rheumatoid arthritis by DXA and DXA-based 3D modelling.</p> <p>[2020]</p> <p>Available here</p>	<p>205 Adults</p> <ul style="list-style-type: none"> 105 RA patients 100 controls group 	<p>3D-DXA allowed us to find changes in trabecular and cortical bone compartments in RA patients otherwise not apparent using standard DXA</p>	 <p>DMARD (n = 75) group showed significantly lower trabecular and cortical vBMD than the CG.</p> <p>Despite the lower values, the b-DMARD group (n = 30) showed no significant differences in most parameters compared with the CG.</p> <p>The trabecular and cortical 3D parameters were significantly lower in the group with an RA disease duration of 1 to 5 years than in the CG, and the trabecular vBMD was significantly lower in the group with a duration of corticosteroid therapy of 1 to 5 years than in the CG.</p>	 <p>Argentina</p> <p>Brance ML, Pons-Estel BA, Quagliato NJ, Jorfen M, Berbotto G, Cortese N, Raggio JC, Palatnik M, Chavero I, Soldano J, Dieguez C, Sánchez A, Del Rio L, Di Gregorio S, Brun LR.</p>

Hypophosphatasia

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS																																																		
<p>Evaluation of bone mineral density and 3D-Shaper parameters in congenital hypophosphatasia of the adult.</p> <p>[2021]</p> <p>Available here</p>	<p>33 Adults with HPP with heterozygous mutation</p> <ul style="list-style-type: none"> 21 women 12 men 	<p>No differences in BMD between subjects with and without stress fractures</p> <p>3D-Shaper showed a decrease in cortical thickness between patients with stress fractures vs without them and those with traumatic fractures</p>	<table border="1"> <thead> <tr> <th>Characteristics</th> <th>TG+ (N=33)</th> </tr> </thead> <tbody> <tr> <td>Age (years), median (IQR)</td> <td>51.01 (37.96-63.02)</td> </tr> <tr> <td>Age (years), mean ± SD</td> <td>50.56 ± 15.08</td> </tr> <tr> <td>Female gender, n (%)</td> <td>21 (63.6%)</td> </tr> <tr> <td>Postmenopausal women, n (%)</td> <td>9 (42.9%)</td> </tr> <tr> <td>Men >50 years, n (%)</td> <td>0 (66.6%)</td> </tr> <tr> <td>BMI (kg/m²), median (IQR)</td> <td>25.91 (22.89-29.25)</td> </tr> <tr> <td>BMI (kg/m²), mean ± SD</td> <td>26.31 ± 4.39</td> </tr> <tr> <td>Caucasian race, n (%)</td> <td>33 (100%)</td> </tr> <tr> <td>Calcium intake (g), median (IQR)</td> <td>400 (250-500)</td> </tr> <tr> <td>Calcium intake (g), mean ± SD</td> <td>401.52 ± 152.32</td> </tr> <tr> <td>Smoking habit, n (%)</td> <td>6 (18.2%)</td> </tr> <tr> <td>Alcohol intake ≥30 g, n (%)</td> <td>0%</td> </tr> <tr> <td>Regular exercise, n (%)</td> <td>19 (57.6%)</td> </tr> <tr> <td>Solar exposure, n (%)</td> <td>19 (57.6%)</td> </tr> <tr> <td>Family history of hip fracture, n (%)</td> <td>4 (12.1%)</td> </tr> <tr> <td>PH traumatic fracture, n (%)</td> <td>10 (30.3%)</td> </tr> <tr> <td>PH fragility fracture, n (%)</td> <td>0 (0%)</td> </tr> <tr> <td>PH stress fractures, n (%)</td> <td>5 (15.2%)</td> </tr> <tr> <td>APH (IU/L), median (IQR)</td> <td>25 (20.5-27.5)</td> </tr> <tr> <td>APH (IU/L), mean ± SD (RN: 46-116 IU/L)</td> <td>25.2 ± 6.53</td> </tr> <tr> <td>PTH (pg/ml), median (IQR)</td> <td>37 (30.5-44)</td> </tr> <tr> <td>PTH (pg/ml), mean ± SD (RN: 10.5-80 pg/ml)</td> <td>44.82 ± 22.41</td> </tr> <tr> <td>Vit. D (ng/ml), median (IQR)</td> <td>19 (13-23.5)</td> </tr> <tr> <td>Vit. D (ng/ml), mean ± SD (RN: 30-100 ng/ml)</td> <td>20 ± 9.75</td> </tr> </tbody> </table> <p>Decrease in cortical thickness (mm) in patients with stress fractures [1.8 (1.77-1.89)] compared to subjects without them [1.94 (1.87-2.03), p=0.03] and compared to those with traumatic fractures [1.97 (1.88-2.04), p=0.03].</p>	Characteristics	TG+ (N=33)	Age (years), median (IQR)	51.01 (37.96-63.02)	Age (years), mean ± SD	50.56 ± 15.08	Female gender, n (%)	21 (63.6%)	Postmenopausal women, n (%)	9 (42.9%)	Men >50 years, n (%)	0 (66.6%)	BMI (kg/m ²), median (IQR)	25.91 (22.89-29.25)	BMI (kg/m ²), mean ± SD	26.31 ± 4.39	Caucasian race, n (%)	33 (100%)	Calcium intake (g), median (IQR)	400 (250-500)	Calcium intake (g), mean ± SD	401.52 ± 152.32	Smoking habit, n (%)	6 (18.2%)	Alcohol intake ≥30 g, n (%)	0%	Regular exercise, n (%)	19 (57.6%)	Solar exposure, n (%)	19 (57.6%)	Family history of hip fracture, n (%)	4 (12.1%)	PH traumatic fracture, n (%)	10 (30.3%)	PH fragility fracture, n (%)	0 (0%)	PH stress fractures, n (%)	5 (15.2%)	APH (IU/L), median (IQR)	25 (20.5-27.5)	APH (IU/L), mean ± SD (RN: 46-116 IU/L)	25.2 ± 6.53	PTH (pg/ml), median (IQR)	37 (30.5-44)	PTH (pg/ml), mean ± SD (RN: 10.5-80 pg/ml)	44.82 ± 22.41	Vit. D (ng/ml), median (IQR)	19 (13-23.5)	Vit. D (ng/ml), mean ± SD (RN: 30-100 ng/ml)	20 ± 9.75	 <p>Spain</p> <p>Tornero C, Coronado M, Humbert L, Navarro-Compán V, García Carazo S, Lancha Hernández C, Balsa A, Aguado Acín P.</p>
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Acromegaly

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>3D DXA Hip Differences in Patients with Acromegaly or Adult Growth Hormone Deficiency.</p> <p>[2021]</p> <p>Available here</p>	<p>67 Subjects</p> <ul style="list-style-type: none"> • 20 Acromegaly • 14 AGHD • 33 Controls 	<p>3D-DXA provided useful information about the characteristics of bone involvement in growth hormone (GH)-related disorders. Patients with AGHD showed distinct involvement of the cortical structure.</p>	 <p>The mean-adjusted 3D-DXA parameters did not differ between acromegaly patients and the controls ($p > 0.05$)</p> <p>Cortical bone impairment (-7.3% to -8.4%; effect size (ES) = 0.78) in AGHD patients ($p < 0.05$).</p> <p>Differences in the cortical bone parameters were more evident when comparing AGHD patients (-8.5% to -16.2%; ES = 1.22 to 1.24) with acromegaly patients ($p < 0.05$).</p>	 <p>Spain</p> <p>Gracia-Marco L, Gonzalez-Salvatierra S, Garcia-Martin A, Ubago-Guisado E, Garcia-Fontana B, Juan Gil-Cosano J, Muñoz-Torres M.</p>
<p>Vertebral Fractures Occur Despite Control of Acromegaly and Are Predicted by Cortical Volumetric Bone Mineral Density.</p> <p>[2021]</p> <p>Available here</p>	<p>70 Acromegaly Subjects</p> <ul style="list-style-type: none"> • 26 Active Acromegaly 	<p>The most sensitive and specific predictor of incident VF was TH cortical vBMD, suggesting that cortical bone is involved in fracture development.</p>	<p>In 13 patients, 9 with controlled disease, VF was observed. A decrease in TBS, sBMD, neck trabecular vBMD, TH, and neck cortical vBMD in VF compared with non-VF subjects was observed ($P < .05$).</p> <p>Multivariate analysis of fracture prediction showed TH cortical vBMD as the best fracture prediction parameter with area under the curve of 0.774.</p> <p>TBS was negatively associated with fasting plasma glucose and glycated hemoglobin (HBA1c) at each time point during the follow-up.</p>	 <p>Slovakia</p> <p>Kužma M, Vaňuga P, Ságová I, Pávai D, Jackuliak P, Killinger Z, Binkley NC, Winzenrieth R, Genant HK, Payer J.</p>

Sport, exercise, muscle & bone

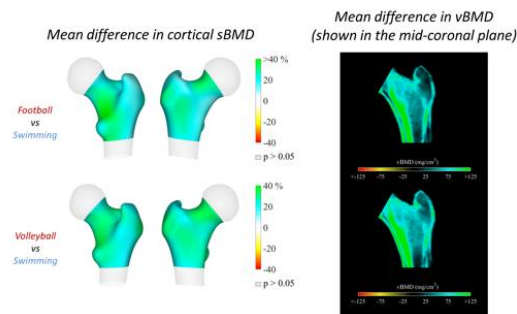

There’s a lot of interest in the field on how non-pharmacological therapies can impact bone health and density and reduce a patient’s chance of fracture. Using 3D-Shaper, clinicians and researchers have been able to fully explore the specific effects that lifestyle changes are having on the bone at a local level (cortical, trabecular and integral bone compartments).

Understanding the Physiological effects of a healthy lifestyle carries great significance, and 3D-Shaper’s technology enables users to *better understand their patients*, thus identifying the best way to manage and treat them.

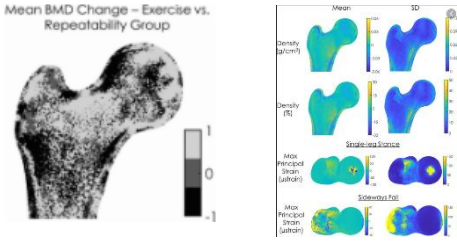

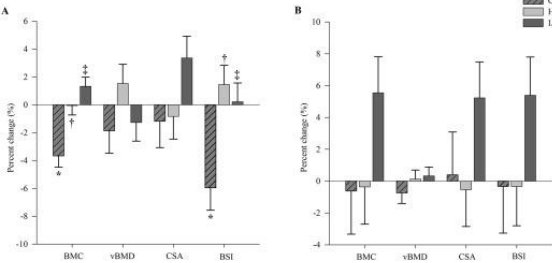

Below are examples of how 3D-Shaper has been used to generate insights into the effect of sport & exercise on bone health and density:

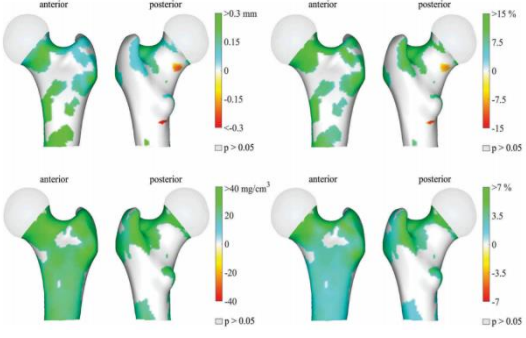

To date, there has been a total of **18** studies across **5** countries:

KEY PUBLICATION

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Femur 3D-DXA assessment in female football players, swimmers and sedentary controls.</p> <p>[2022]</p> <p>Available here</p>	<p>Elite female athletes (from FC Barcelona & Spanish national swimming teams);</p>	<p>3D-DXA modelling could provide insight into bone remodelling in sports field, allowing to evaluate femoral trabecular and cortical strength from standard DXA scans.</p>	 <p>Football (Soccer) players showed 20% higher cortical sBMD and 17% higher trabecular vBMD.</p> <p>3D-DXA modelling revealed statistical differences in cortical thickness and vBMD between athletes engaged in weight-bearing (football) and non-weight bearing (swimming) sports.</p> <p>No differences between the non-weight bearing sport and the sedentary controls.</p>	 <p>Spain</p> <p>Amani A, Bellver M, Del Rio L, Ramon Torrella, J Lizarraga A, Humbert L, Drobnic F.</p>



STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Assessment of femoral neck strength and bone mineral density changes following exercise using 3D-DXA images.</p> <p>[2021]</p> <p>Available here</p>	<p>10 females and 26 males</p>	<p>3D-DXA technology can assess the effect of exercise interventions in large cohorts</p>	 <p>In the repeated images, the total hip vBMD difference was $0.5 \pm 2.5\%$. Element-by-element BMD differences reached $30 \pm 50\%$.</p> <p>The exercise group had a mean bone accrual exceeding repeatability values in the femoral head and cortical regions. The case with the highest vBMD change (6.4%) caused 18% and -7% strength changes under single-leg stance and sideways fall.</p>	 <p>Australia</p> <p>O'Rourke D, Beck B, Harding A, Watson S, Pivonka P, Martelli S.</p>
<p>Effects of Supervised High-Intensity Resistance and Impact Training or Machine-Based Isometric Training on Regional Bone Geometry and Strength in Middle-Aged and Older Men With Low Bone Mass: The LIFTMOR-M Semi-Randomised Controlled Trial.</p> <p>[2020]</p> <p>Available here</p>	<p>93 Men with lower than average aBMD</p>	<p>Findings indicate that supervised HiRIT provides a positive stimulus to cortical bone at the medial FN compared with supervised IAC exercise</p> <p>Both HiRIT and IAC preserve bone strength at the distal tibia and distal radius.</p> <p>Effects may translate into a reduced risk of lower and upper extremity fracture in middle-aged and older men with low bone mass.</p>	 <p>HiRIT improved medial FN cortical thickness compared with CON ($5.6 \pm 1.7\%$ versus $-0.1 \pm 1.9\%$, $p = 0.028$) and IAC ($5.6 \pm 1.7\%$ versus $0.7 \pm 1.7\%$, $p = 0.044$). Distal tibia total BMC, vBMD, area and bone strength index, and trabecular BMC and bone strength index all declined for CON compared with maintenance for both HiRIT and IAC (all $p < 0.05$). HiRIT maintained distal tibia trabecular area compared with a loss in CON ($0.2 \pm 0.5\%$ versus $-1.6 \pm 0.5\%$, $p = 0.013$)</p>	 <p>Australia</p> <p>Harding A, Weeks B, Lambert C, Watson S, Weis L, Beck B.</p>

STUDY	COHORT	OUTCOMES	RESULTS & VISUALIZATIONS	COUNTRY & AUTHORS
<p>Cortical and trabecular bone analysis of professional dancers using 3D-DXA: a case-control study.</p> <p>[2018]</p> <p>Available here</p>	<p>80 Subjects</p> <ul style="list-style-type: none"> 40 Professional dancers 40 Controls 	<p>Elite ballet dancing does not appear to have a deleterious effect on bone health.</p> <p>Professional ballet dancers have higher BMD for both cortical and trabecular bone compartments.</p>	 <p>Compared to non-exercising participants, dancers exhibited significantly higher volumetric density for integral, cortical and trabecular bone, and thicker cortex at the femur.</p>	 <p>Portugal</p> <p>Freitas L, Amorim T, Humbert L, Fonollá R, Flouris AD, Metsios GS, Jamurtas AZ, Koutedakis Y.</p>

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Association with Fracture

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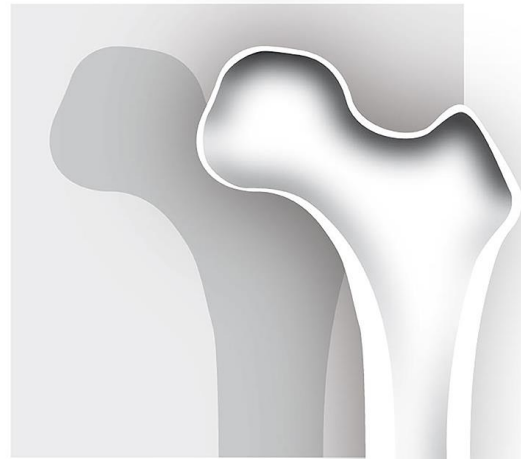
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