

Supplementary Material

Material i. Proposed REMS interpretation template.

Examination: Radiofrequency Echographic Multi-Spectrometry (REMS) scan*

Indication:

Patient information:

History of Surgical Instrumentation (spine implants or hip implants):

Comparison of current REMS scan with a previous REMS scan on the same patient:

REMS scans were performed employing a dedicated echographic device (EchoStation / EchoS Plus, Echolight Spa, Lecce, Italy), equipped with a convex transducer operating at the nominal frequency of 3.5 MHz and used as recommended by the manufacturer.

Three anatomical sites were used for measurements: Lumbar spine, left hip, and right hip.

These areas were prepared for the examination as below.

Lumbar Spine Evaluation:

The patient was positioned supine. Ultrasound gel was applied in the midline cephalad and caudal to the umbilicus for the examination. As there were no noted abnormal reactions the scan proceeded. Lumbar scans were performed by placing the echographic transducer in a cephalo-caudal trans-abdominal position. L3 was localized with the umbilicus as the surface anatomical landmark. The transducer was then repositioned in the cephalad to caudal direction to confirm visualization of L1-L4. The position of L1 is located caudal to the sternum. The scan began at L1 and progressed to L4 according to a dedicated software-guide. After the echographic scan was completed, the acquired data was automatically analyzed by the software. Firstly, the quality of the B-Mode acquisition was assessed for diagnostic purposes. Secondly, the bone mineral density (BMD) and Fragility Score (FS), the former being a representation of bone quantity and the latter bone quality, were respectively automatically calculated.

Left/Right Hip Evaluation:

The patient was maintained in a supine position. Ultrasound gel was applied for examination(s) and no noted abnormal reactions were noted. The ultrasonographic examination of the hip(s) was

performed by placing the echographic transducer parallel to the head-neck axis of the femur, to visualize the typical proximal femur profile (Head-neck-trochanter). After the echographic scan was completed, the acquired data was analyzed and determined to be of acceptable quality for diagnostic purposes. The BMD and FS values were calculated by the software.

After completion of the studies, ultrasound gel was removed from the examined areas.

Findings:

(Figure 2)

Lumbar spine (L1-L4):

Bone Mineral Density *** g/cm², T-score ***, Z-score ***

Compared to the previous bone mineral density taken on ***, the patient has an increase/decrease from the previous of ***%

Fragility score: ***/100

Five-year risk of Major Osteoporosis Fracture: ***/1000

Left femoral neck:

Bone Mineral Density *** g/cm², T-score ***, Z-score ***

Compared to the previous bone mineral density taken on ***, the patient has an increase/decrease from the previous of ***%

Fragility score: ***/100

5-year risk of Hip Osteoporosis Fracture: ***/1000

Left total hip

Bone Mineral Density *** g/cm², T-score ***, Z-score ***

Right femoral neck:

Bone Mineral Density *** g/cm², T-score ***, Z-score ***

Compared to the previous bone mineral density taken on ***, the patient has an increase/decrease from the previous of ***%

Fragility score: ***/100

5-year risk of Hip Osteoporosis Fracture: ***/1000

Right total hip:

Bone Mineral Density *** g/cm², T-score ***, Z-score ***

IMPRESSION:

- 1. Normal/osteopenia/osteoporosis if T-scores are used,
- 2. Normal or low BMD if Z-scores are used.
- **3.** Fragility Score for the lumbar spine is ____, indicating the bone quality is normal/decreased/low
- **4.** 5-year risk for major osteoporosis fractures is based on a Matrix that combines the T-Score and Fragility Score at the lumbar spine. The 5-year risk for hip fracture is *** 0/00 or ***%.
- **5.** The Fragility Score of the hip is _____indicating the bone quality is normal/decreased/low.
- **6.** 5-year risk for hip fractures is based on a Matrix that combines the T-Score and Fragility Score for the femoral neck. The 5-year risk for hip fracture is *** 0/00 or ***%.

Definitions:

The T-score compares the patient's bone mineral density to the peak bone mass of young, medically normal adults. The lower (i.e., more negative) the number, the greater the loss of bone.

The Z-score compares this patient's bone density to others of the same age and biological sex.

Intra-operator repeatability (precision) is: 0.38% for the lumbar spine and 0.32% for the femoral neck; inter-operator repeatability is 0.54% for the lumbar spine and 0.48% for the femoral neck.

The Least Significant Change (LSC): 1.05% for the lumbar spine and 0.88% for the femoral neck.

WORLD HEALTH ORGANIZATION T-SCORE CRITERIA FOR BONE ASSESSMENT:

T-score: +2.0 to -1.0 S.D. = Normal.

T-score: -1.0 to -2.4 S.D. = Osteopenia.

T-Score: -2.5 S.D. and lower = Osteoporosis.

Fragility score (FS): FS evaluates the microstructural quality of the bone independently from BMD and is an non-dimensional parameter, ranging from 0 to 100 (with increasing values indicating lower quality of bone architecture). The FS is obtained by comparing the spectra of the acquired ultrasound signals with the spectral reference models obtained from patients who did, or did not, develop an osteoporotic fracture.

FS classification: Normal/Decreased/Low

Combining Matrix of REMS BMD and Fragility Score

		REMS T-SCORE classification		
		NORMAL	OSTEOPENIA	OSTEOPOROSIS
REMS FRAGILITY SCORE Classification	NORMAL	R1	R3	R5
	DECREASED	R2	R4	R6
	LOW	R3	R5	R7

Total Fracture Risk at 5 years (‰)

Risk class	Risk of major osteoporotic fracture per 1000 subjects per 5 years		
R1	≤ 5		
R2	[5-10]		
R3	[10-20]		
R4	[20-35]		
R5	[35-60]		
R6	[60-100]		
R7	> 100		

REMS performed by technologist/provider:

I personally reviewed the examination and the obtained diagnostic report. I have reviewed and noted my interpretation.

Signature:

Date:

*Of note, the graphic on page 1 of the REMS report generated by the scanner is for illustrative purposes only and does not represent real-time imaging.