

ΑΝΑΒΟΛΙΚΗ ΘΕΡΑΠΕΙΑ

ΚΩΝ/ΝΟΣ ΔΙΟΝ. ΣΤΑΘΟΠΟΥΛΟΣ M.D., Ph.D
ΟΡΘΟΠΑΙΔΙΚΟΣ ΧΕΙΡΟΥΡΓΟΣ
ΕΠΙΣΤΗΜΟΝΙΚΟΣ ΣΥΝΕΡΓΑΤΗΣ ΙΑΤΡΙΚΗΣ ΣΧΟΛΗΣ ΕΚΠΑ
ΠΜΣ “ΜΕΤΑΒΟΛΙΚΑ ΝΟΣΗΜΑΤΑ ΟΣΤΩΝ”







ΔΗΛΩΣΗ ΣΥΜΦΕΡΟΝΤΩΝ -DISCLOSURES

(LECTURE FEES/CONSULTING FEES/ADVISORY BOARDS)

- AMGEN HELLAS
- BIANEΞ
- ITF HELLAS

Modeling-Based Bone Formation After 2 Months of Romosozumab Treatment: Results From the FRAME Clinical Trial

Erik F Eriksen,^{1,2}  Roland Chapurlat,³  Rogely Waite Boyce,⁴ Yifei Shi,⁴ Jacques P Brown,⁵ Stéphane Horlait,⁶ Donald Betah,⁴ Cesar Libanati,⁷  and Pascale Chavassieux³ 

Journal of Bone and Mineral Research, Vol. 37, No. 1, January 2022, pp 36–40.

Επιστημονικό Πρόγραμμα

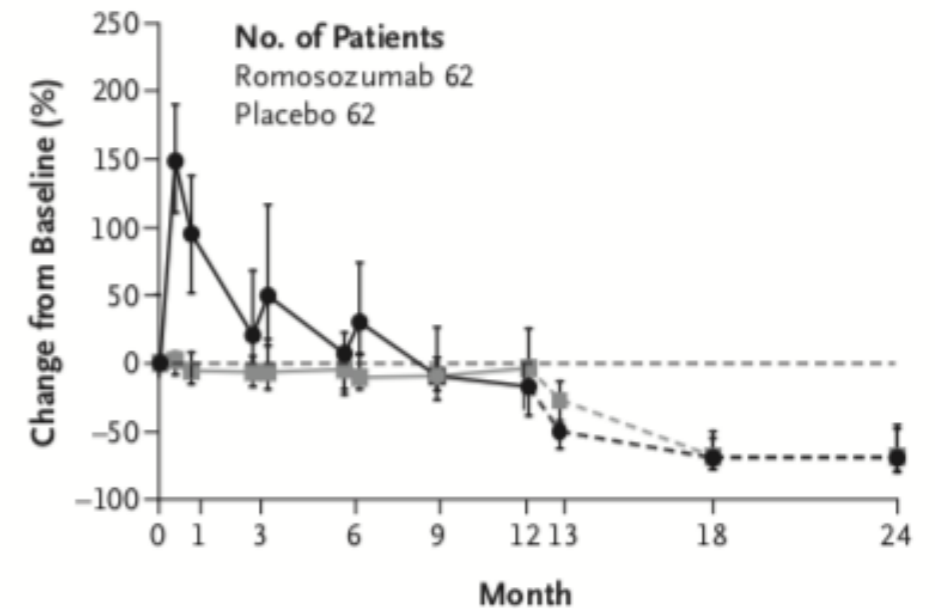
2^η ΗΜΕΡΑ | Σάββατο | 19 Μαρτίου 2022



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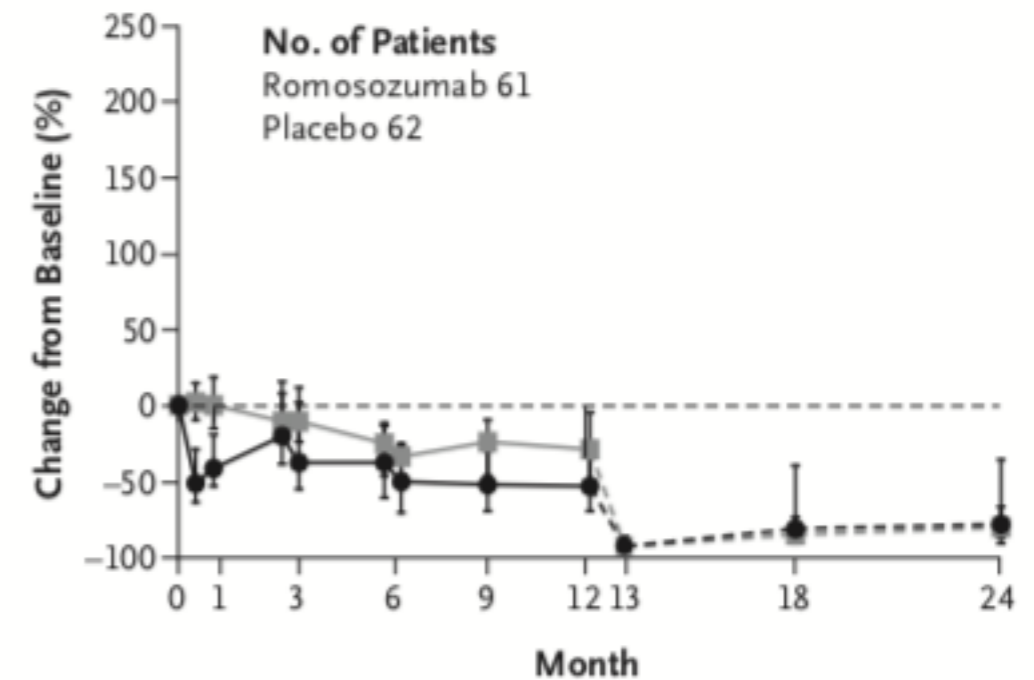
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D Change in P1NP Level



**ΔΙΠΛΗ ΔΡΑΣΗ ROMOSUZUMAB:
ΑΥΞΗΣΗ (ΑΡΧΙΚΑ) ΟΣΤΙΚΗΣ ΠΑΡΑΓΩΓΗΣ
+
ΕΛΑΤΤΩΣΗ ΟΣΤΙΚΗΣ ΑΠΟΡΡΟΦΗΣΗΣ
(ΑΠΟ ΤΗΝ ΠΡΩΤΗ ΔΟΣΗ
ΚΑΙ ΣΕ ΟΛΗ ΤΗ ΔΙΑΡΚΕΙΑ ΤΗΣ ΘΕΡΑΠΕΙΑΣ 1 ΕΤΟΥΣ)**

E Change in β -CTX Level



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ΜΕ ΠΟΙΑ ΚΥΤΤΑΡΙΚΗ ΔΙΕΡΓΑΣΙΑ ΤΟ ROMOSUZUMAB ΑΥΞΑΝΕΙ ΤΗΝ ΟΣΤΙΚΗ ΠΑΡΑΓΩΓΗ? ΟΣΤΙΚΗ ΚΑΤΑΣΚΕΥΗ VS ΟΣΤΙΚΗ ΑΝΑΚΑΤΑΣΚΕΥΗ (BONE MODELING vs BONE REMODELING)

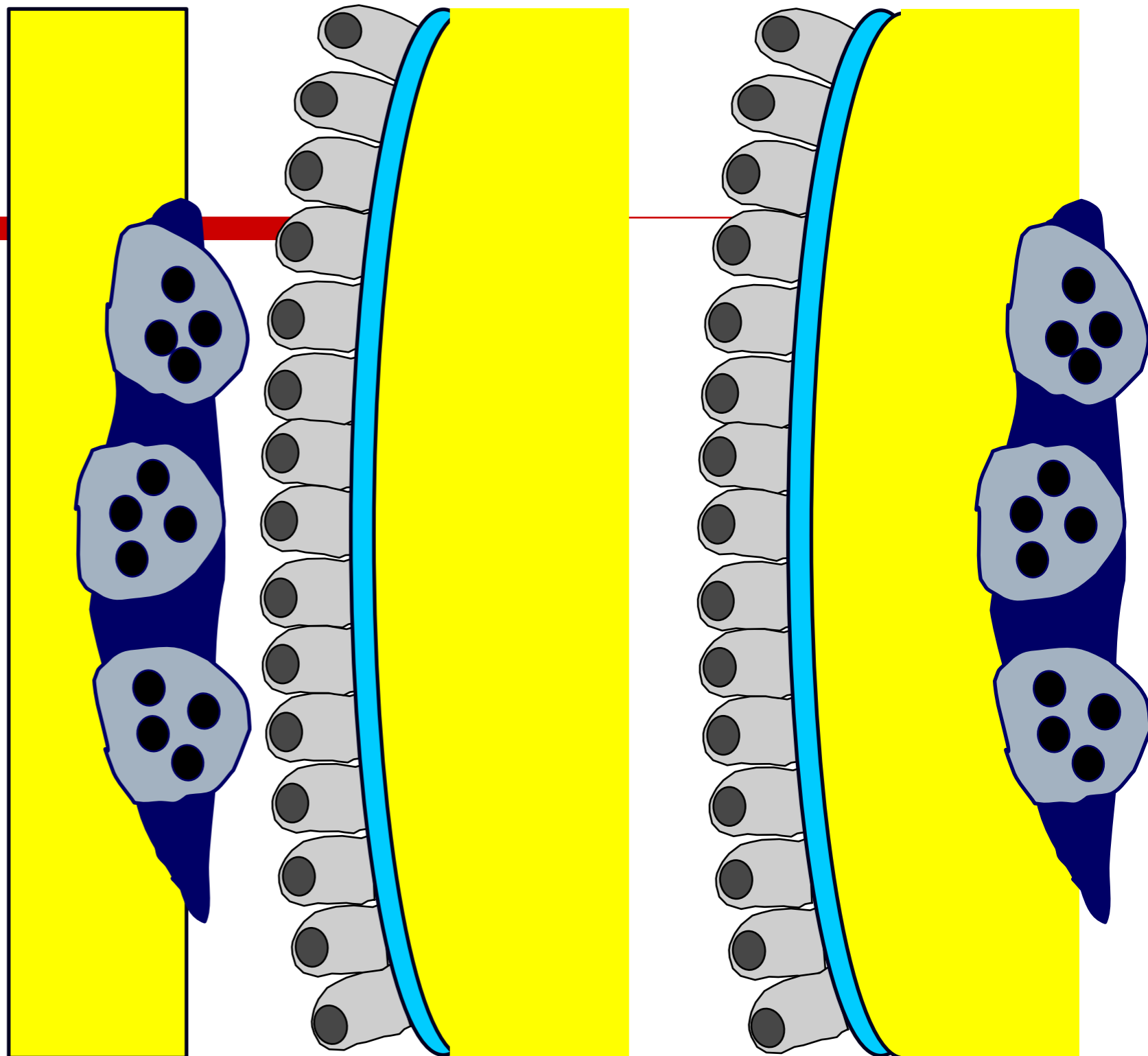
Επιστημονικό Πρόγραμμα

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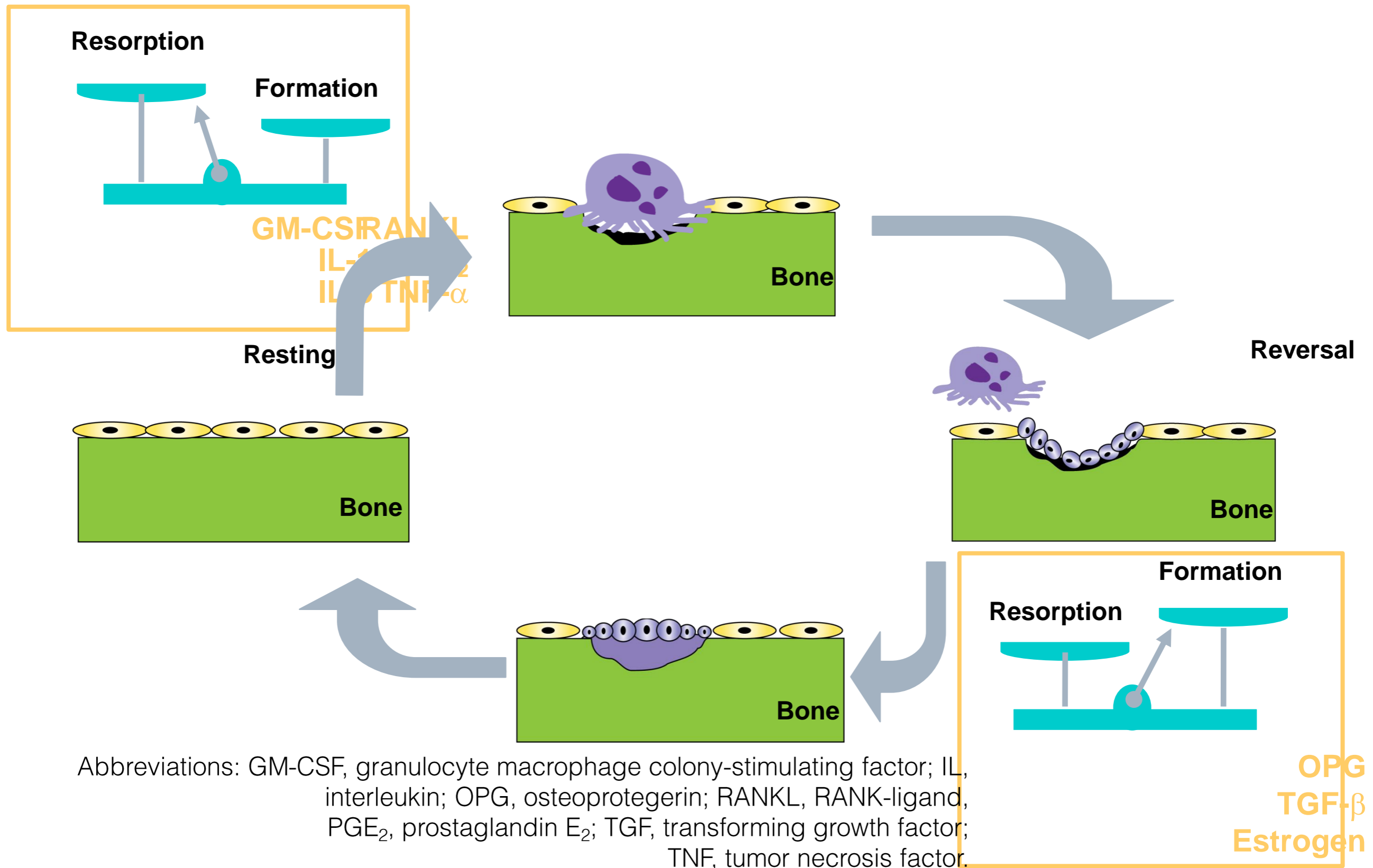


BONE MODELING-ΟΣΤΙΚΗ ΚΑΤΑΣΚΕΥΗ

ΑΛΛΑΓΕΣ ΣΤΗ ΜΑΖΑ,
ΓΕΩΜΕΤΡΙΑ ΚΑΙ
ΑΡΧΙΤΕΚΤΟΝΙΚΗ ΤΩΝ
ΟΣΤΩΝ, ΠΟΥ
ΠΡΟΚΑΛΟΥΝΤΑΙ ΑΠΟ
ΔΡΑΣΗ ΟΣΤΕΟΚΛΑΣΤΩΝ
ΚΑΙ ΟΣΤΕΟΒΛΑΣΤΩΝ ΣΕ
ΔΙΑΦΟΡΕΤΙΚΕΣ ΘΕΣΕΙΣ
ΚΑΘΕ ΦΟΡΑ



ΟΣΤΙΚΗ ΑΝΑΚΑΤΑΣΚΕΥΗ (BONE REMODELING)



Modeling-Based Bone Formation After 2 Months of Romosozumab Treatment: Results From the FRAME Clinical Trial

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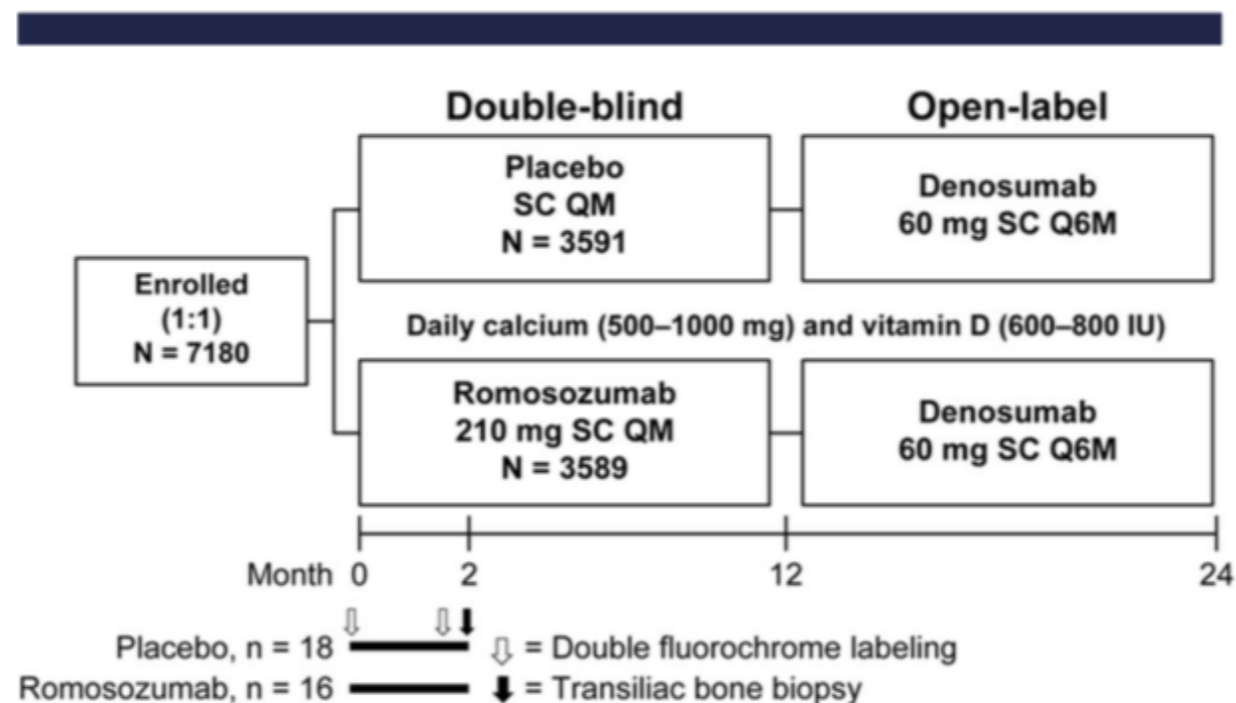
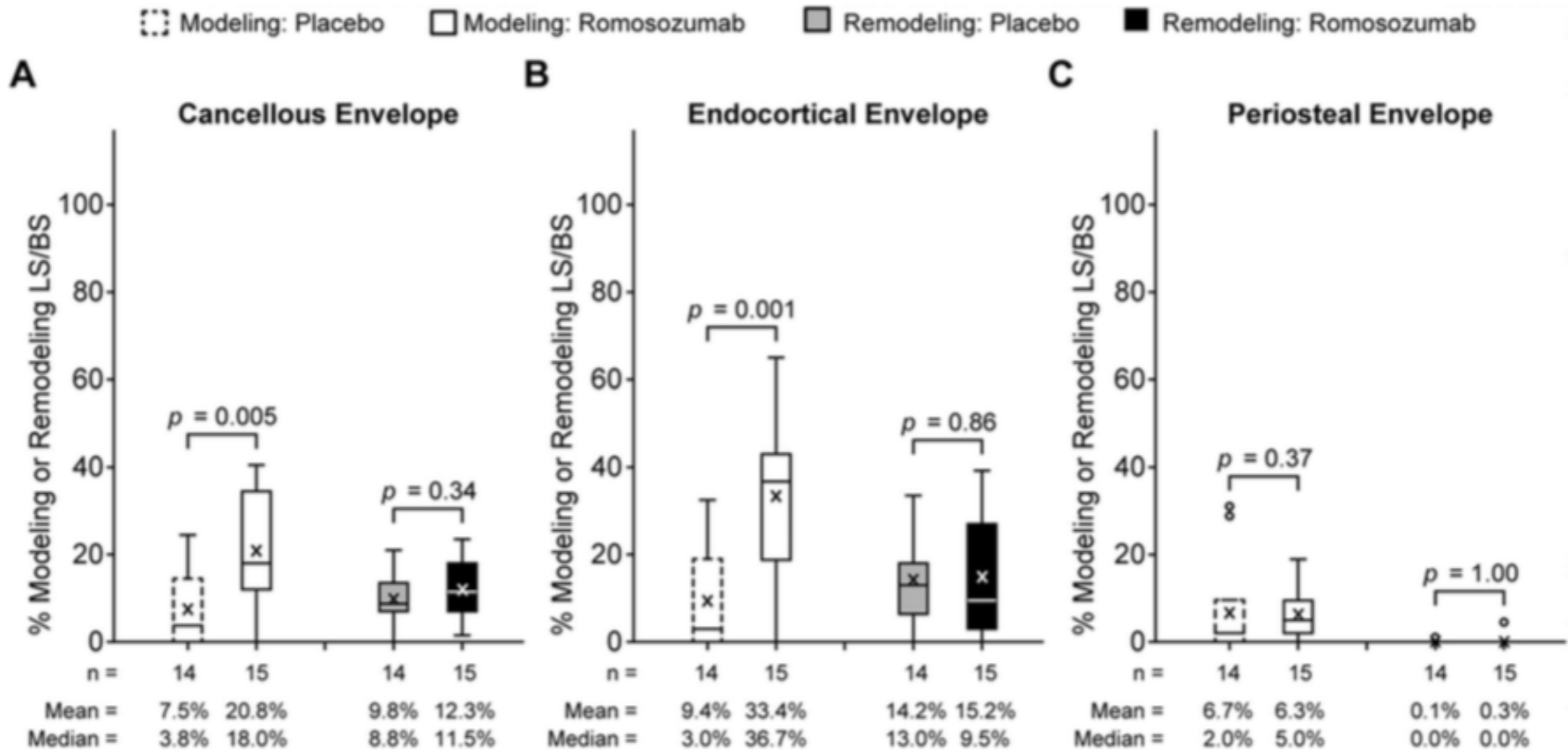


Fig 1. FRAME bone biopsy substudy design. Patients in the bone biopsy substudy underwent transiliac bone biopsies at month 2 ($n = 34$) and received quadruple labeling (double labeling at baseline and before biopsy). Twenty-nine biopsies of 34 obtained biopsies were suitable for histomorphometric analysis (placebo, $n = 14$; romosozumab, $n = 15$). Five biopsies of the 34 obtained biopsies were excluded due to reasons including crush artifact or insufficient cancellous bone surface. Q6M = every 6 months; QM = every month.

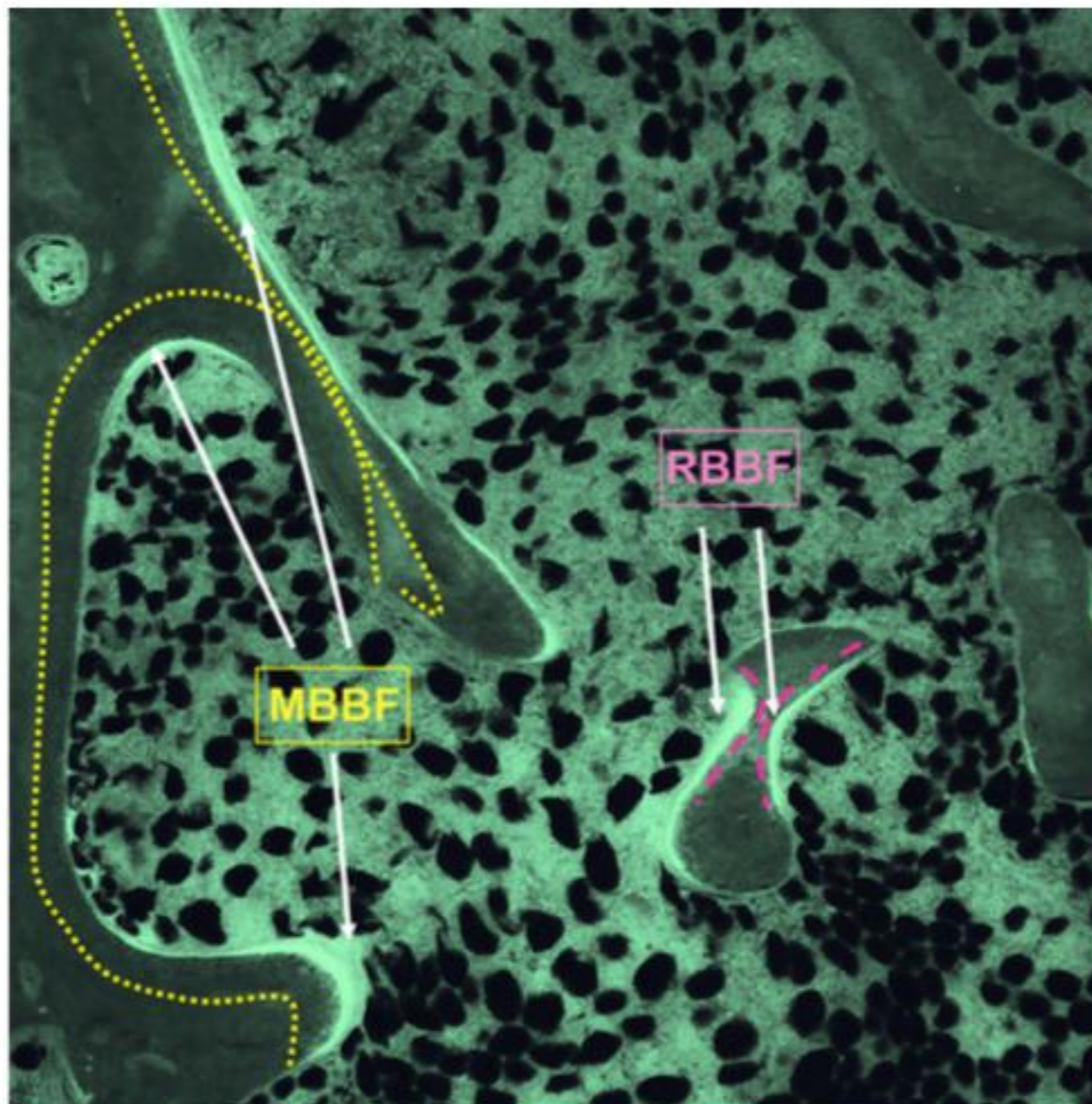
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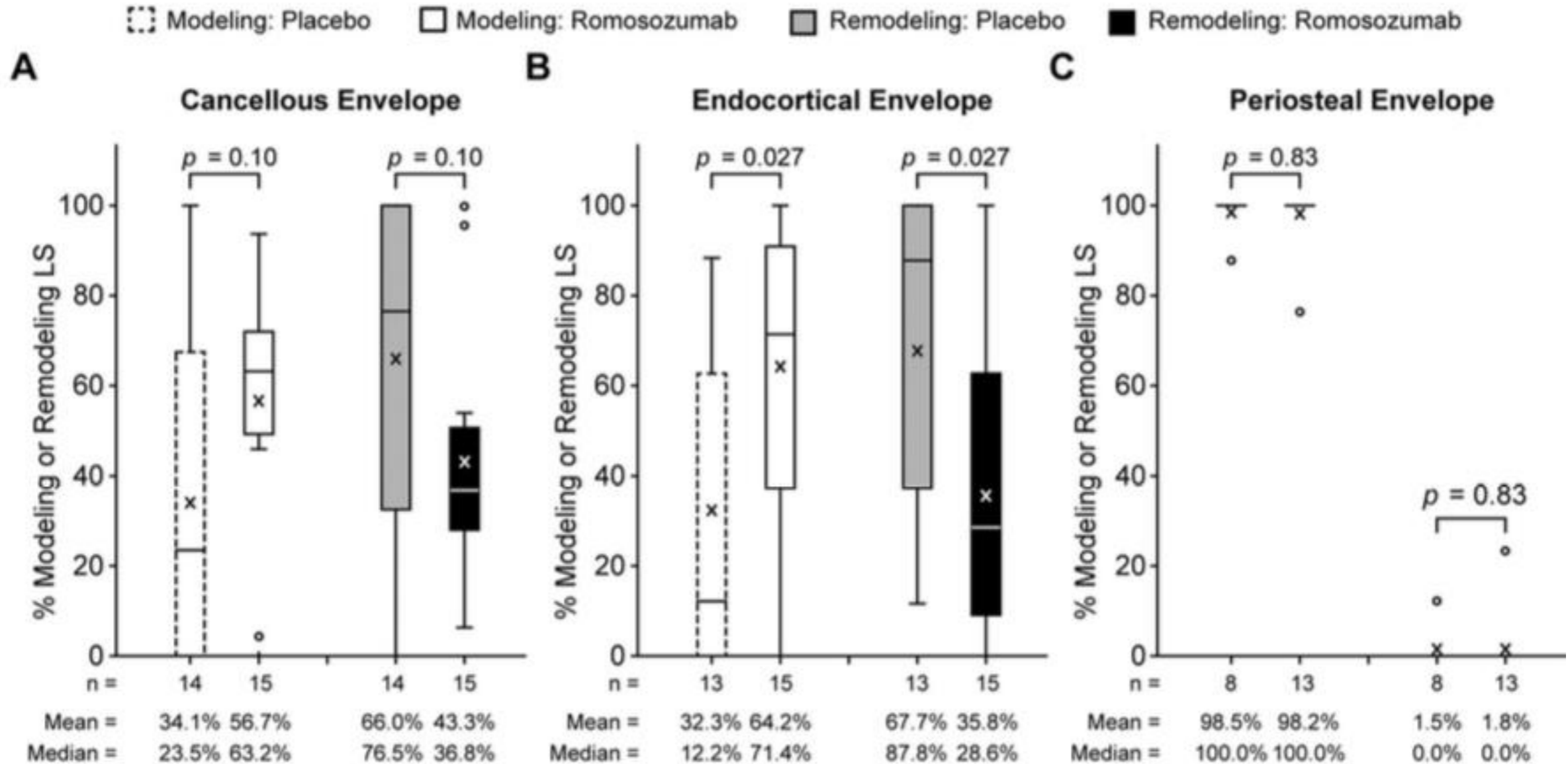
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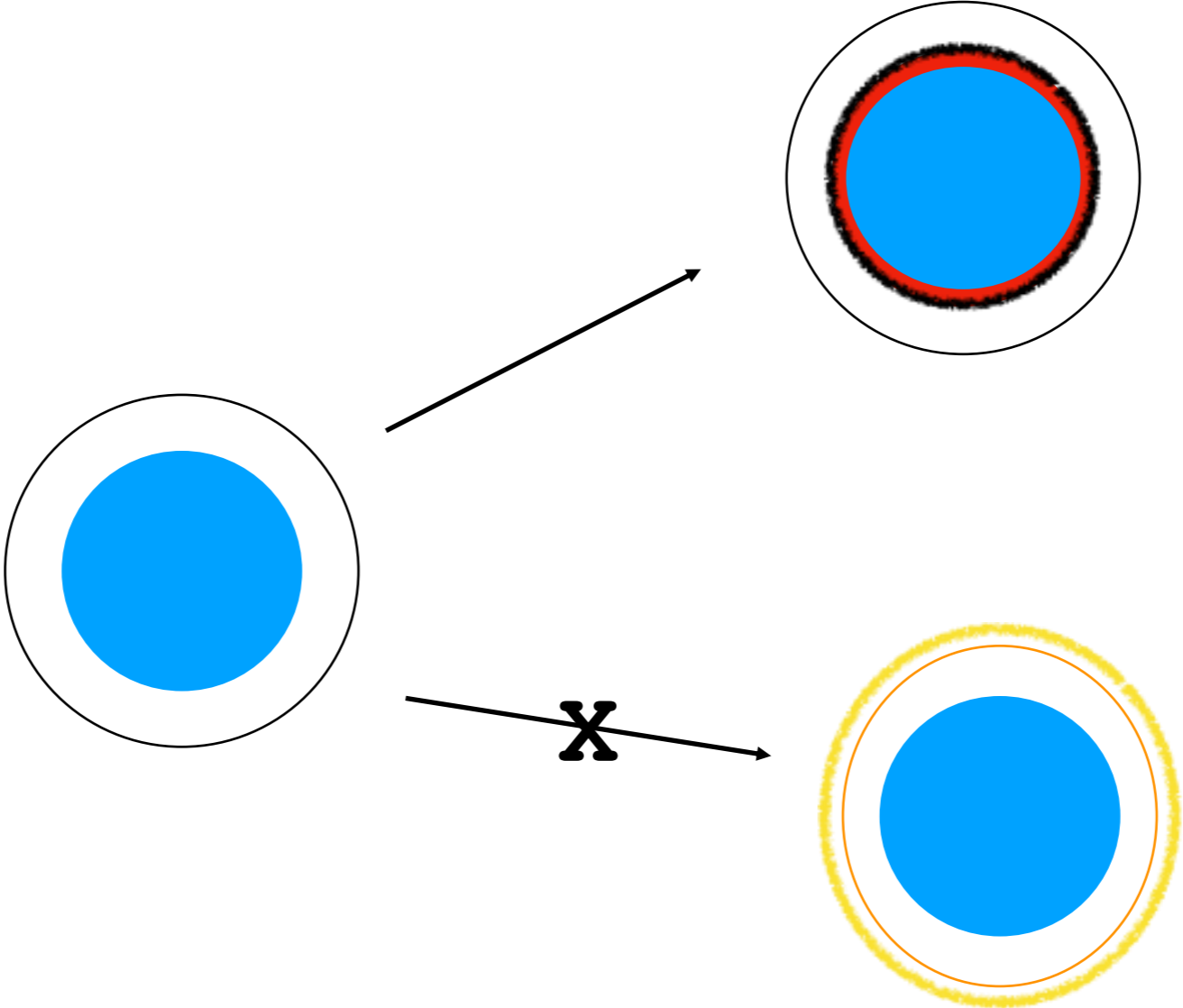


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ΕΝΔΟΣΤΙΚΗ vs ΠΕΡΙΟΣΤΙΚΗ ΕΝΑΠΟΘΕΣΗ



Skeletal responses to romosozumab after 12 months of denosumab

Michael R. McClung,^{1,2}  Michael A. Bolognese,³ Jacques P. Brown,⁴ Jean-Yves Reginster,^{5,6} Bente L. Langdahl,⁷  Yifei Shi,⁸ Jen Timoshanko,⁹ Cesar Libanati,⁹  Arkadi Chines,⁸ and Mary K. Oates⁸




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Επιστημονικό Πρόγραμμα

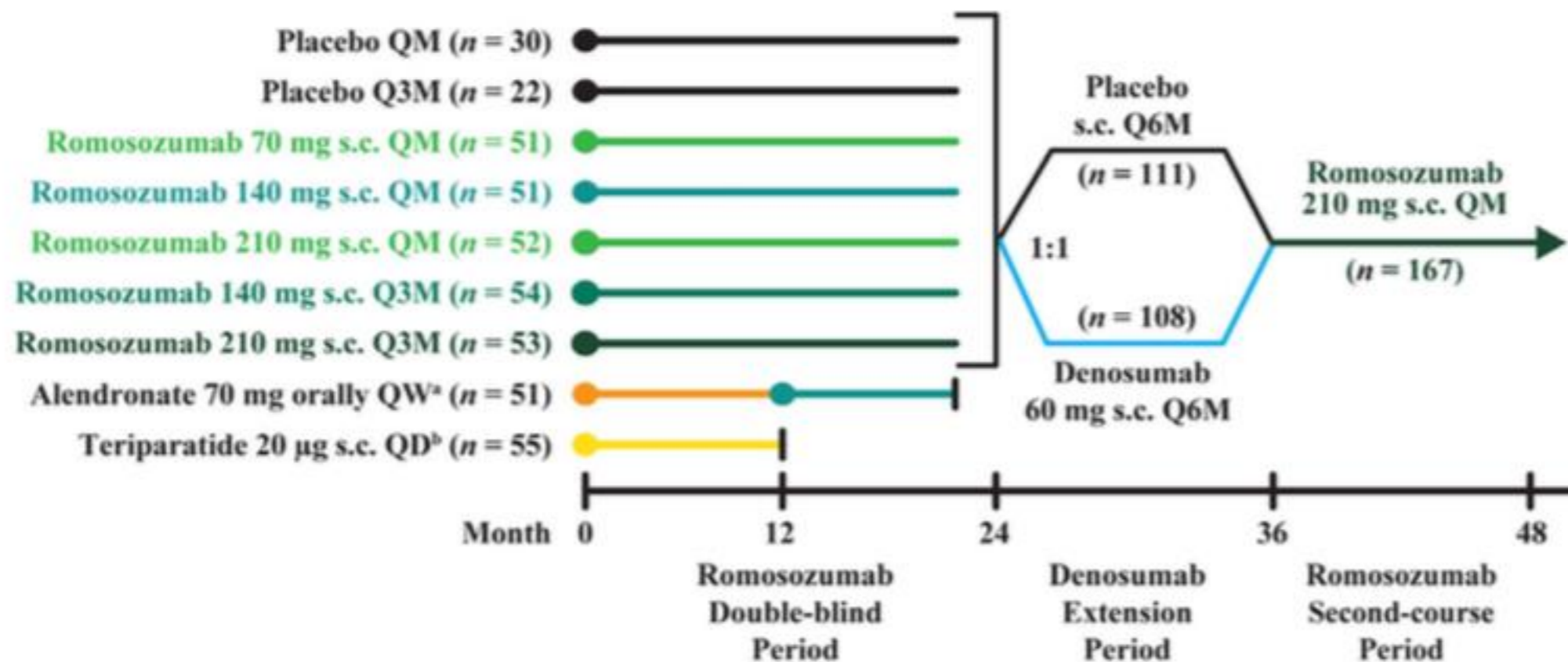
2^η ΗΜΕΡΑ | Σάββατο | 19 Μαρτίου 2022






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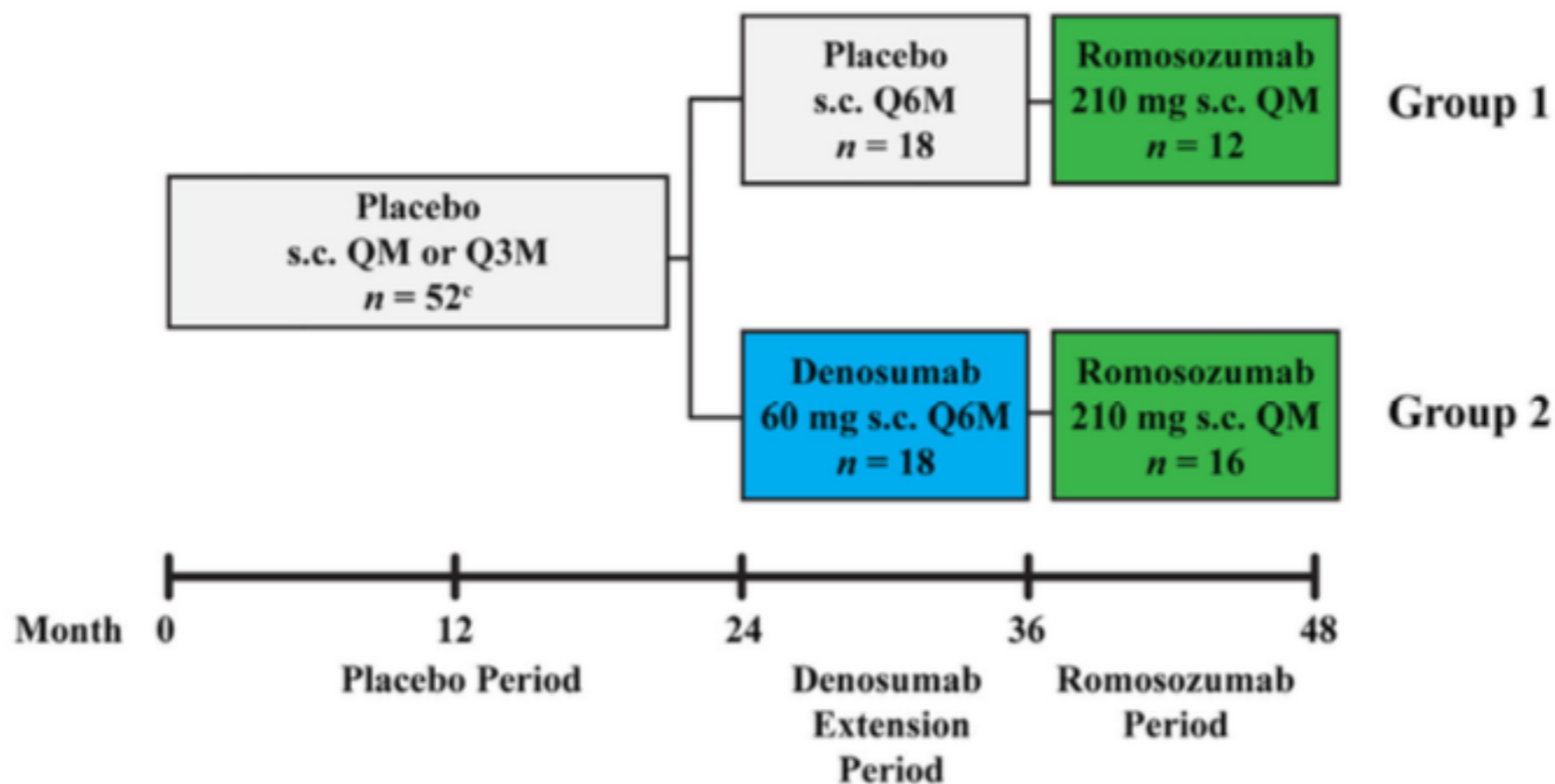
A. Phase 2 study and extensions (N = 419)



Skeletal responses to romosozumab after 12 months of denosumab

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B. Treatment-naïve patients ($n = 52$)



Skeletal responses to romosozumab after 12 months of denosumab




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Table 1. Baseline characteristics of the subset of women who were randomized to placebo for 24 months, denosumab or placebo for 12 months, and then received romosozumab for 12 months

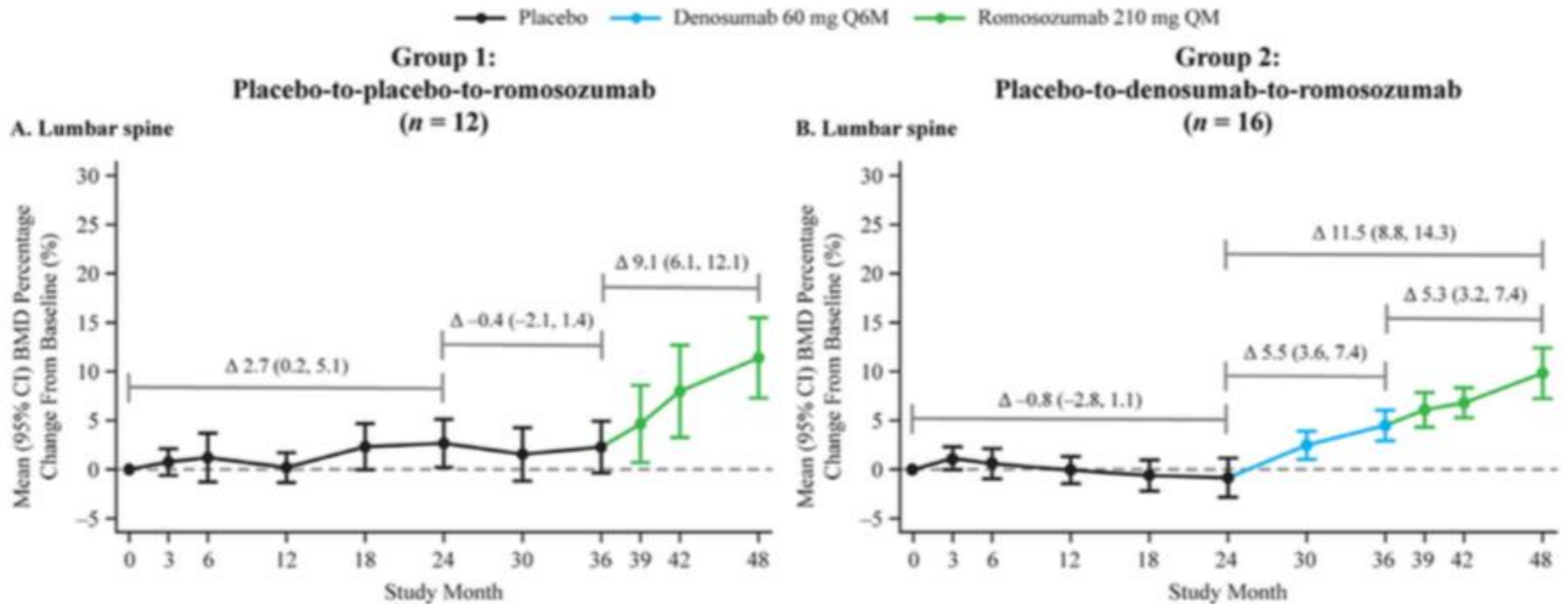
	Month 0 baseline		Month 24 baseline	
	Group 1 (n = 12)	Group 2 (n = 16)	Group 1 (n = 12)	Group 2 (n = 16)
Treatment from month 0–24	Placebo	Placebo	Placebo	Placebo
Treatment from month 24–36	Placebo	Denosumab 60 mg Q6M	Placebo	Denosumab 60 mg Q6M
Treatment from month 36–48	Romosozumab 210 mg QM	Romosozumab 210 mg QM	Romosozumab 210 mg QM	Romosozumab 210 mg QM
Age (years), mean ± SD	68.2 ± 6.5	63.8 ± 4.1	70.7 ± 6.4	66.1 ± 4.1
Years since menopause, mean ± SD	20.3 ± 9.8	16.9 ± 6.4	22.3 ± 9.8	18.9 ± 6.4
BMD T-score, mean ± SD				
Lumbar spine	−2.3 ± 0.6	−2.4 ± 0.4	−2.1 ± 0.7	−2.4 ± 0.4
Total hip	−1.3 ± 0.7	−1.1 ± 0.6	−1.5 ± 0.7	−1.2 ± 0.6
Femoral neck	−1.8 ± 0.6	−1.6 ± 0.5	−1.9 ± 0.6	−1.7 ± 0.4
P1NP (µg/L), median (Q1, Q3)	37.0 (33.8, 41.0)	52.4 (44.9, 59.2)	38.2 (30.0, 55.6)	50.0 (40.0, 56.0)
β-CTX (ng/L), median (Q1, Q3)	372.0 (306.0, 415.5)	503.5 (392.5, 635.5)	534.0 (433.5, 692.0)	626.0 (466.0, 833.0)

Notes: Reference ranges for the study are 9.7–92.5 µg/L for P1NP and 16.0–430.0 ng/L for β-CTX. n = number of women enrolled from month 36 to month 48.




Abbreviations: β-CTX, β-isomer of the C-terminal telopeptide of type I collagen; BMD, bone mineral density; P1NP, procollagen type I N-terminal propeptide; Q1, first quartile; Q3, third quartile; Q6M, every 6 months; QM, monthly; SD, standard deviation.

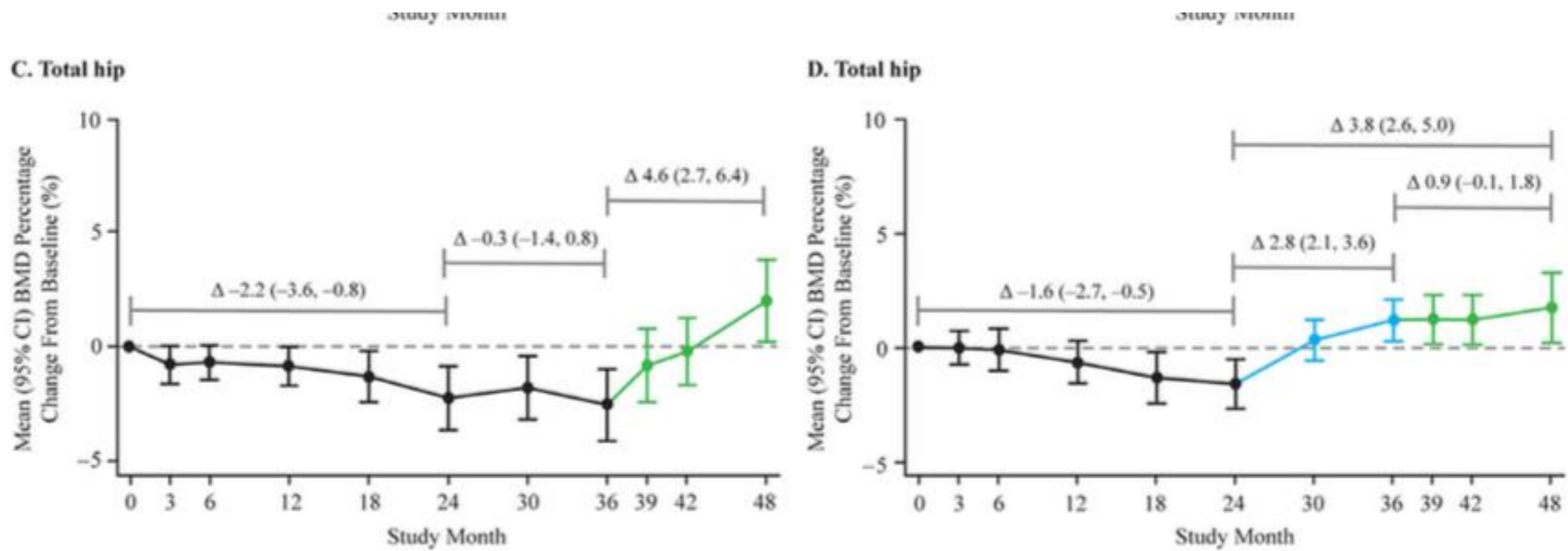
Skeletal responses to romosozumab after 12 months of denosumab

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Table 2. Mean BMD percentage changes from baseline at the lumbar spine, total hip, and femoral neck

	Group 1 (n = 12)	Group 2 (n = 16)
Treatment from month 0–24	Placebo	Placebo
Treatment from month 24–36	Placebo	Denosumab 60 mg Q6M
Treatment from month 36–48	Romosozumab 210 mg QM	Romosozumab 210 mg QM
BMD (% change), mean (95% CI)		
Lumbar spine		
Month 0–24	2.7 (0.2, 5.1)	−0.8 (−2.8, 1.1)
Month 24–36	−0.4 (−2.1, 1.4)	5.5 (3.6, 7.4)
Month 36–48	9.1 (6.1, 12.1)	5.3 (3.2, 7.4)
Month 24–48	8.9 (5.5, 12.4)	11.5 (8.8, 14.3)
Total hip		
Month 0–24	−2.2 (−3.6, −0.8)	−1.6 (−2.7, −0.5)
Month 24–36	−0.3 (−1.4, 0.8)	2.8 (2.1, 3.6)
Month 36–48	4.6 (2.7, 6.4)	0.9 (−0.1, 1.8)
Month 24–48	4.7 (2.7, 6.7)	3.8 (2.6, 5.0)
Femoral neck		
Month 0–24	−1.3 (−2.7, 0.1)	−1.8 (−3.3, −0.4)
Month 24–36	−0.7 (−1.7, 0.3)	2.3 (1.0, 3.6)
Month 36–48	3.9 (1.7, 6.1)	1.0 (−1.0, 2.9)
Month 24–48	3.1 (0.8, 5.3)	3.2 (1.4, 5.0)

Note: n = number of women enrolled from month 36 to month 48.

Abbreviations: BMD, bone mineral density; CI, confidence interval; Q6M, every 6 months; QM, monthly.

Skeletal responses to romosozumab after 12 months of denosumab




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Table 3. Proportion of women who experienced BMD percentage decrease from baseline >3% at the lumbar spine, total hip, and femoral neck

	Group 1 (n = 12)	Group 2 (n = 16)
Treatment from month 0–24	Placebo	Placebo
Treatment from month 24–36	Placebo	Denosumab 60 mg Q6M
Treatment from month 36–48	Romosozumab 210 mg QM, n2/n1 (%)	Romosozumab 210 mg QM, n2/n1 (%)
Lumbar spine		
Month 0–24	0/12 (0)	7/16 (43.8)
Month 24–36	1/12 (8.3)	0/16 (0)
Month 36–48	0/11 (0)	0/13 (0)
Month 24–48	0/10 (0)	0/13 (0)
Total hip		
Month 0–24	5/12 (41.7)	4/16 (25.0)
Month 24–36	0/12 (0)	0/16 (0)
Month 36–48	0/11 (0)	0/13 (0)
Month 24–48	0/10 (0)	0/13 (0)
Femoral neck		
Month 0–24	3/12 (25.0)	5/16 (31.3)
Month 24–36	1/12 (8.3)	0/16 (0)
Month 36–48	0/11 (0)	2/13 (15.4)
Month 24–48	0/10 (0)	0/13 (0)

Optimizing Sequential and Combined Anabolic and Antiresorptive Osteoporosis Therapy

Benjamin Z Leder^{1,2}

¹Harvard Medical School, Boston MA, USA

²Endocrine Unit, Massachusetts General Hospital, Boston MA, USA

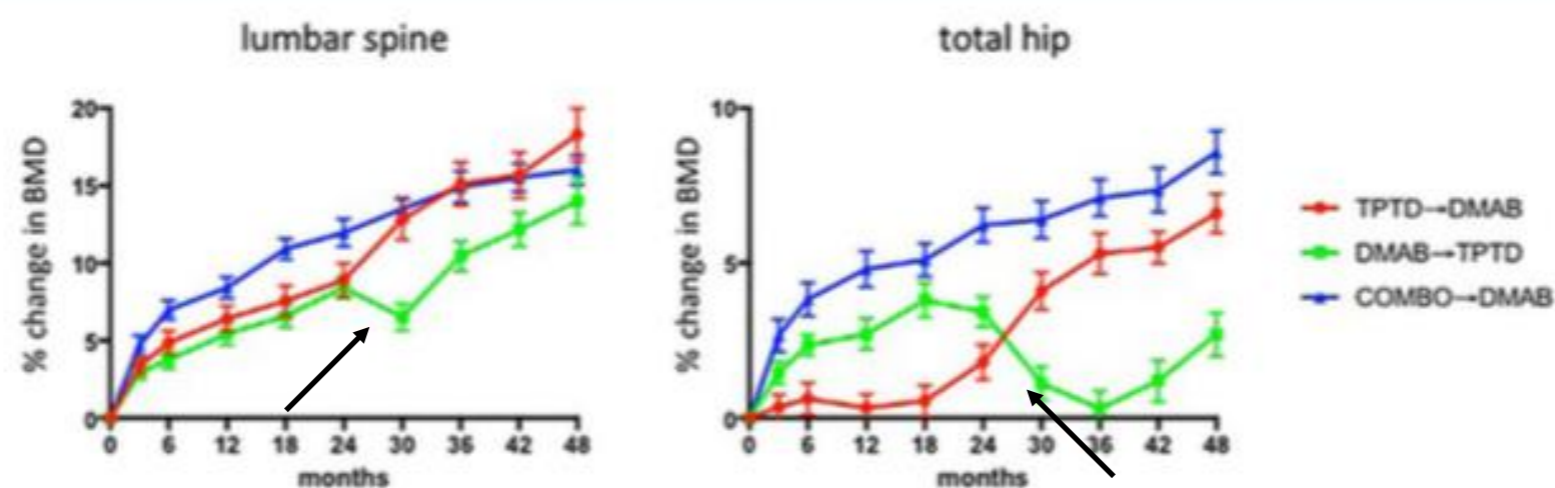



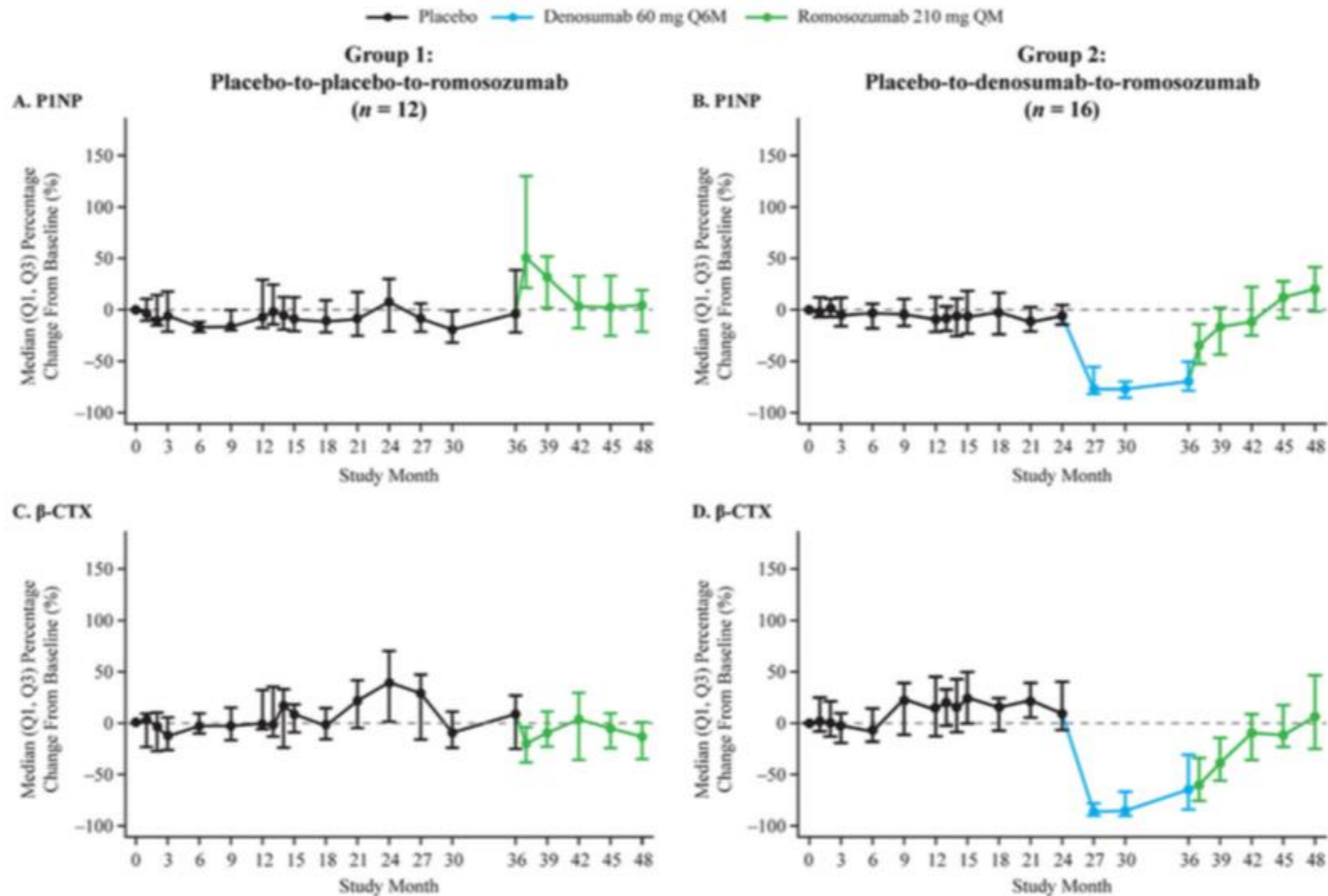





Fig. 1. Change in lumbar spine and total hip BMD in osteoporotic women who received 2 years of teriparatide followed by 2 years of denosumab (red circles), 2 years of denosumab followed by 2 years of teriparatide (green squares), and 2 years of both drugs followed by 2 years of denosumab (blue triangles). All groups differ significantly at the hip, but not the spine, at month 48. (Adapted from Leder and colleagues.⁽⁴³⁾)

Skeletal responses to romosozumab after 12 months of denosumab

Michael R. McClung,^{1,2}  Michael A. Bolognese,³ Jacques P. Brown,⁴ Jean-Yves Reginster,^{5,6} Bente L. Langdahl,⁷  Yifei Shi,⁸ Jen Timoshanko,⁹ Cesar Libanati,⁹  Arkadi Chines,⁸ and Mary K. Oates⁸



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Interpreting the BMD and BTM responses in women transitioning from denosumab to any other therapy is complicated by the dynamic changes in bone remodeling known to occur in the several months following denosumab discontinuation.^(20,21) The BMD response during the 12 months of romosozumab after denosumab in our study is, at least in relative terms, greater than is apparent because a significant decrease in bone density would have been expected upon stopping denosumab without further therapy.^(20,21)

ΜΕΙΟΝΕΚΤΗΜΑΤΑ ΜΕΛΕΤΗΣ:
Post-hoc analysis
ΜΙΚΡΟΣ ΑΡΙΘΜΟΣ ΑΣΘΕΝΩΝ
ΜΙΚΡΗ ΔΙΑΡΚΕΙΑ ΛΗΨΗΣ Dmab



Article

Cardiovascular Safety Profile of Romosozumab: A Pharmacovigilance Analysis of the US Food and Drug Administration Adverse Event Reporting System (FAERS)

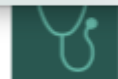
Annika Vestergaard Kvist ^{1,†}, Junaid Faruque ^{2,†} , Enriqueta Vallejo-Yagüe ¹ , Stefan Weiler ^{1,3}, Elizabeth M. Winter ⁴  and Andrea M. Burden ^{1,*} 

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Επιστημονικό Πρόγραμμα

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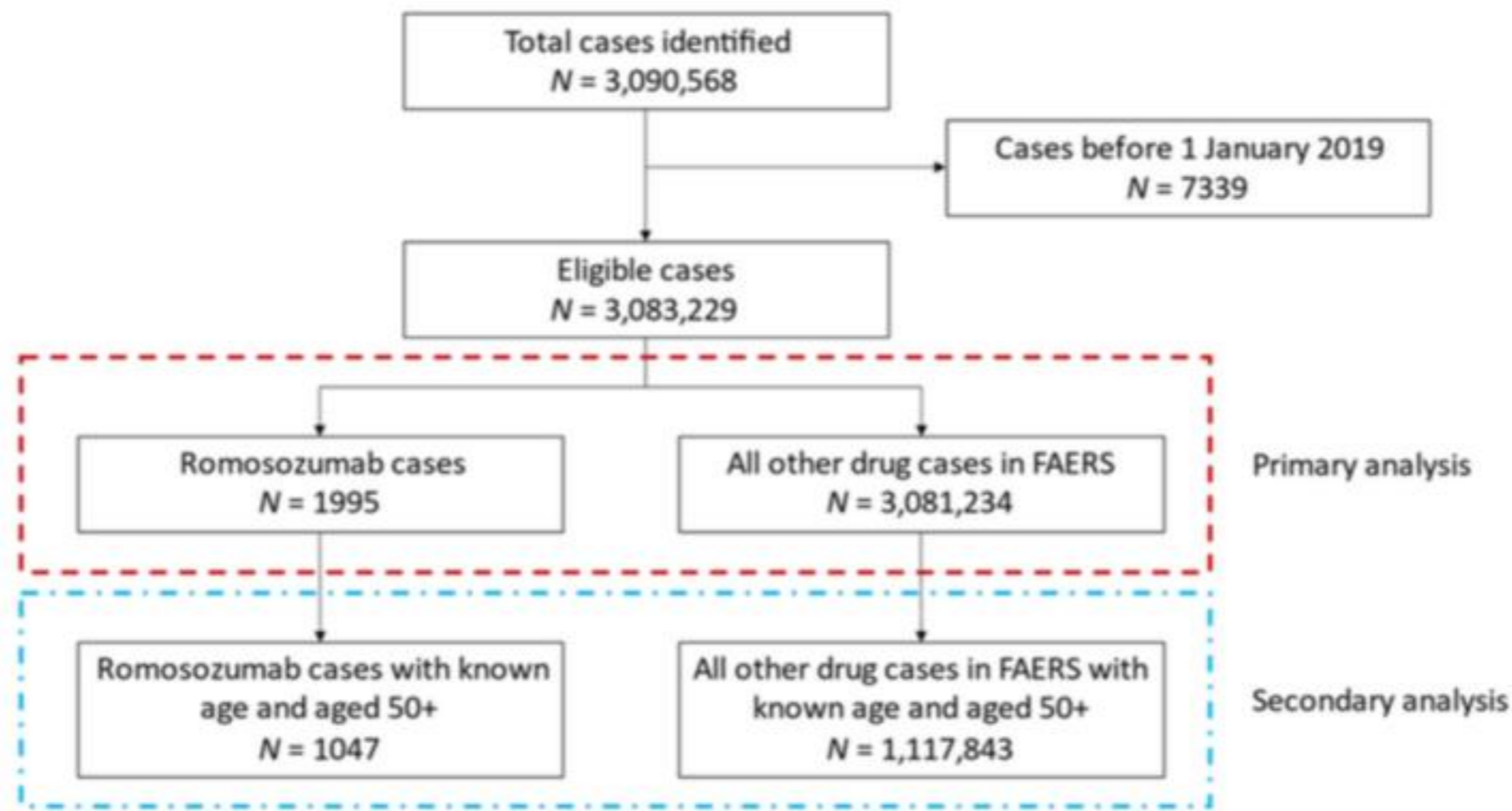


Figure 1. Study flow diagram for included cases identified from quarterly files in the US Food and Drug Administration Adverse Event Reporting System (FAERS) between 1 January 2019 and 31 December 2020.

Article

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Table 1. Demographic characteristics of individual case safety reports with romosozumab, overall (N = 1995), and stratified by region of report (the United States, N = 787) and Japan (N = 1188).

	Total	United States	Japan
	1995	787 (39.4%)	1188 (59.5%)
Sex			
Female	1518 (76.1%)	833 (70.1%) †	16 (80.0%)
Male	177 (8.9%)	154 (13.0%) †	<5
Unknown	300 (15.0%)	201 (16.9%)	<5
Age			
Mean (SD)	77.0 (10.2)	71.7 (8.5)	80.2 (9.5) †
18–59	46 (2.3%)	29 (3.7%)	16 (1.4%) †
60–69	175 (16.6%)	117 (14.9%)	55 (4.6%) †
70–79	385 (36.4%)	167 (21.2%)	211 (17.8%)
80+	451 (42.7%)	70 (8.9%)	380 (32.0%) †
Unknown age	938 (47.0%)	404 (51.3%)	526 (44.3%) †
Seriousness Criteria			
Death	176 (8.8%)	18 (2.3%)	158 (13.3%) †
Hospitalized or Required Intervention	660 (33.1%)	67 (8.5%)	589 (49.6%) †
Life Threatening	48 (2.4%)	6 (0.8%)	41 (3.5%) †
Disabled	22 (1.1%)	6 (0.8%)	16 (1.3%)
Outcomes of Interest			
Major Cardiovascular Event	206 (10.3%)	41 (5.2%)	164 (13.8%) †
Myocardial Infarction	42 (2.1%)	13 (1.7%)	28 (2.4%)
Stroke	84 (4.2%)	27 (3.4%)	57 (4.8%)
Cardiovascular Death	86 (4.3%)	<5	83 (7.0%) †
Other Cardiovascular Event	58 (2.9%)	16 (2.0%)	42 (3.5%)
General cardiac events	16 (0.8%)	6 (0.8%)	10 (0.8%)
Bleeding	19 (1.0%)	–	19 (1.6%)
Thrombosis	23 (1.2%)	10 (1.3%)	13 (1.1%)
Other reported cardiovascular drugs			
Anticoagulants	38 (1.9%)	9 (1.1%)	29 (2.4%)
Antiplatelets	60 (3.0%)	12 (1.5%)	47 (4.0%) †
ACE inhibitors	14 (0.7%)	11 (1.4%)	<5
Angiotensin receptor blockers	65 (3.3%)	<5	61 (5.1%)
Beta-blockers	47 (2.4%)	14 (1.8%)	33 (2.8%)
Calcium channel blockers	99 (5.0%)	8 (1.0%)	91 (7.7%) †

Article
Cardiovascular Safety Profile of Romosozumab: A Pharmacovigilance Analysis of the US Food and Drug Administration Adverse Event Reporting System (FAERS)

Annika Vestergaard Kvist ^{1,†}, Junaid Faruque ^{2,†}, Enriqueta Vallejo-Yagüe ¹, Stefan Weiler ^{1,3}, Elizabeth M. Winter ⁴ and Andrea M. Burden ^{1,*}

Table 2. Demographic characteristics of case reports with romosozumab (N = 1995), stratified by cardiovascular events.

	Non-Cardiovascular	MACE	Other Cardiovascular	Any Cardiovascular *
	1740	206	58	255
Sex				
Female	1323 (76.0%)	159 (77.2%) †	43 (74.1%)	195 (76.5%)
Male	143 (8.2%)	30 (14.6%) †	5 (8.6%)	34 (13.3%)
Unknown	274 (15.7%)	17 (8.3%) †	10 (17.2%)	26 (10.2%)
Age				
Mean (SD)	76.4 (9.9)	81.2 (9.5) †	79.0 (7.3)	81.1 (9.9)
18–59	41 (2.3%)	5 (2.4%)	–	5 (2.0%)
60–69	165 (9.5%)	6 (2.9%) †	4 (6.9%)	10 (3.9%)
70–79	324 (18.6%)	53 (25.7%) †	12 (20.7%)	61 (23.9%)
80+	335 (19.3%)	98 (47.6%) †	20 (34.5%)	116 (45.5%)
Unknown age	875 (50.3%)	44 (21.4%) †	22 (37.9%)	63 (24.7%)
Region of reporting				
United States	731 (42.0%)	41 (19.9%) †	16 (27.6%)	56 (22.0%)
Japan	990 (56.9%)	164 (79.6%) †	42 (72.4%)	198 (77.6%)
Other	19 (1.1%)	<5	–	<5
Seriousness				
Death	117 (6.7%)	54 (26.2%) †	7 (12.1%)	59 (23.1%)
Hospitalized or Required Intervention	526 (30.2%)	117 (56.8%) †	21 (36.2%)	134 (52.5%)
Life Threatening	19 (1.1%)	24 (11.7%) †	6 (10.3%)	29 (11.4%)
Disabled	10 (0.6%)	12 (5.8%) †	–	12 (4.7%)
Other co-reported cardiovascular drugs				
Anticoagulants	21 (1.2%)	13 (6.3%) †	4 (6.9%)	17 (6.7%)
Antiplatelets	34 (2.0%)	22 (10.7%) †	8 (13.8%)	26 (10.2%)
ACE inhibitors	9 (0.5%)	<5	<5	5 (2.0%)
Angiotensin receptor blockers	40 (2.3%)	22 (10.7%) †	5 (8.6%)	25 (9.8%)
Beta-blockers	25 (1.4%)	20 (9.7%) †	<5	22 (8.6%)
Calcium channel blockers	60 (3.4%)	34 (16.5%) †	6 (10.3%)	39 (15.3%)

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Table 3.

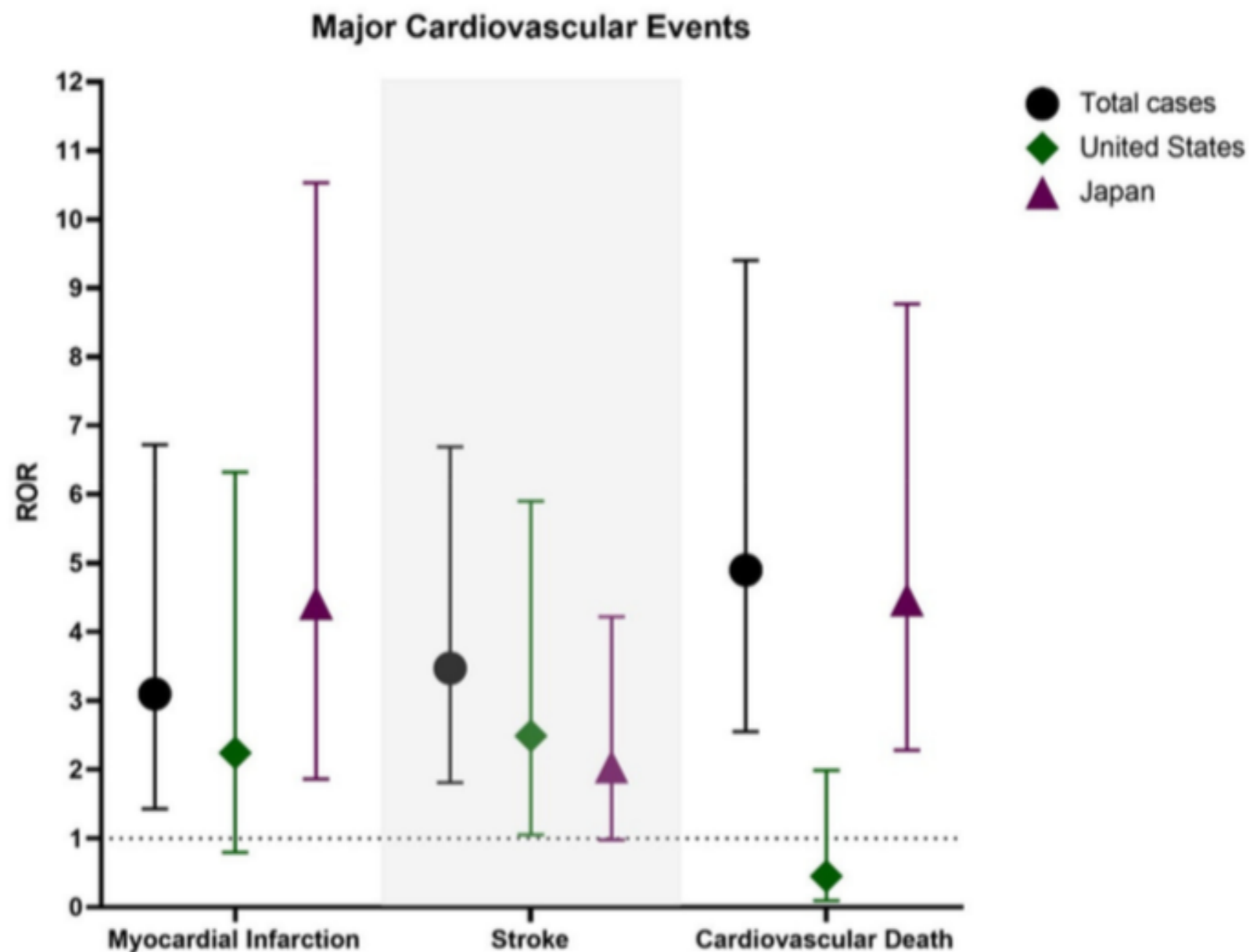
Table 3. Disproportionality analysis for the outcomes of interest, comparing events with romosozumab to events with all other drugs in the Food and Drug Administration Adverse Event Reporting System (FAERS) between 01 January 2019 and 31 December 2020.

	Romosozumab		All other Drugs		ROR (95% CI)	IC	IC ₀₂₅
	Event	No Event	Event	No Event			
MACE	206	1789	84,723	2,996,511	4.07 (2.39–6.93)	1.90	1.67
Myocardial infarction	42	1953	21,253	3,059,981	3.10 (1.43–6.72)	1.57	1.06
Stroke	84	1911	38,489	3,042,745	3.47 (1.81–6.69)	1.73	1.37
Cardiovascular death	86	1909	28,070	3,053,164	4.90 (2.55–9.40)	2.21	1.85
Other cardiovascular event	58	1937	56,239	3,024,995	1.61 (0.79–3.29)	0.66	0.23
General cardiac events	16	1979	16,880	3,064,354	1.47 (0.55–3.92)	0.53	−0.31
Bleeding	19	1976	20,699	3,060,535	1.42 (0.55–3.64)	0.49	−0.28
Thrombosis	23	1972	19,753	3,061,481	1.81 (0.74–4.44)	0.82	0.12

Abbreviations: ROR (reporting odds ratio), CI (confidence interval), IC (information component), IC₀₂₅ (lower bound credibility interval for the IC). The outcomes of interest were identified using single or multiple preferred terms (PT) according to the Medical Dictionary for Regulatory Activities (MedDRA). A complete list can be found in the Supplementary Materials Table S1.

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Annika Vestergaard Kvist ^{1,†}, Junaid Faruque ^{2,†}, Enriqueta Vallejo-Yagüe ¹, Stefan Weiler ^{1,3},
Elizabeth M. Winter ⁴ and Andrea M. Burden ^{1,*}

ROMOSOZUMAB





ΠΕΡΙΟΡΙΣΜΟΙ ΜΕΛΕΤΗΣ

1) ΠΙΘΑΝΕΣ ΠΡΟΚΑΤΕΙΛΗΜΜΕΝΕΣ ΑΝΑΦΟΡΕΣ (potential reporting bias) ΛΟΓΩ ΔΙΑΦΟΡΩΝ ΣΤΙΣ ΠΡΑΚΤΙΚΕΣ ΑΝΑΦΟΡΑΣ ΑΝΕΠΙΘΥΜΗΤΩΝ ΣΥΜΒΑΝΤΩΝ ΣΤΙΣ ΔΙΑΦΟΡΕΣ ΧΩΡΕΣ ΤΟΥ ΚΟΣΜΟΥ. ΠΧ ΟΤΑΝ ΕΝΑ ΦΑΡΜΑΚΟ ΠΑΙΡΝΕΙ ΠΡΟΕΙΔΟΠΟΙΗΣΗ ΑΣΦΑΛΕΙΑΣ, ΠΙΘΑΝΟΝ ΕΠΑΓΓΕΛΜΑΤΙΕΣ ΥΓΕΙΑΣ ΝΑ ΥΠΕΡ-ΑΝΑΦΕΡΟΥΝ ΣΧΕΤΙΚΕΣ ΑΝΕΠΙΘΥΜΗΤΕΣ ΕΝΕΡΓΕΙΕΣ ΛΟΓΩ ΤΗΣ ΠΡΟΕΙΔΟΠΟΙΗΣΗΣ ΑΣΦΑΛΕΙΑΣ. ΥΠΟ-ΑΝΑΦΟΡΑ ΜΠΟΡΕΙ ΕΠΙΣΗΣ ΝΑ ΣΥΜΒΕΙ ΜΕ ΤΟ ΣΚΕΠΤΙΚΟ ΟΤΙ ΟΙ ΣΥΓΚΕΚΡΙΜΜΕΝΕΣ ΑΝΕΠΙΘΥΜΗΤΕΣ ΕΝΕΡΓΕΙΕΣ ΗΤΑΝ ΓΝΩΣΤΟ ΟΤΙ ΘΑ ΜΠΟΡΟΥΣΑΝ ΝΑ ΣΥΜΒΟΥΝ. ΔΕΝ ΕΙΝΑΙ ΓΝΩΣΤΟ ΣΤΟΥΣ ΣΥΓΓΡΑΦΕΙΣ ΣΕ ΤΙ ΠΟΣΟΣΤΟ ΘΑ ΜΠΟΡΟΥΣΑΝ ΑΥΤΑ ΝΑ ΣΥΜΒΟΥΝ ΣΤΗ ΜΕΛΕΤΗ. Η ΔΙΑΦΟΡΑ ΣΤΙΣ ΑΝΑΦΟΡΕΣ ΜΕΤΑΞΥ ΙΑΠΩΝΙΑΣ-ΗΠΑ ΘΑ ΜΠΟΡΟΥΣΑΝ ΝΑ ΟΦΕΙΛΟΝΤΑΙ ΣΕ ΤΕΤΟΙΕΣ ΠΕΡΙΠΤΩΣΕΙΣ.

2) ΑΙΤΙΩΔΗΣ ΣΥΝΑΦΕΙΑ ΜΕΤΑΞΥ ΛΗΨΗΣ ΦΑΡΜΑΚΟΥ ΚΑΙ ΚΑΡΔΙΑΓΓΕΙΑΚΩΝ ΣΥΜΒΑΝΤΩΝ ΔΕΝ ΜΠΟΡΕΙ ΝΑ ΤΕΚΜΗΡΙΩΘΕΙ ΣΤΗΝ ΠΑΡΟΥΣΑ ΜΕΛΕΤΗ, ΚΑΘΩΣ ΟΙ ΣΥΓΓΡΑΦΕΙΣ ΔΕΝ ΔΙΑΘΕΤΟΥΝ ΠΛΗΡΗ ΣΤΟΙΧΕΙΑ ΓΙΑ ΤΟ ΙΣΤΟΡΙΚΟ ΑΣΘΕΝΩΝ Ή ΤΗ ΧΡΟΝΙΚΗ ΣΤΙΓΜΗ ΤΗΣ ΑΝΑΦΕΡΟΜΕΝΗΣ ΑΝΕΠΙΘΥΜΗΤΗΣ ΕΝΕΡΓΕΙΑΣ

3) ΑΔΥΝΑΜΙΑ ΑΙΤΙΟΛΟΓΙΚΗΣ ΣΥΣΧΕΤΙΣΗΣ ΣΕ ΣΥΣΧΕΣΗ ΜΕ ΠΙΘΑΝΟΥΣ ΑΛΛΟΥΣ ΠΑΡΑΓΟΝΤΕΣ

Romozozumab Enhances Vertebral Bone Structure in Women With Low Bone Density

Kenneth ES Poole,¹  Graham M Treece,² Rose A Pearson,² Andrew H Gee,² Michael A Bolognese,³  Jacques P Brown,⁴ Stefan Goemaere,⁵ Andreas Grauer,⁶ David A Hanley,⁷ Carlos Mautalen,⁸ Chris Recknor,⁹ Yu-Ching Yang,⁶ Maria Rojas,⁶ Cesar Libanati,¹⁰  and Tristan Whitmarsh¹¹ 





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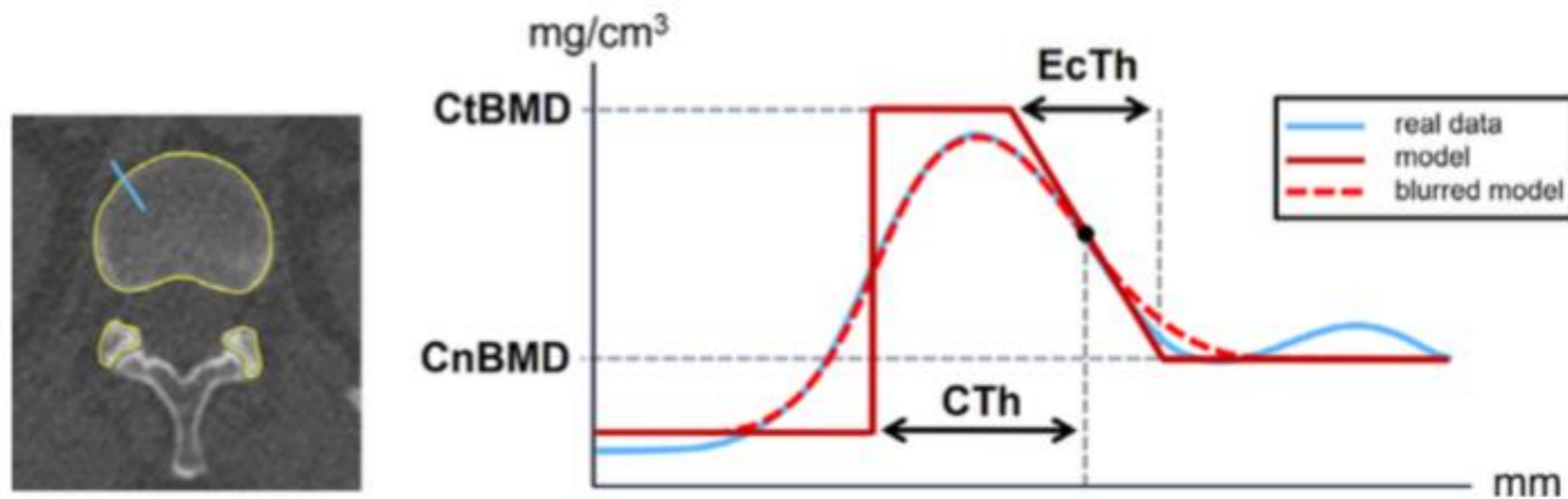






Fig. 1. A schematic visualization of the cortical measurement process. Left: A CT slice with the surface mesh shown in yellow and the sampling line in blue. Right: The registration of the blurred cortical model, which is described by the various cortical parameters, onto the real data.

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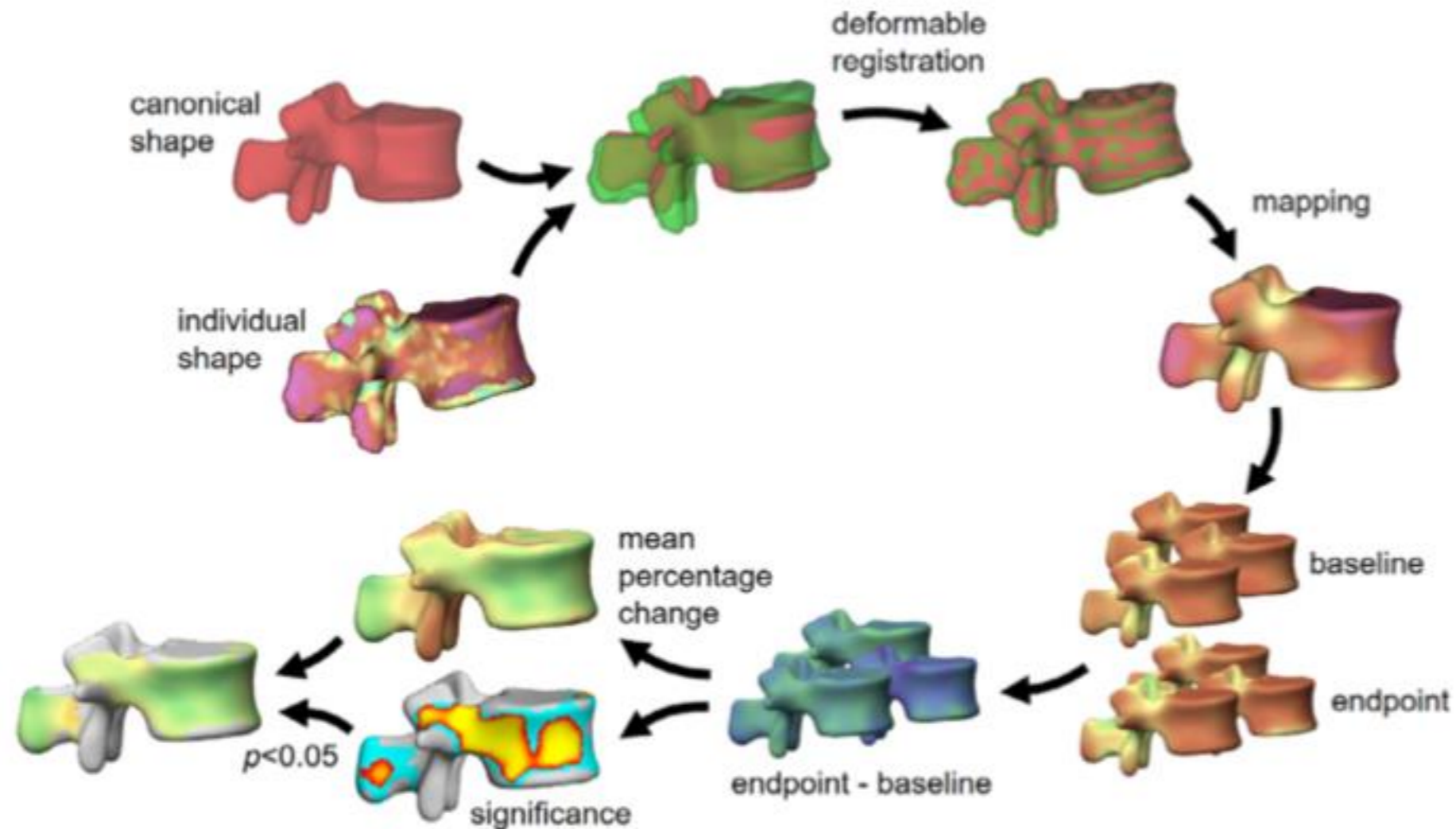


Fig. 2. The cortical parameter mapping pipeline.

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Fig. 2. The cortical parameter mapping pipeline.

Table 2. Mean (\pm Standard Deviation) Percentage Changes From Baseline at 12 Months of the Cortical Parameters for Each Treatment Group

	Placebo ($n = 20$)	Teriparatide ($n = 19$)	Romozosumab ($n = 17$)
Ct.Th	0.6 \pm 3.4	4.3 \pm 3.4***	10.3 \pm 4.9*****
Ct.BMD	-0.3 \pm 2.6	-0.1 \pm 2.8	2.1 \pm 3.3*****
Cn.BMD ^a	-4.6 \pm 6.1*	18.1 \pm 14.4***	22.2 \pm 6.6***
Ec.Th ^a	8.2 \pm 29.7	47.5 \pm 34.5***	137.6 \pm 80.5*****
CMSD	0.2 \pm 2.0	3.8 \pm 2.7***	12.4 \pm 4.7*****

Ct.Th = cortical thickness; Ct.BMD = cortical bone mineral density; Cn.BMD = cancellous bone mineral density; Ec.Th = endocortical thickness; CMSD = cortical mass surface density.





^aCn.BMD and Ec.Th values are of the vertebral body only.

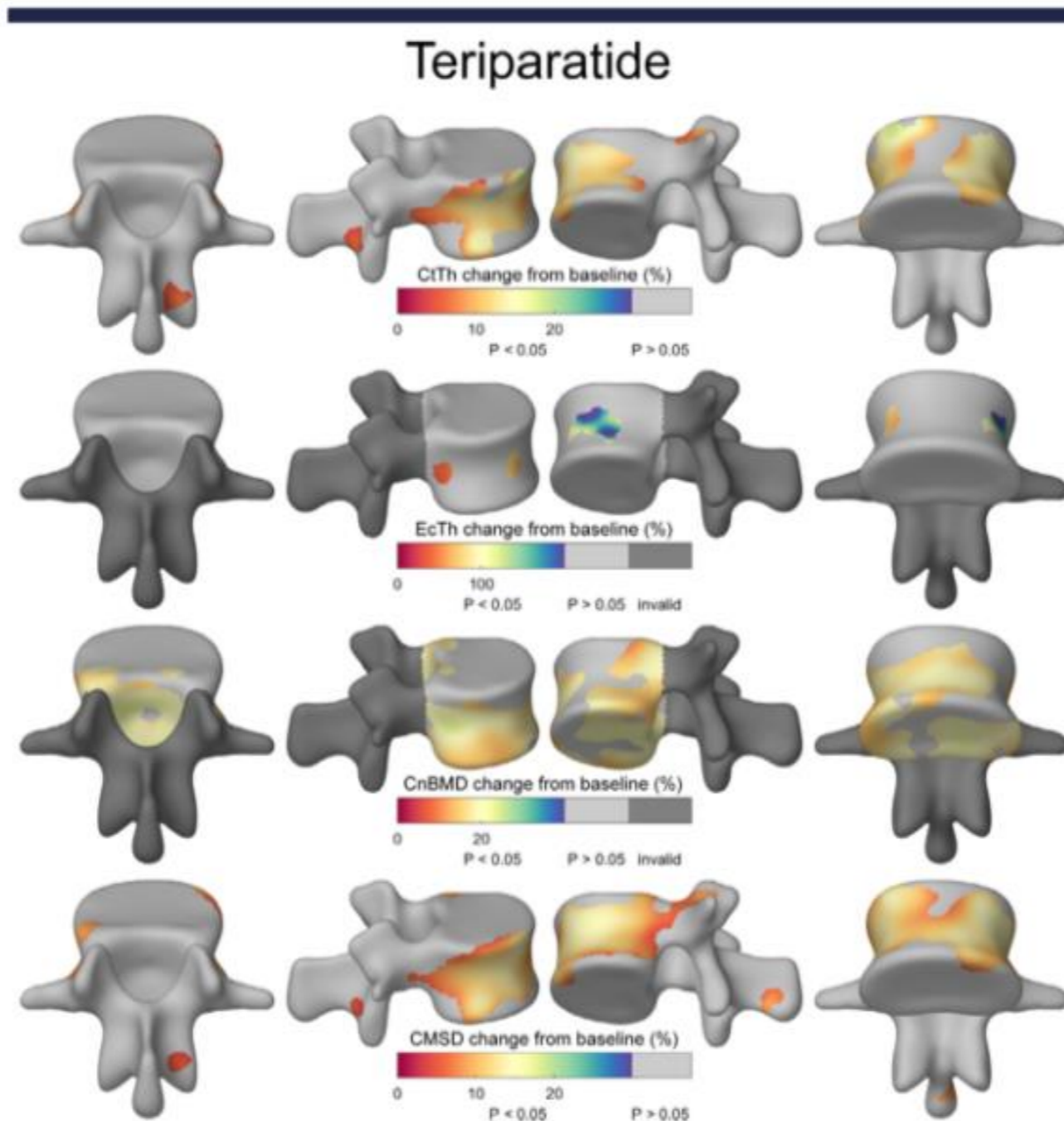
* $p \leq 0.05$ versus baseline.

** $p \leq 0.05$ versus placebo.




*** $p \leq 0.05$ versus teriparatide, using two-tailed t tests.

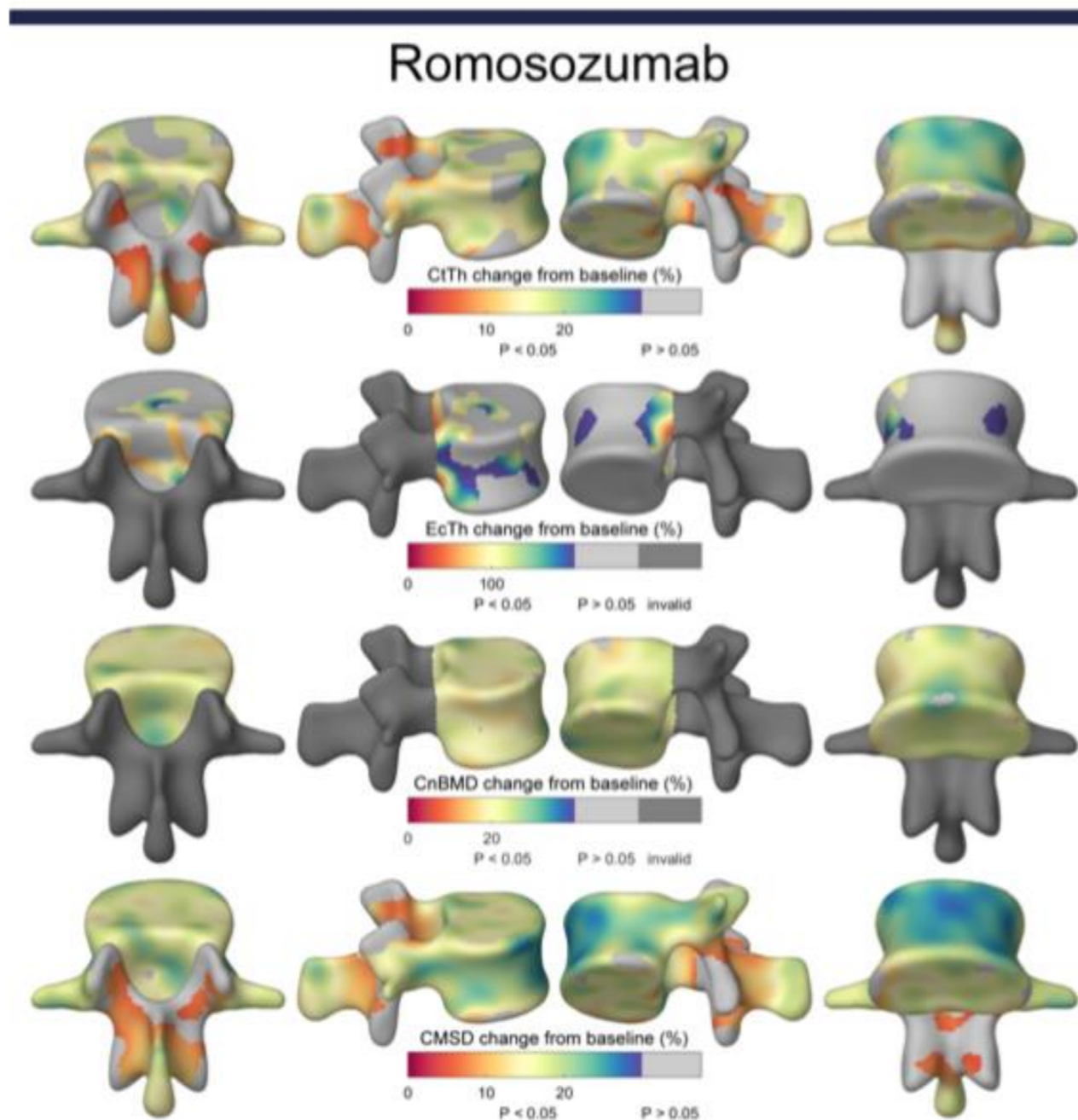
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Full Length Article

Effects of teriparatide and loading modality on modeling-based and remodeling-based bone formation in the human femoral neck

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Briefly, participants were postmenopausal women and men (age 60–89 y) who had severe hip osteoarthritis requiring an imminent elective total hip replacement (THR); inclusion did not require a diagnosis of osteoporosis. Exclusions were tetracycline allergy, rheumatologic disease other than osteoarthritis, severe renal dysfunction, persistent vitamin D deficiency, recent use of glucocorticoids, osteoporosis medication within 3 months, use of bisphosphonates within the prior year, and all contraindications to TPTD. Participants were randomly assigned to receive daily sc TPTD (20 µg) or identically appearing daily sc placebo (PBO) for a mean treatment period of 40 days prior to THR [6]. TPTD and PBO were supplied by Eli Lilly. Double tetracycline labeling was initiated 21 days prior to THR following a standard protocol and the THR was performed approximately 5 days after the last demeclocycline dose. During the THR, an intact 1.0–1.5 cm thick cross-section of the mid-FN was procured, fixed in 10% formalin and embedded without decalcification following standard protocol for iliac crest



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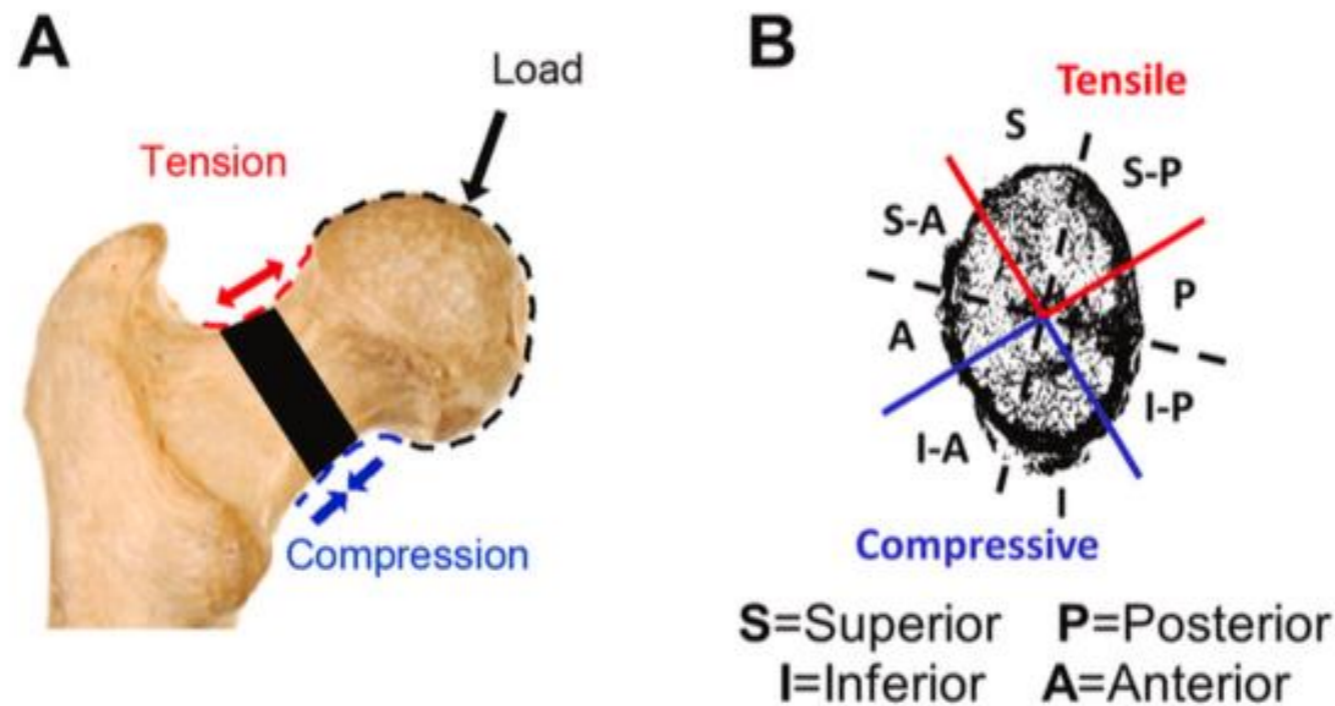


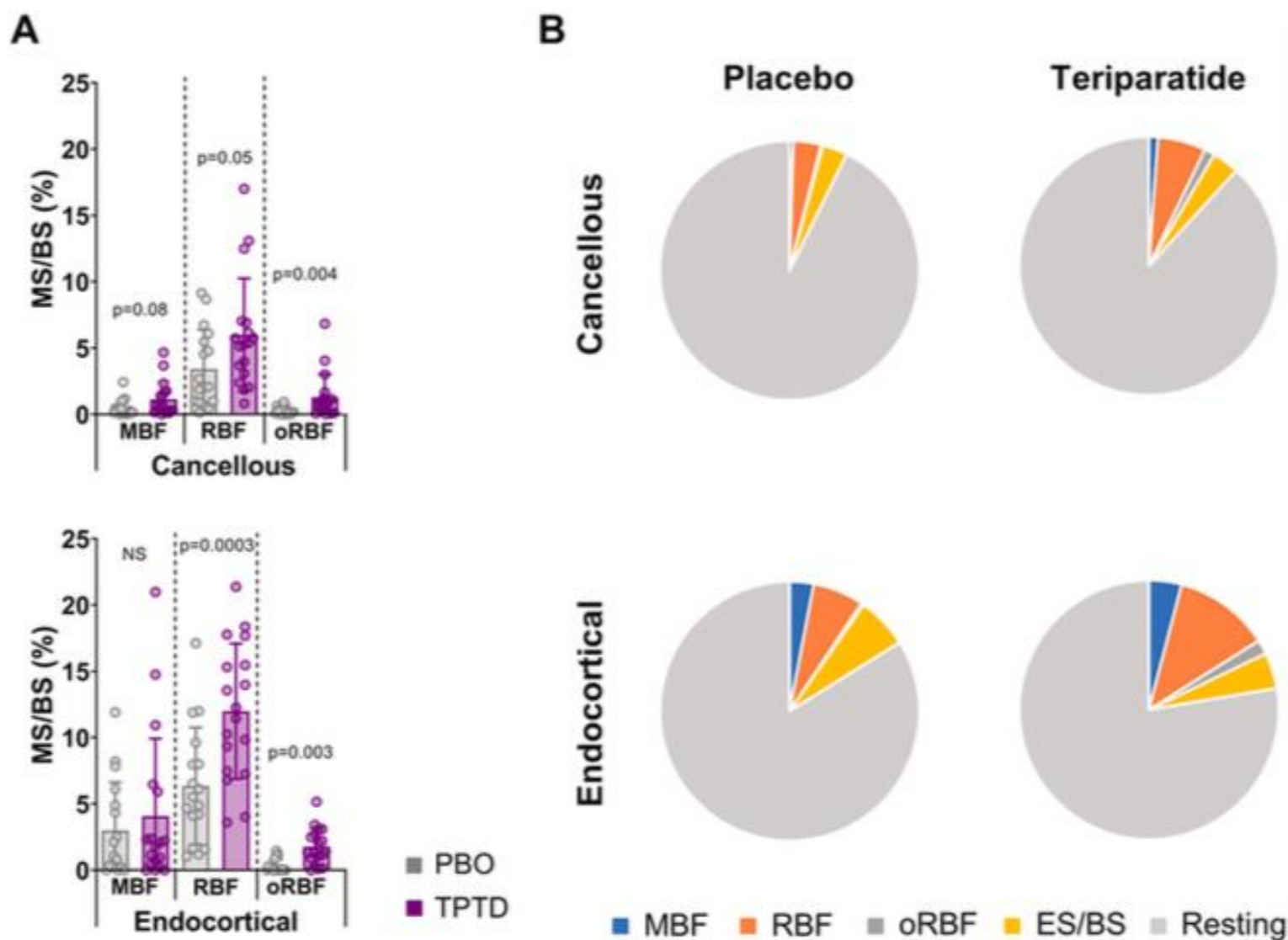
Fig. 1. Sample location and definition of loading modality regions. A) Samples were taken from the mid-femoral neck, shown in black. B) Daily activity produces tension in the superior and superior-posterior regions (S, S-P) and compression in the inferior and inferior-anterior regions (I, I-A), as shown in the representative FN cross section.



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A.M. Rooney et al.

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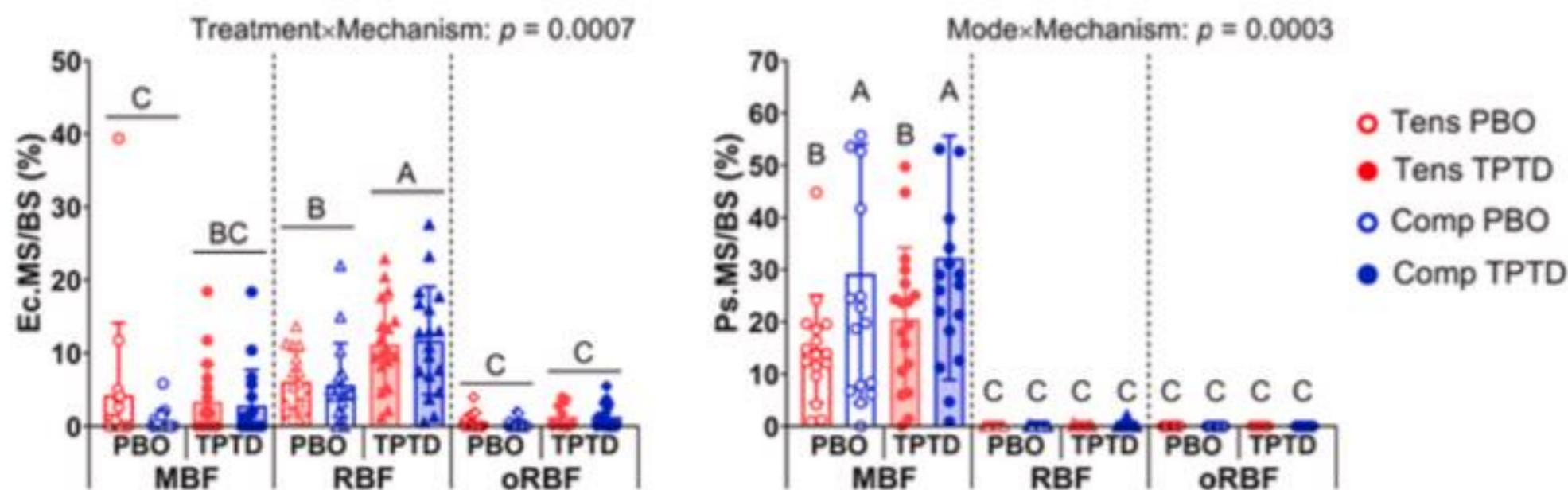


Fig. 4. TPTD increased RBF on the endocortical surface, with a trend toward increased MBF driven by the compressive region. TPTD did not affect bone formation on the periosteal surface, although MBF was greater on the compressive than the tensile periosteal surface. Data are mean \pm SD. Groups sharing a letter are not statistically different. A > B > C by linear mixed-effects model with a random patient effect.



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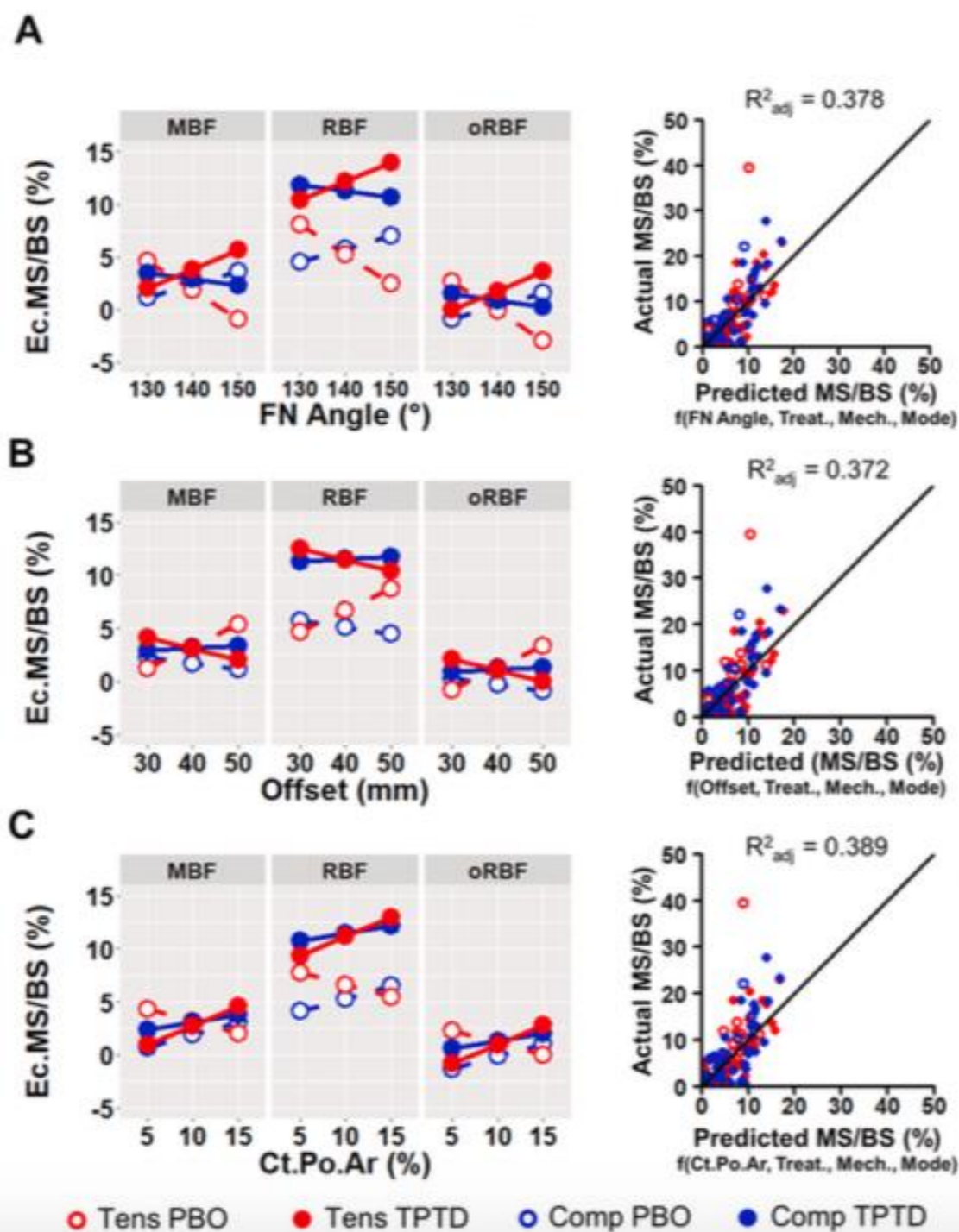


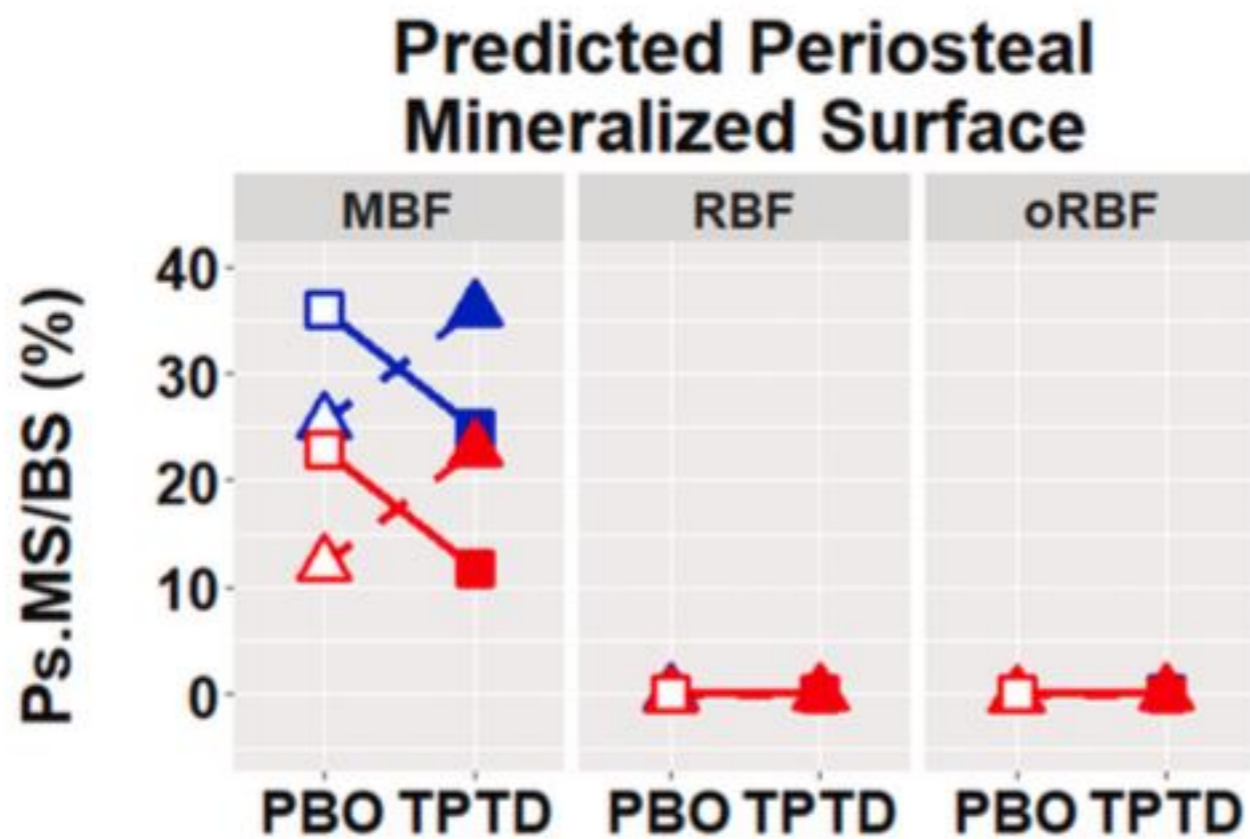
Fig. 5. Linear mixed-effects models for endocortical formation as functions of treatment (Treat.), formation mechanism (Mech.), loading modality (Mode), and A) FN angle, B) offset, or C) cortical porosity. Model predictions for a range of patient variables are shown with a plot of the model predicted versus actual MS/BS values. TPTD was predicted to increase tensile RBF in patients with larger FN angles and smaller offsets, and compressive RBF in patients with smaller FN angles and larger offsets. TPTD was also predicted to increase tensile RBF for patients with higher cortical porosity.



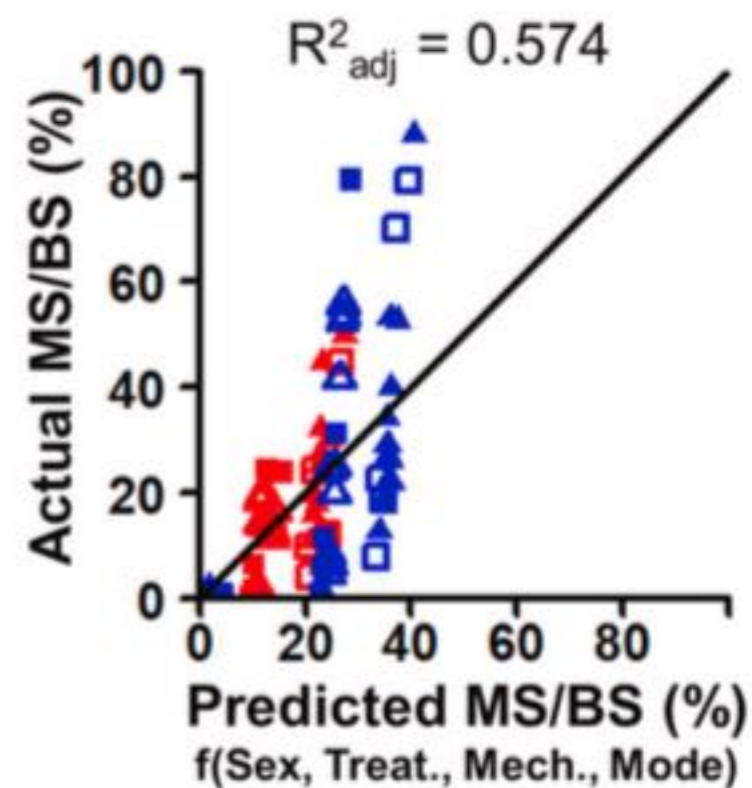
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- Male
- Tens PBO
- Comp PBO
- △ Female
- Tens TPTD
- Comp TPTD





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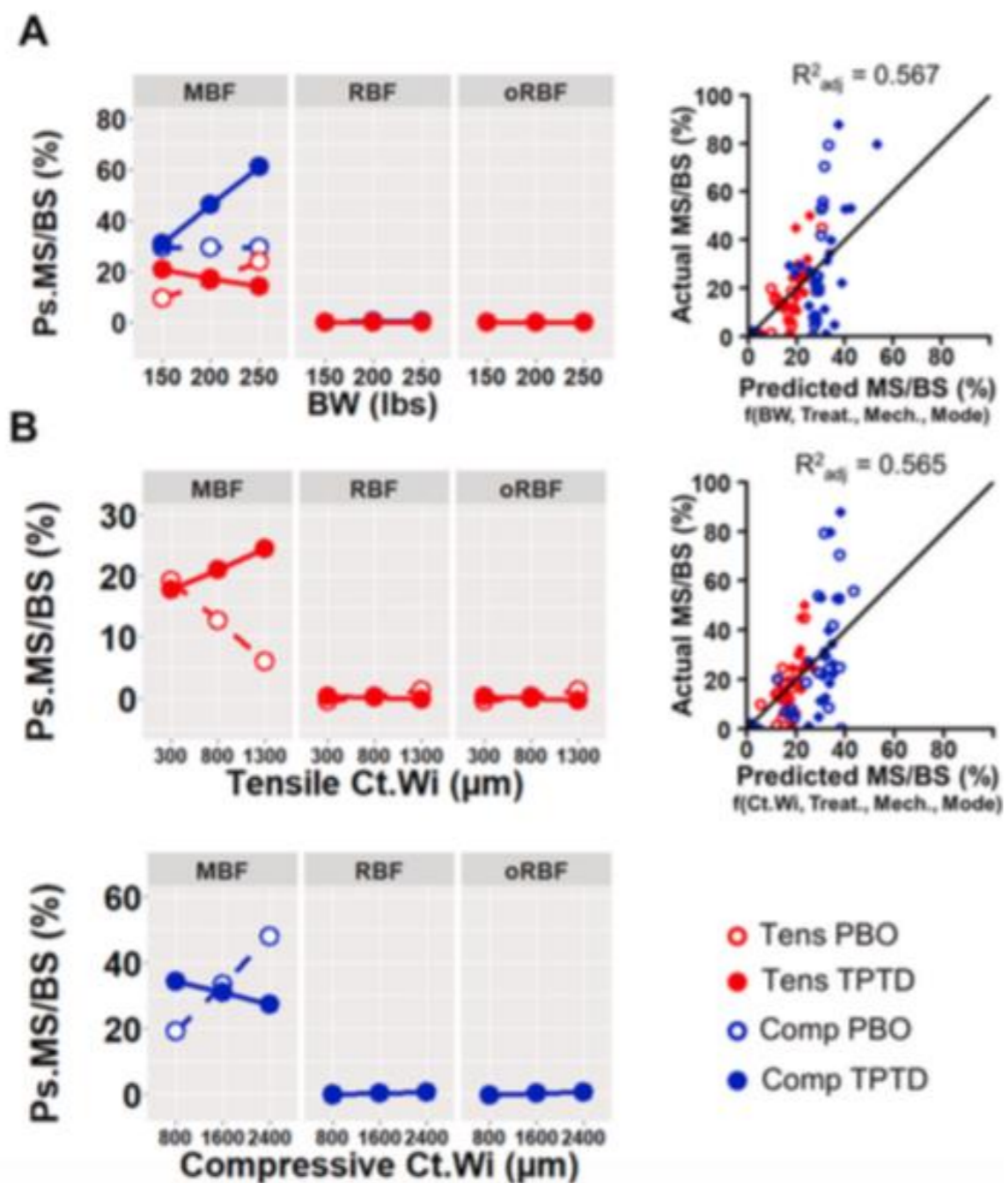


Fig. 7. Linear mixed-effects models for periosteal formation as functions of treatment (Treat.), formation mechanism (Mech.), loading modality (Mode), and A) body weight (BW) or B) cortical width (Ct. Wi). Model predictions for a range of patient variables are shown with a plot of the model predicted versus actual MS/BS values. TPTD was predicted to increase compressive MBF in patients with higher BW. TPTD was more beneficial for thicker cortices in the tensile region and thinner cortices in the compressive region.



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Hip & Pelvis

The Effect of Teriparatide on the Hip: A Literature Review

Kwangkyoun Kim, MD, Ye-yeon Won, MD*, Seok-won Lee, MD, Kyung-deok Seo, MD

*Department of Orthopaedic Surgery, Konyang University College of Medicine, Daejeon, Korea,
Department of Orthopedic Surgery, Ajou University College of Medicine, Suwon, Korea**

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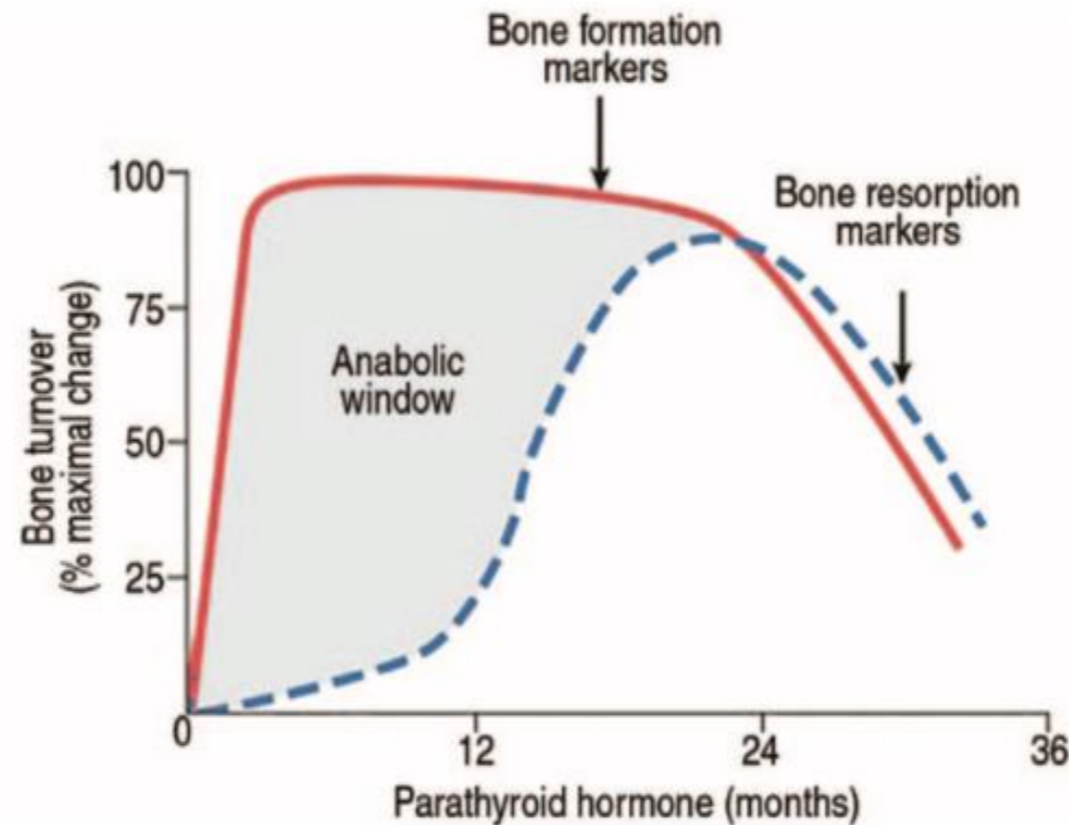


Fig. 1. Changes in bone markers during the anabolic window. Bone formation markers increase more rapidly and earlier during the course of therapy than those reflecting bone resorption. Modified from the article of Pazianas [Trends Endocrinol Metab. 2015;26:111-3]⁸¹ with original copyright holder's permission.



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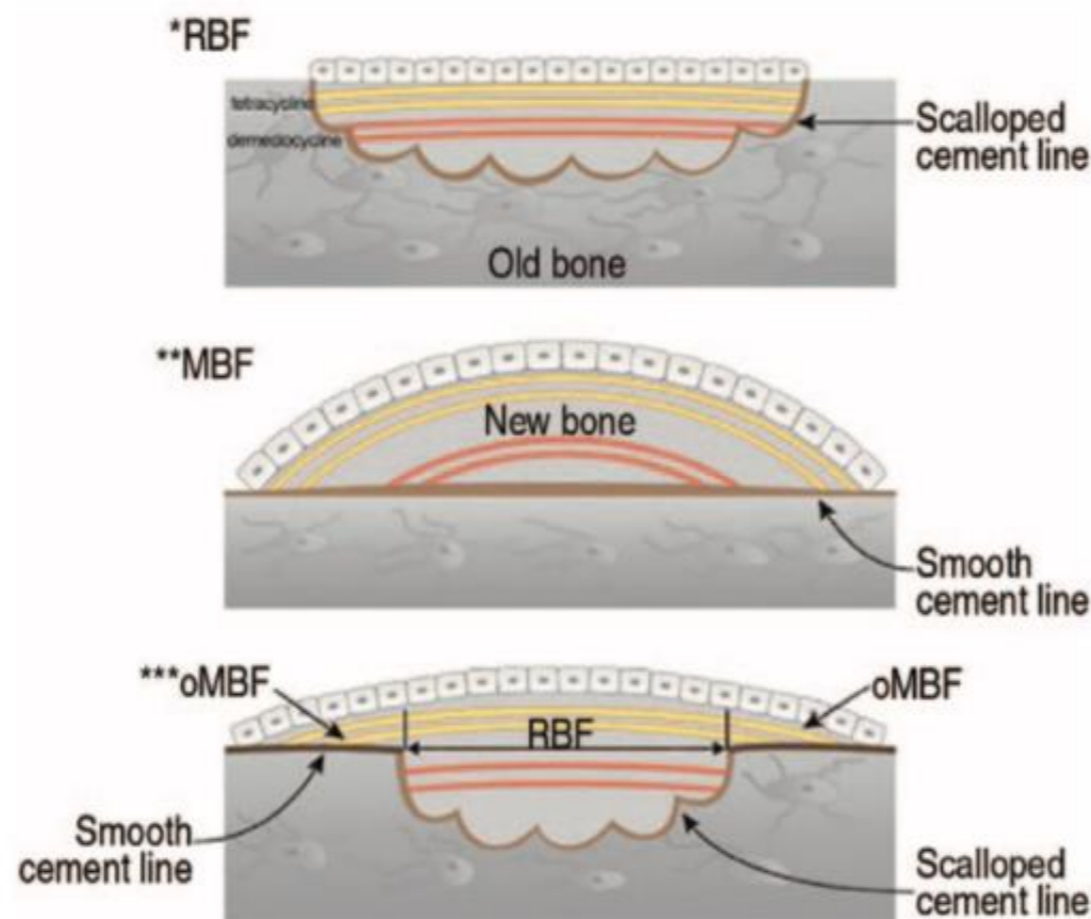


Fig. 2. Types of bone formation assessed with quadruple labeling. Shown are schematic illustrations of *remodeling-based formation (RBF), **modelingbased formation (MBF), and ***overflow modeling-based formation (oMBF). Modified from the article of Dempster et al. (J Bone Miner Res. 2018;33: 298-306)¹⁰⁾ with original copyright holder's permission.



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 Department of Orthopaedic Surgery, Konyang University College of Medicine, Daejeon, Korea,
 Department of Orthopedic Surgery, Ajou University College of Medicine, Suwon, Korea*

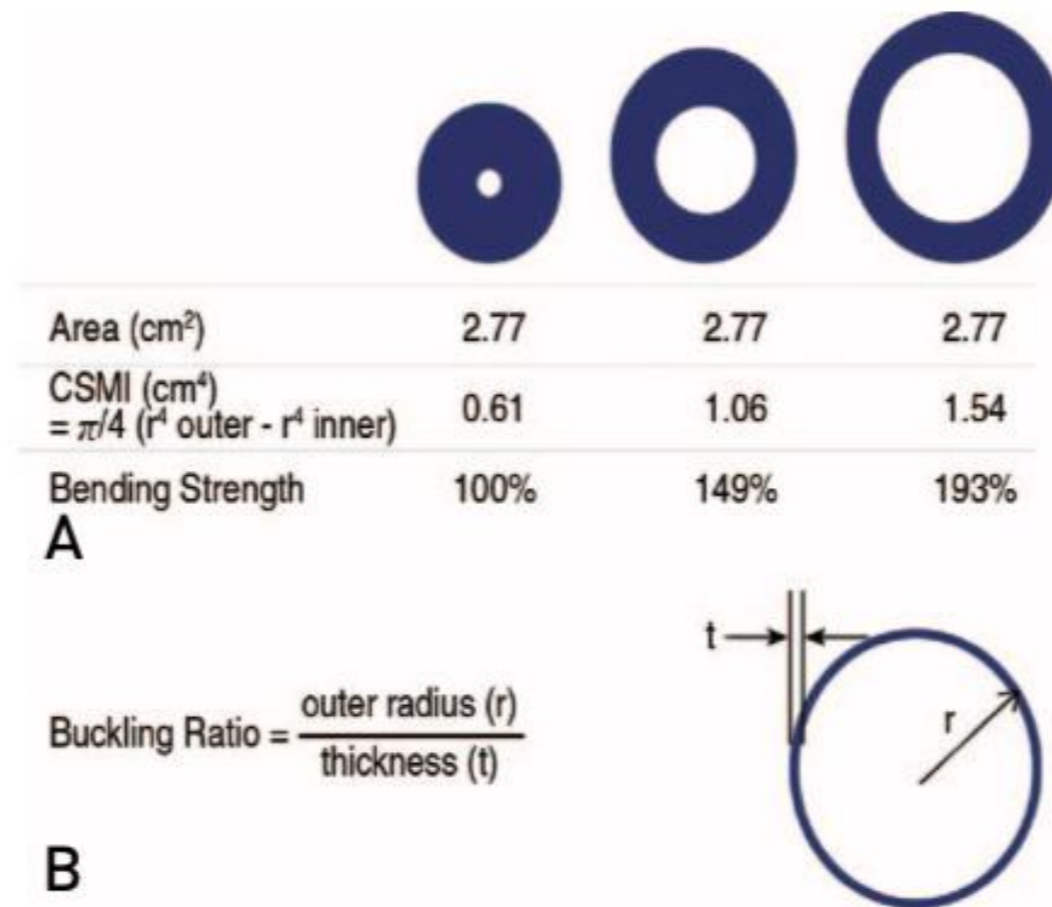


Fig. 3. (A) Although density decreased, the same section modulus is obtained by diameter expansion. (B) Buckling is the sudden change in shape (deformation) of a structural component unload. Local buckling begins to occur with a buckling ratio >10.



The Effect of Teriparatide on the Hip: A Literature Review

Kwangkyoun Kim, MD, Ye-yeon Won, MD*, Seok-won Lee, MD, Kyung-deok Seo, MD

Department of Orthopaedic Surgery, Konyang University College of Medicine, Daejeon, Korea,

*Department of Orthopedic Surgery, Ajou University College of Medicine, Suwon, Korea**

- FRT: 1 ΚΑΤΑΓΜΑ ΙΣΧΙΟΥ ΣΤΗΝ ΟΜΑΔΑ ΤΕΡΙΠΑΡΑΤΙΔΗΣ ΚΑΙ 4 ΣΤΗΝ ΟΜΑΔΑ ΕΙΚΟΝΙΚΟΥ ΦΑΡΜΑΚΟΥ (ΑΔΥΝΑΜΙΑ ΣΤΑΤΙΣΤΙΚΗΣ ΣΗΜΑΝΤΙΚΟΤΗΤΑΣ)
- ΑΥΞΗΣΗ BMD ΑΥΧΕΝΑ ΜΗΡΙΑΙΟΥ 3.6% (FRT) ΚΑΙ 3.9% (FACT study) ΣΥΓΚΡΙΤΙΚΑ ΜΕ ΕΙΚΟΝΙΚΟ ΦΑΡΜΑΚΟ. Η ΑΥΞΗΣΗ ΑΥΤΗ ΕΞΗΓΕΙ ΤΟ 44-67% ΤΟΥ ΕΛΑΤΤΩΜΕΝΟΥ ΚΑΤΑΓΜΑΤΙΚΟΥ ΚΙΝΔΥΝΟΥ (Black et al)
- ΑΥΞΗΣΗ ΤΗΣ ΕΞΩΤΕΡΙΚΗΣ ΔΙΑΜΕΤΡΟΥ ΤΟΥ ΦΛΟΙΟΥ ΚΑΙ ΤΟΥ ΠΑΧΟΥΣ ΤΟΥ ΦΛΟΙΟΥ ΜΕΣΩ ΤΟΥ ΜΗΧΑΝΙΣΜΟΥ ΟΣΤΙΚΗΣ ΚΑΤΑΣΚΕΥΗΣ (BONE MODELING) ΚΑΙ oMBF (OVERFLOW MODELING BASED FORMATION) ΟΠΩΣ ΑΠΟΔΕΙΧΘΗΚΕ ΑΠΟ ΤΙΣ ΕΡΓΑΣΙΕΣ ΜΕ ΒΙΟΨΙΑ ΛΑΓΟΝΙΟΥ ΑΠΟ ΤΟΥΣ Ma et al
- ΑΥΞΗΣΗ ΤΗΣ ΠΟΡΩΤΙΚΟΤΗΤΑΣ ΟΣΤΟΥ (CORTICAL STEAL PHENOMENON) ΚΥΡΙΩΣ ΣΤΟ ΕΝΔΟΦΛΟΙΩΔΕΣ ΔΙΑΜΕΡΙΣΜΑ ΧΩΡΙΣ ΑΥΤΟ ΝΑ ΣΥΝΕΠΑΓΕΤΑΙ ΣΗΜΑΝΤΙΚΕΣ ΑΛΛΑΓΕΣ ΣΤΗΝ ΟΣΤΙΚΗ ΑΝΤΟΧΗ (BURR CYNOMOLOGUS MONKEYS ΒΡΑΧΙΟΝΙΟ ΟΣΤΟΥΝ, SATO et al ΣΕ ΠΕΙΡΑΜΑΤΟΖΩΑ, HANSEN et al ΣΕ ΑΝΘΡΩΠΟΥΣ = ΑΥΞΗΣΗ ΠΟΡΩΤΙΚΟΤΗΤΑΣ 32±37% (P<0.01) ΚΑΙ ΠΤΩΣΗ BMD ΣΤΟ ΑΠΩ ΤΡΙΤΗΜΟΡΙΟ ΚΕΡΚΙΔΑΣ ΑΛΛΑ ΤΟ ΠΑΧΟΣ ΤΟΥ ΦΛΟΙΟΥ ΕΠΙΒΛΕΠΕ ΑΥΧΗΘΗΚΕ 0.9-2.0% (P<0.05) ΧΩΡΙΣ ΝΑ ΠΑΡΑΤΗΡΗΣΕΙ ΑΙΑΦΟΡΑ ΕΤΣΙΝ

ΕΥΧΑΡΙΣΤΩ!



Επιστημονικό Πρόγραμμα

2^η ΗΜΕΡΑ | **Σάββατο** | **19 Μαρτίου 2022**

