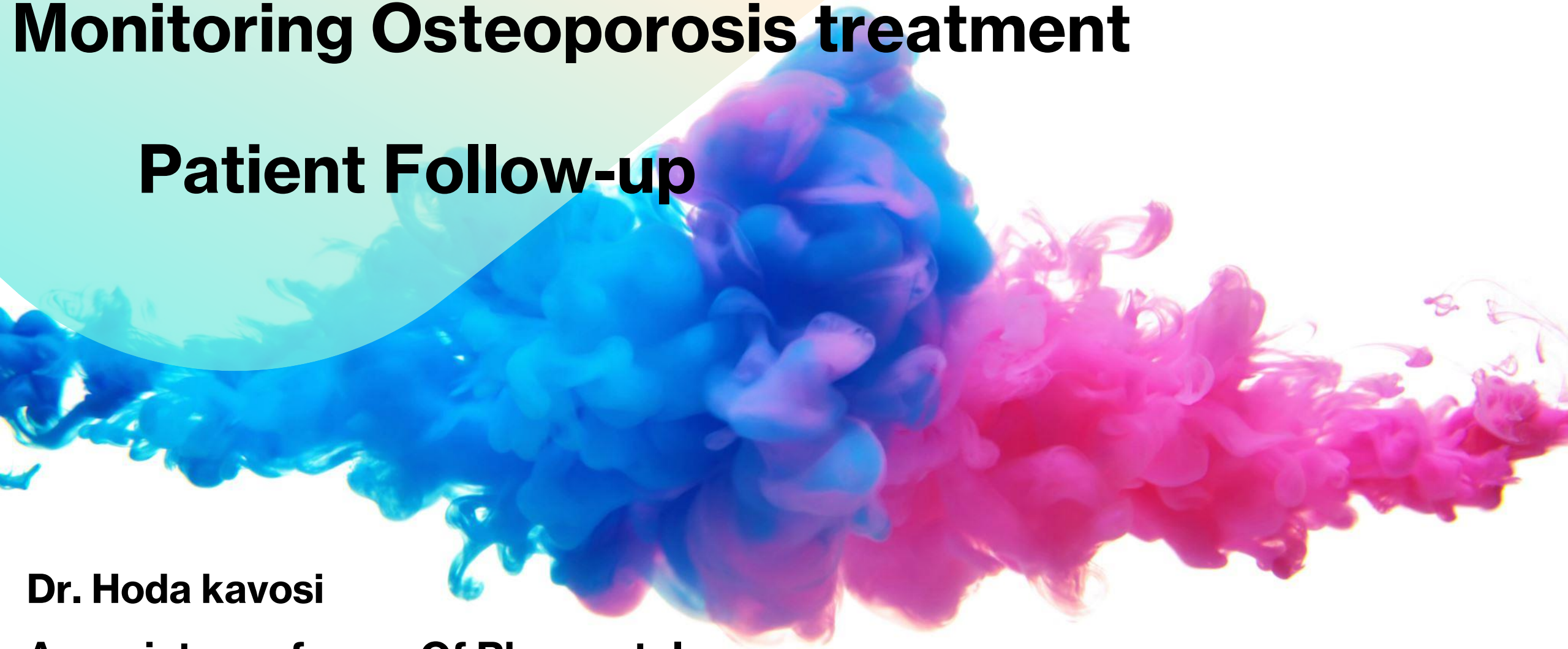
Monitoring Osteoporosis treatment

Patient Follow-up



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Aim of monitoring

- reduction of future fracture risk
- stabilize or increase bone mass
- preserve or improve bone quality
- increase treatment adherence

Treatment option	
Antiresorptive (Bisphosphonate)	Oral 5 years IV 3 years
Antiresorptive (denosumab) Anabolic (teriparatide)	**Denosumab 5 years** **Forteo 2 years**
Romosozumab	**One year**

How to monitor

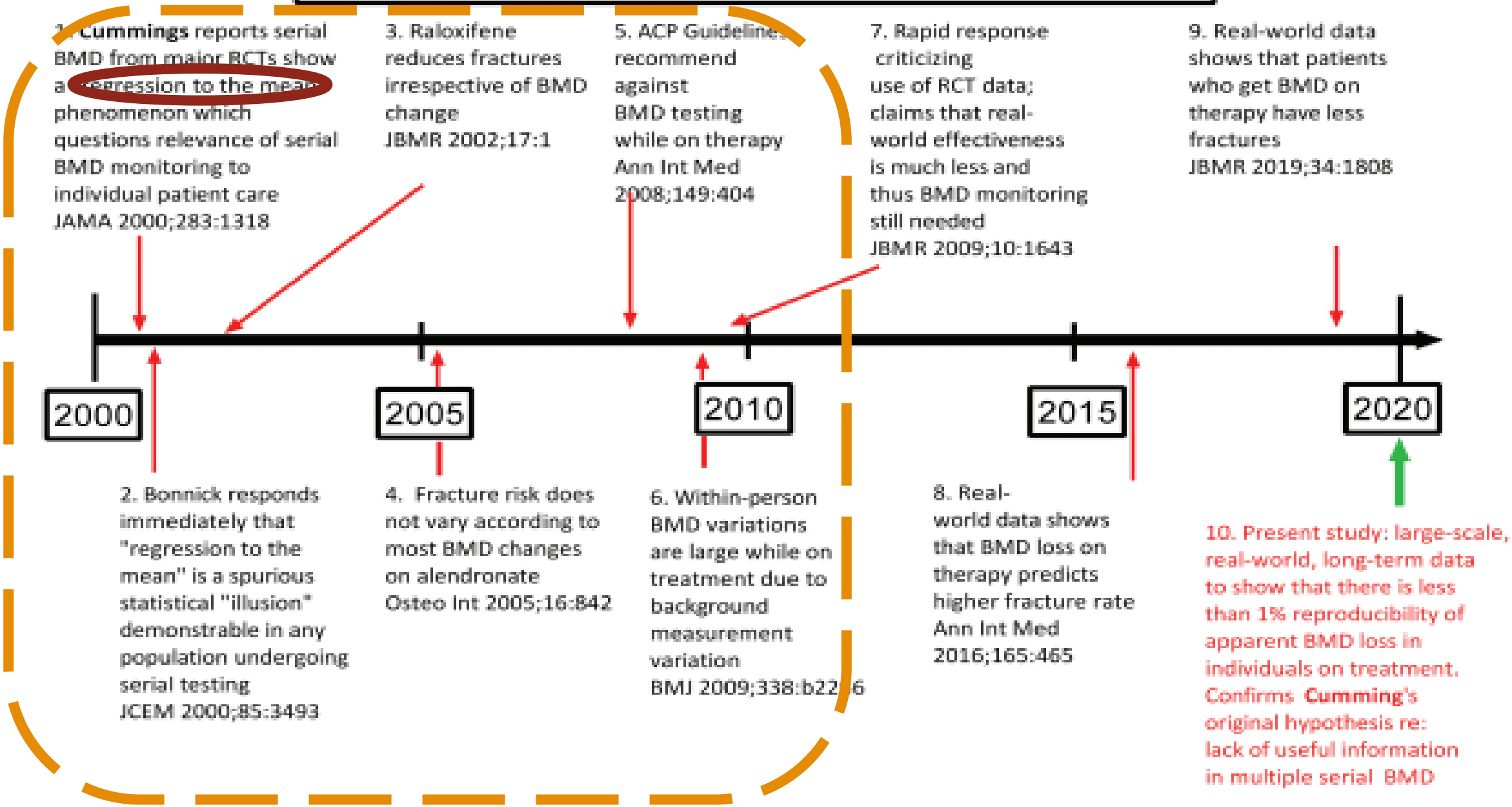
BMD Measurement

every 1-3 years after initiation of therapy

Central DXA of the spine or hip

Patient follow-up ideally with the same facility using the same machine

The History of the "Serial BMD While on Therapy" Debate: full circle in 20 years



Bone Turnover Markers

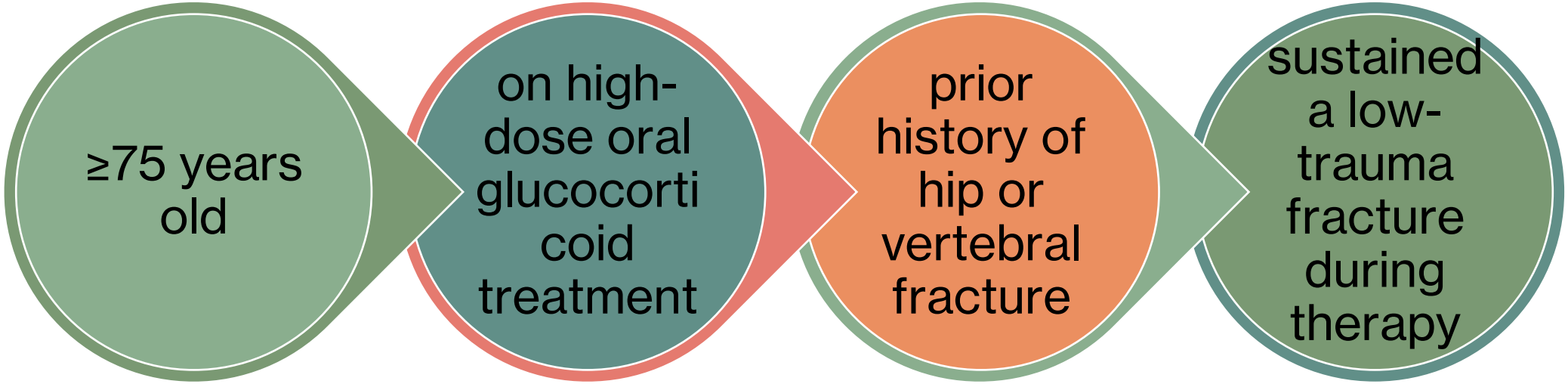
Bone resorption markers (CTX) may be measured before starting therapy and 3 or 6 months later

Bone formation markers (P1NP) may be measured before starting therapy and 6 months later

Resorption markers may be used for assessing fracture risk in selected patients when **BMD and clinical risk factors are not sufficient** to make treatment decisions

Duration of treatment

Bisphosphonate therapy can be continued beyond 3-5 years



BMD >-2.5	withholding treatment and advise patient to follow-up every 2-3 years
BMD<-2.5 high FX risk	consider continuing bisphosphonate therapy or may change into other agents
FX happened	Use the second line treatment

Treatment failure

≥2 incident fragility fractures

one incident fracture and elevated serum CTX or P1NP at baseline with no significant reduction during treatment

no significant decrease in serum CTX or P1NP but a significant decrease in BMD

Significant decrease in BMD

Scan Date	Age	BMD (g/cm^2)	T - score	BMD Change vs Baseline	BMD Change vs Previous
24.11.2020	58	0.634	-0.9	-3.3%	-3.3%
13.05.2018	56	0.656	-0.7		

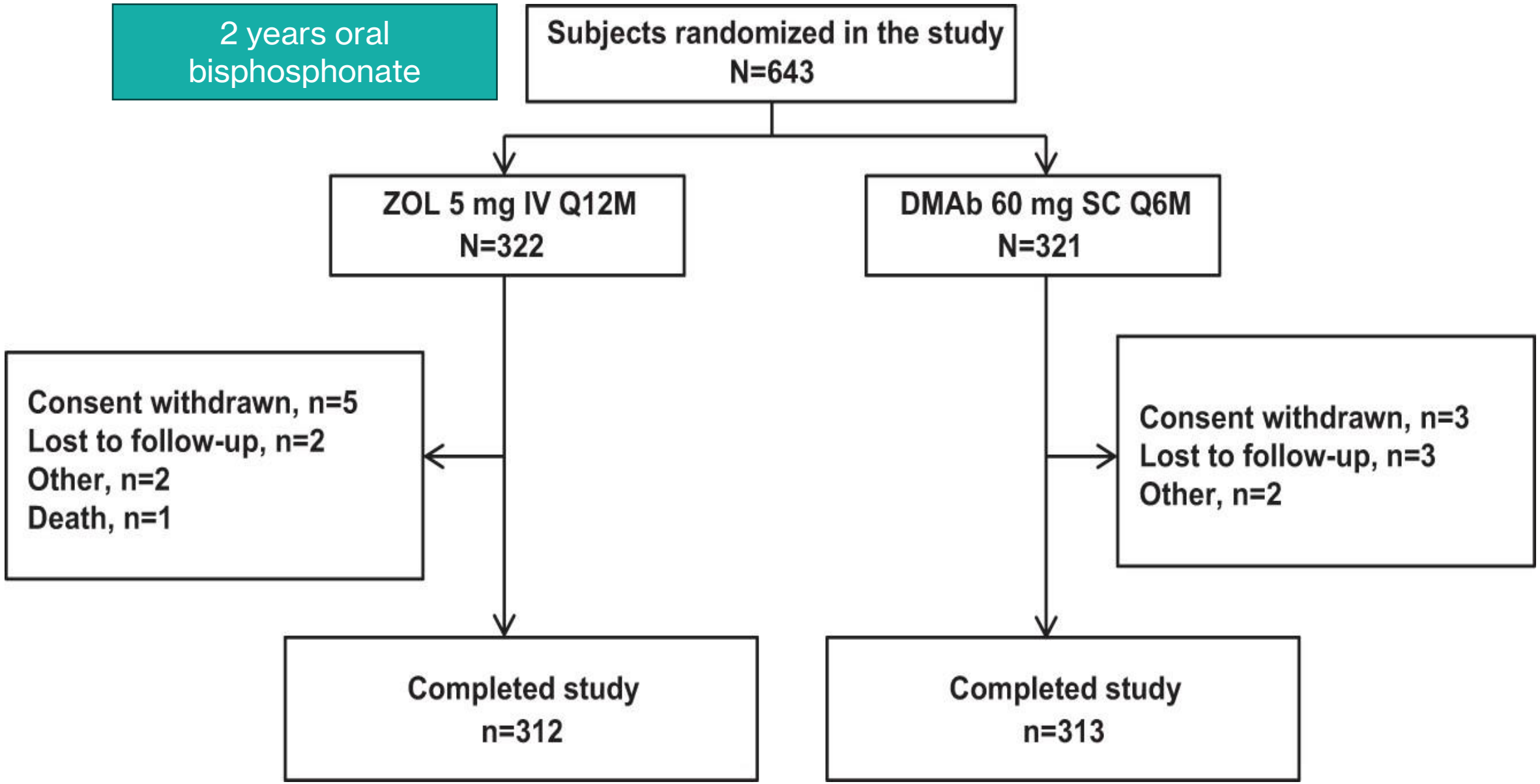
* Denotes significance at 95% confidence level. LSC is 0.045 g/cm^2

doi: 10.32592/RR.2024.9.1.62

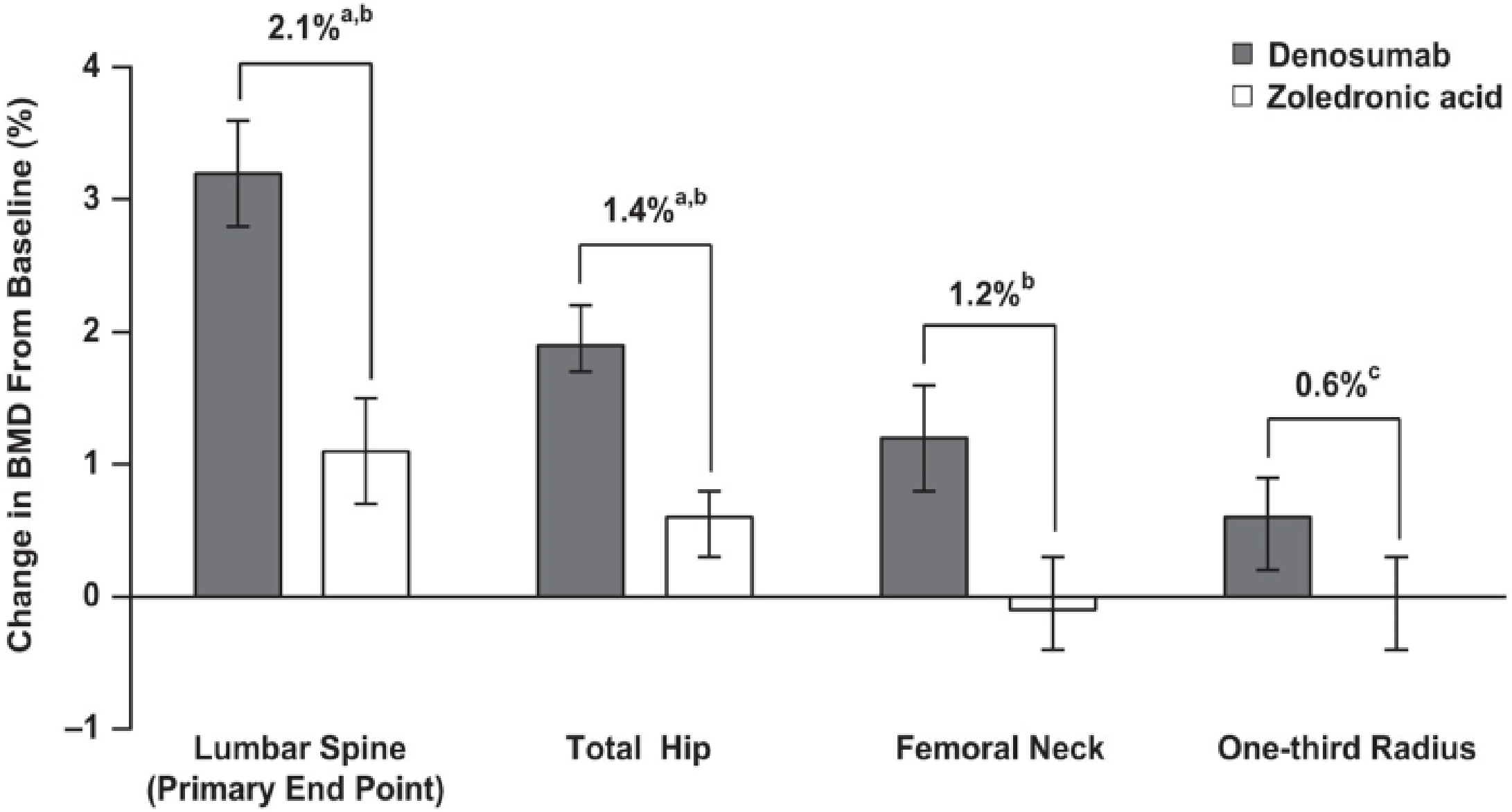
What should we do in treatment failure?

- **Change of treatment**

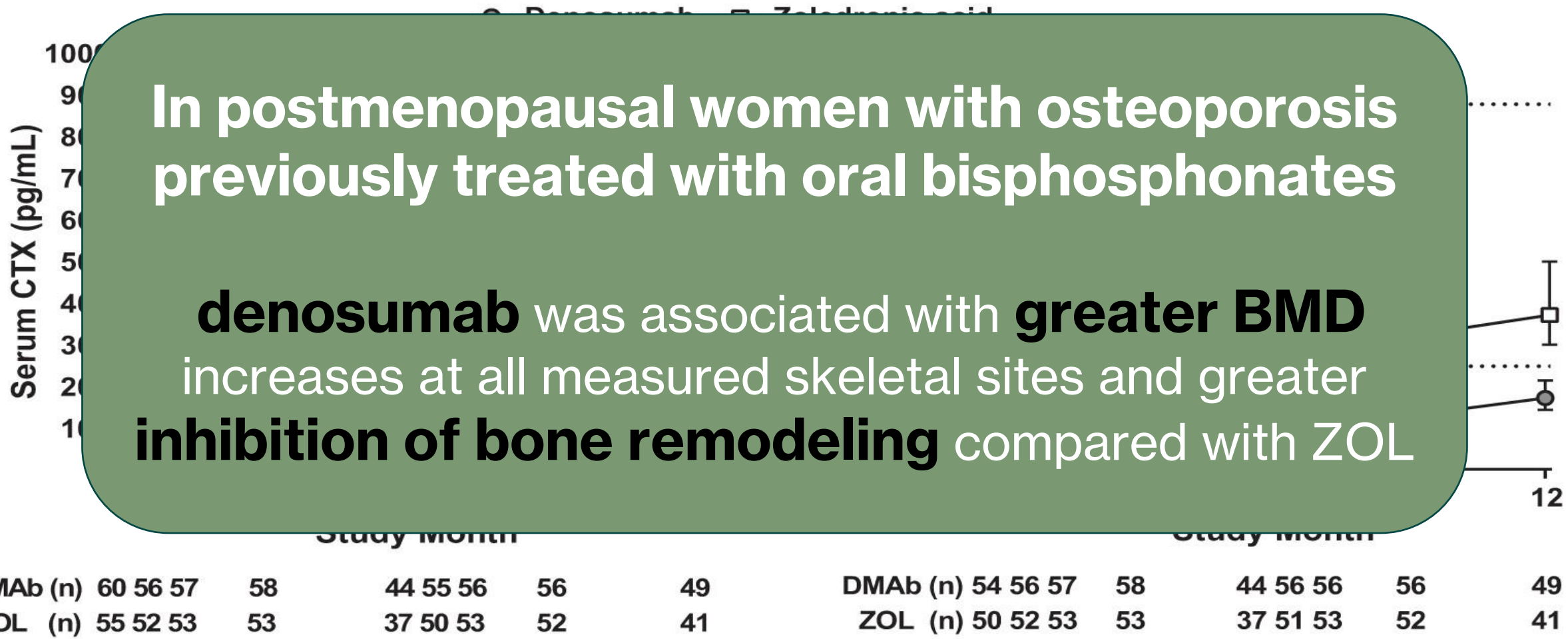
- another anti-resorptive treatment
- bone-forming or dual-action treatment



doi: 10.1210/jc.2016-1801 J Clin Endocrinol Metab, August 2016


2.1%a,b
1.4%a,b
1.2%b
0.6%c
Denosumab
Zoledronic acid
Change in BMD From Baseline (%)
4
3
2
1
0
–1
Lumbar Spine
(Primary End Point)
Total Hip
Femoral Neck
One-third Radius

Serum CTX and P1NP concentrations.



In postmenopausal women with osteoporosis previously treated with oral bisphosphonates

denosumab was associated with **greater BMD** increases at all measured skeletal sites and greater **inhibition of bone remodeling** compared with ZOL

J Clin Endocrinol Metab, Volume 101, Issue 8, 1 August 2016, Pages 3163–3170, https://doi.org/10.1210/jc.2016-1801

Anabolic and Antiresorptive Therapy for Osteoporosis

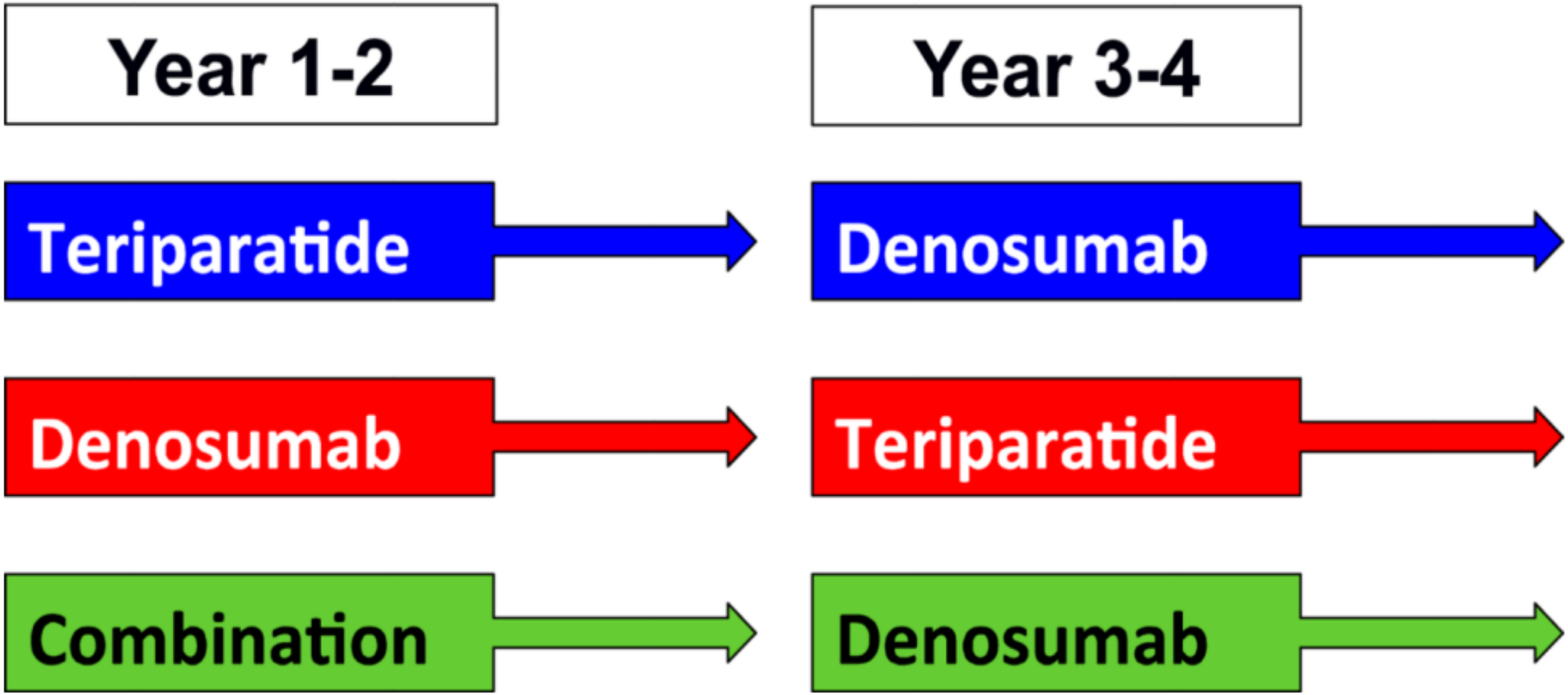
Hip BMD Effect of Switching From Potent Antiresorptive Therapy to TPTD

Study	Sample size	Treatment paradigm	% Change in total hip BMD during TPTD/PTH treatment			
			6 mo	12 mo	18 mo	24 mo
Ettinger et al.[27]	33	Alendronate (mean 29.3 mo) → TPTD (18 mo)	−1.8%	−1.0%	+0.3%	–
Boonen et al.[24]	107	Alendronate (median 29.2 mo) → TPTD (24 mo)	−1.2%	−0.6%	+0.6%	+2.1%
Boonen et al.[24]	59	Risedronate (median 23.4 mo) → TPTD (24 mo)	−1.6%	−0.4%	+0.9%	+2.9%
Miller et al.[30]	158	Risedronate (mean 37.2 mo) → TPTD (12 mo)	−1.2%	−0.3%	–	–
Miller et al.[30]	166	Alendronate (mean 38.0 mo) → TPTD (12 mo)	−1.9%	−1.7%	–	–
Cosman et al.[26]	50	Alendronate (mean 45.7 mo) → TPTD (18 mo)	−0.8%	–	+0.9%	–
Leder et al.[28]	27	Denosumab (24 mo) → TPTD (24 mo)	−1.7%	−2.7%	−1.7%	−0.7%

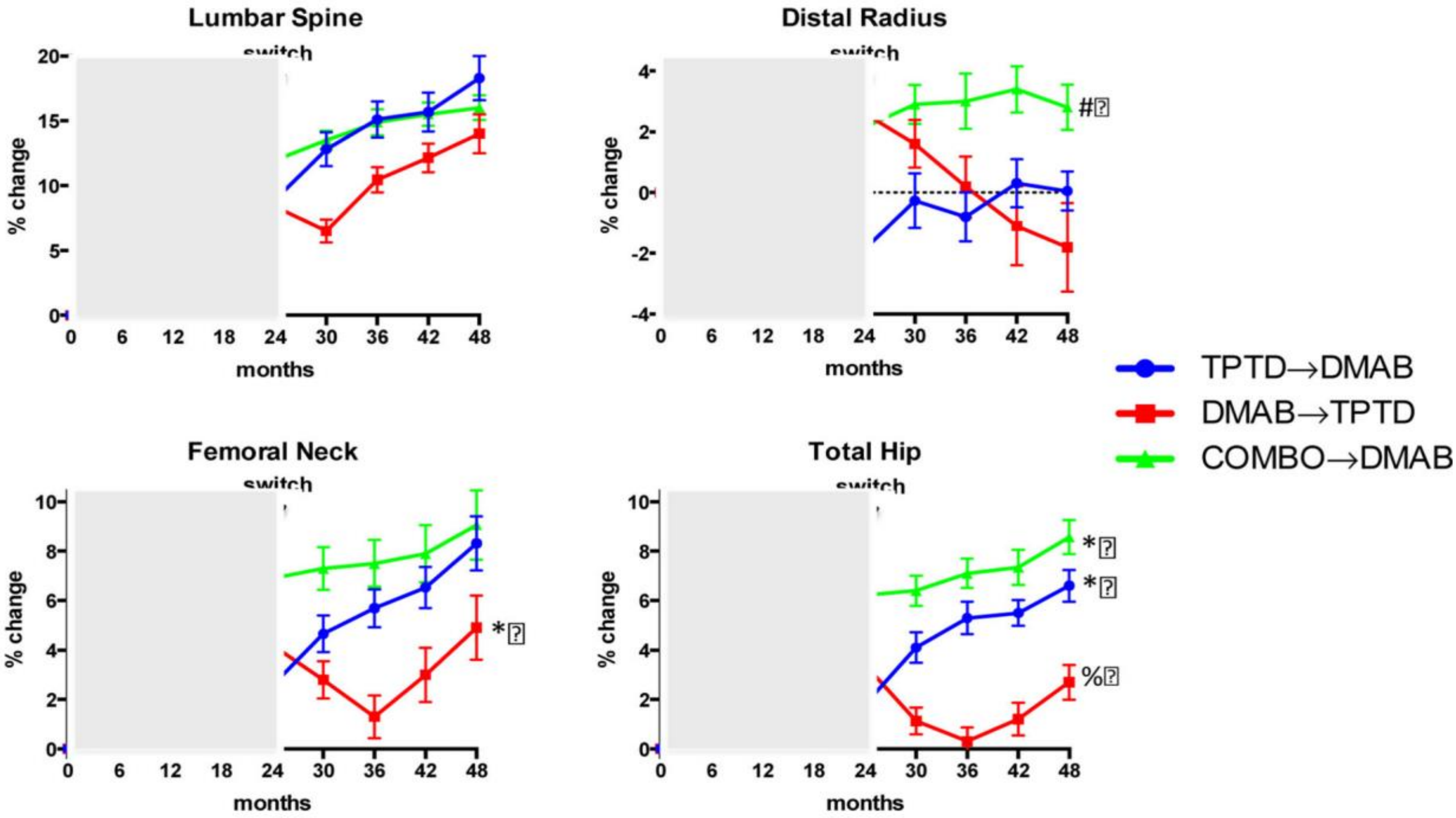
mo = months.

In some cases, numbers are estimated by extrapolation from graph in article.

DATA-Switch Study Design

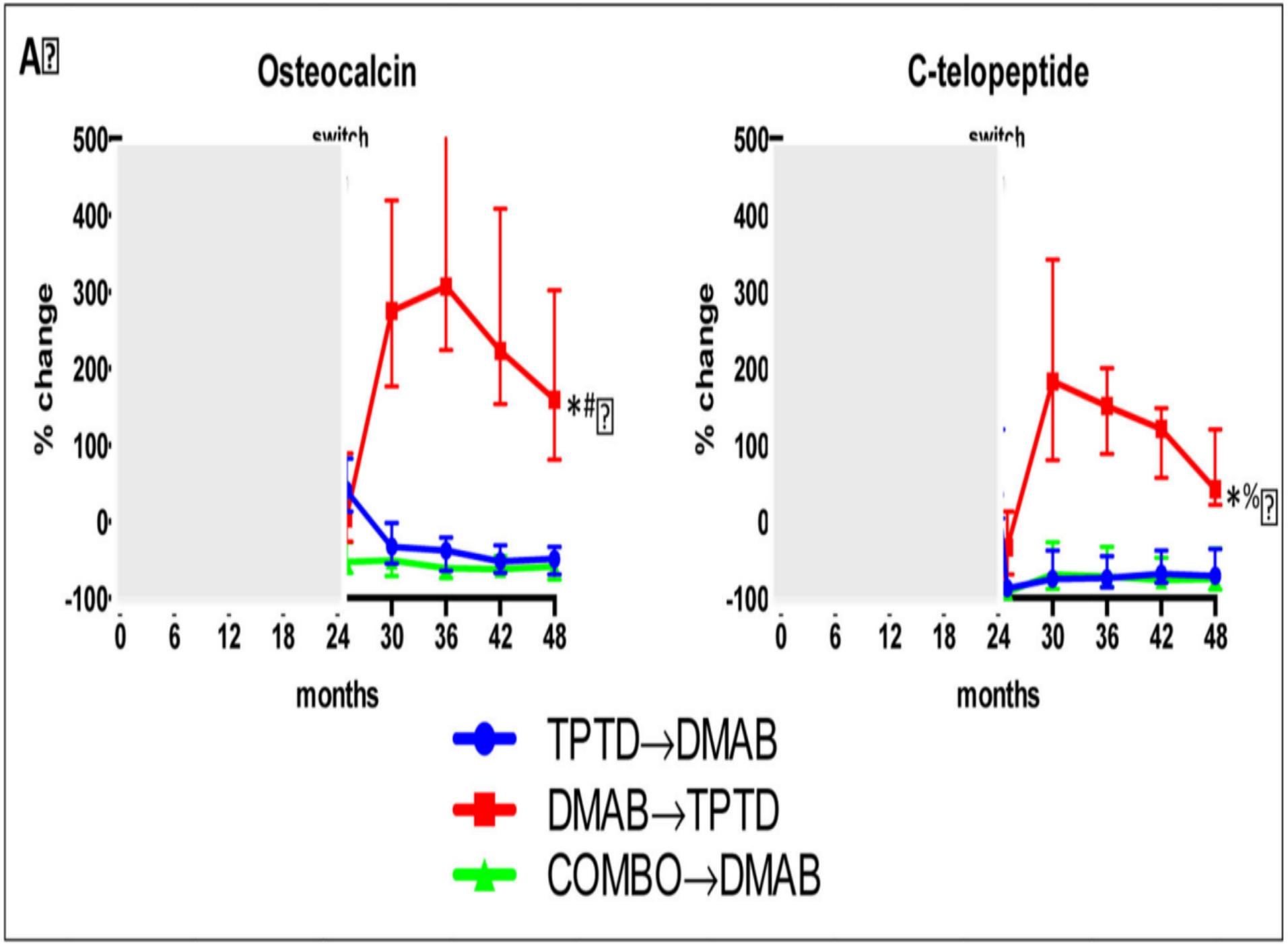


B. Z. Leder, Tsai, et al. 2015

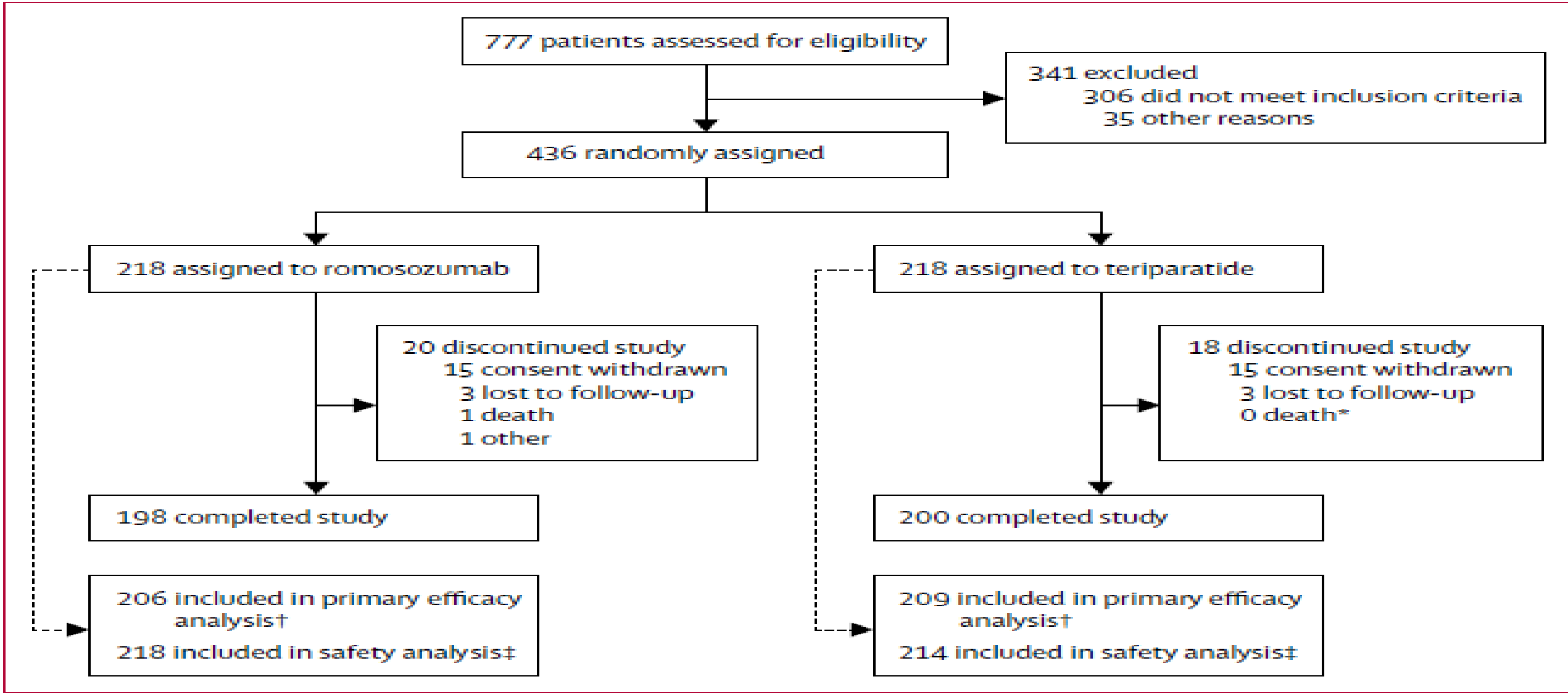

Lumbar Spine
switch
% change
months
Distal Radius
switch
% change
months
#
Femoral Neck
switch
% change
months
*
Total Hip
switch
% change
months
*
*
%
TPTD→DMAB
DMAB→TPTD
COMBO→DMAB

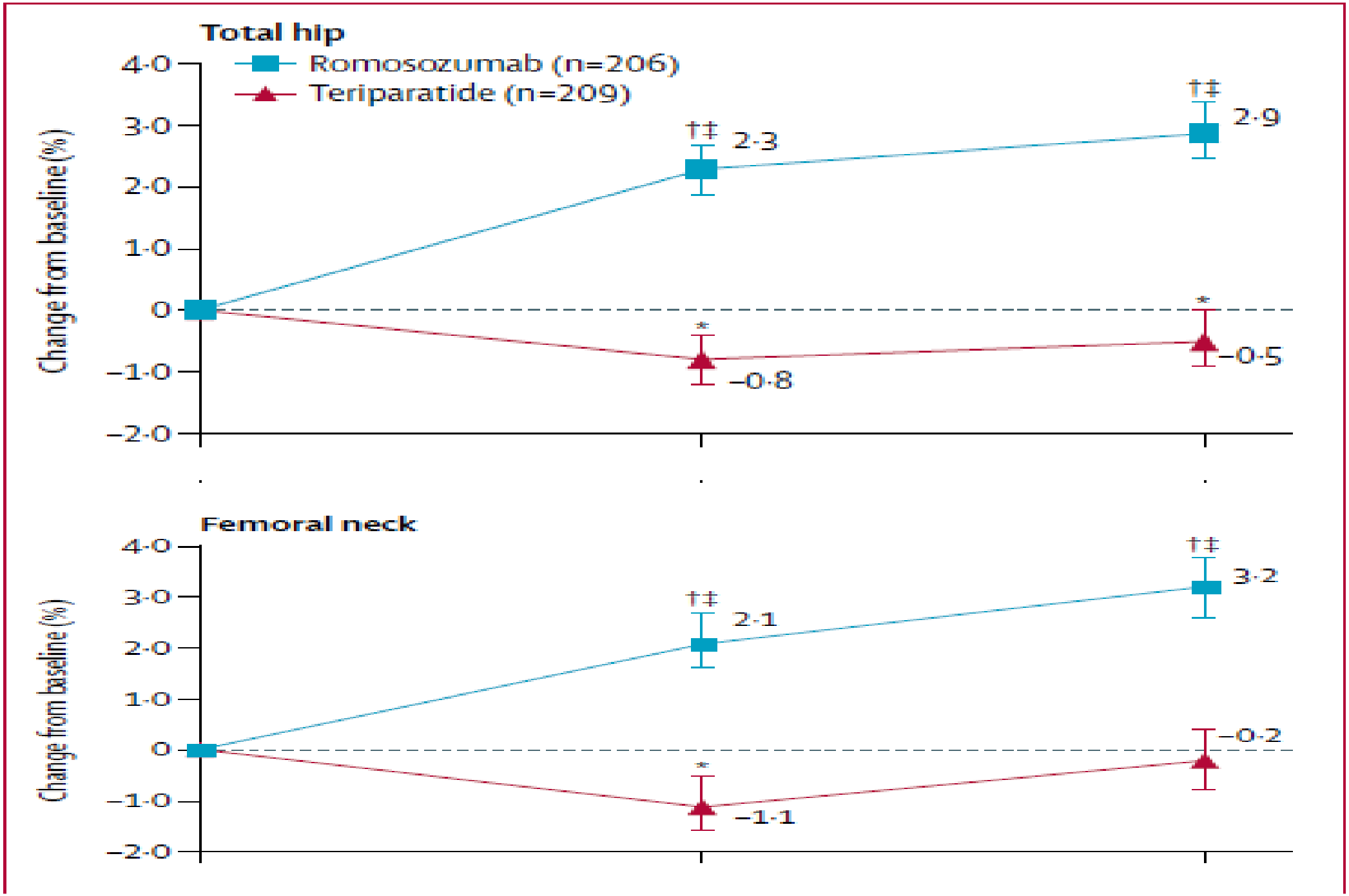
DATA-switch study

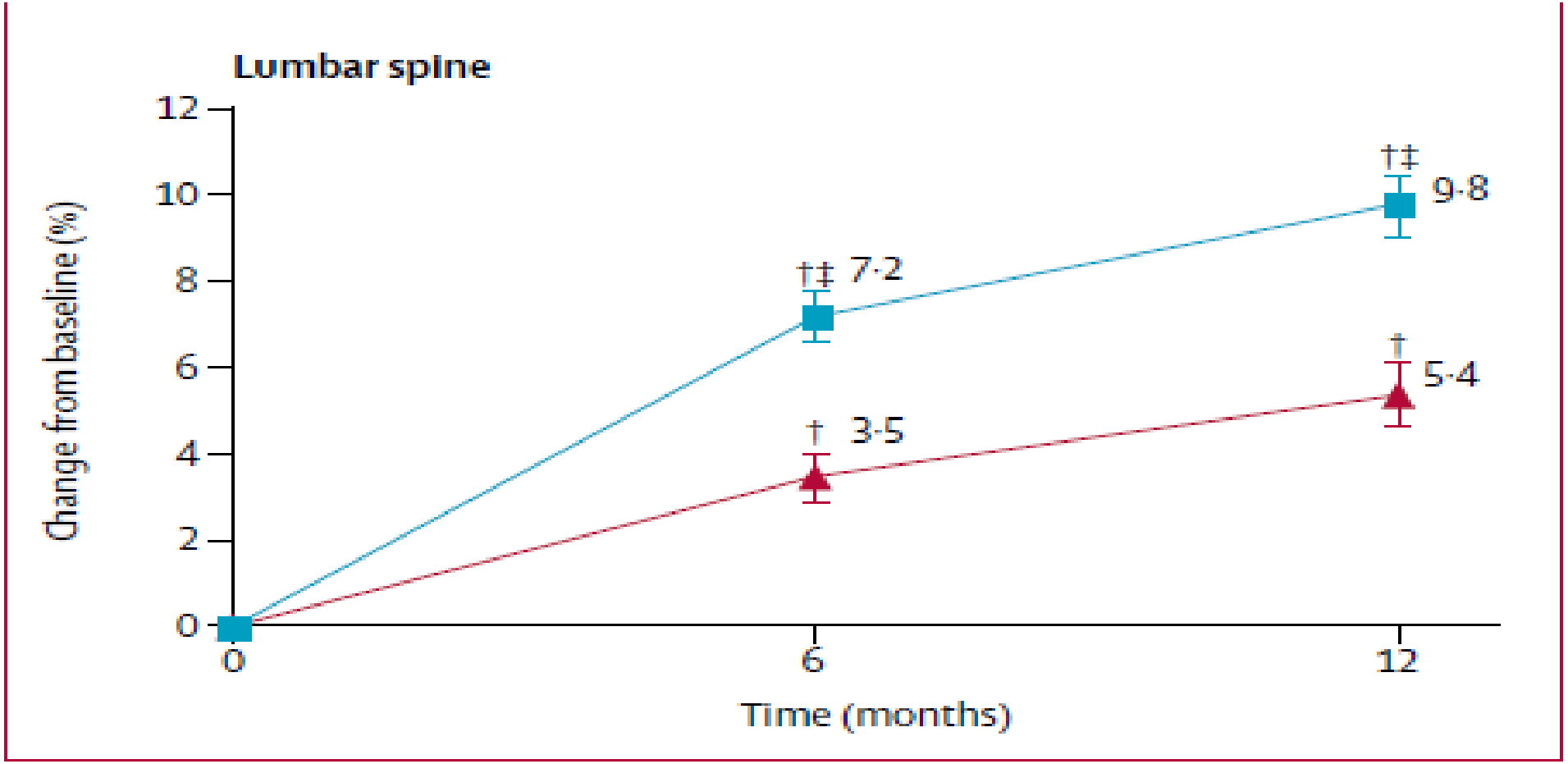
continue denosumab concomitantly with teriparatide either for part of or the full duration of teriparatide



Romosozumab (sclerostin monoclonal antibody) versus **teriparatide** in postmenopausal women with osteoporosis transitioning from oral bisphosphonate therapy 6 years: a randomised, open-label, phase 3 trial




Total hip
Romosozumab (n=206)
Teriparatide (n=209)
Change from baseline (%)
4·0
3·0
2·0
1·0
0
−1·0
−2·0
†‡
2·3
†‡
2·9
*
−0·8
*
−0·5
Femoral neck
Change from baseline (%)
4·0
3·0
2·0
1·0
0
−1·0
−2·0
†‡
2·1
†‡
3·2
*
−1·1
−0·2



In both treatment groups

BMD increases **were blunted** compared to increase in treatment-naïve women.

Treatment option in severe cases

Antiresorptive (Bisphosphonate)

Antiresorptive (denosumab)

Anabolic (teriparatide)

Romosozumab

Followed by antiresorptive treatment

Kendler et al., 2018

What should we do after discontinuation of treatment?

Some recommend discontinuation for fixed duration of 2 years

some recommend monitoring with **bone turnover markers** and restart treatment when the markers are no longer suppressed.

While others recommend following **bone mineral density** and when a significant bone mineral density loss occurs treatment is restarted

Finally, most agree that a new major osteoporotic fracture would be an indication for restarting treatment

conclusion

Monitoring with BMD in 2 years interval may recommended and after treatment

Complete the duration of disease and start holiday

Extended duration of treatment in treatment failure or T<-2,5 is recommended

In severe cases starting treatment with anabolic is preferred

Thank you