Conclusions: We conclude that 12 months of treatment with ibandronate in women with osteopenia did not affect trabecular bone microarchitecture, but improved cortical vBMD at the tibia at 12 and 24 months, as well as Ct.Th at the tibia. This might be relevant regarding protection against nonvertebral fracture

Acknowledgement: This trial has been funded and sponsored by Roche

Disclosure of Interest: RD Chapurlat: Conferences and/or research support and/or board membership: Amgen, Novartis, Roche, Merck, Servier, sanofi-aventis, Lilly. M Laroche: CME, expertises, research support: Servier, Lilly, GSK, Amgen, PG, Warner&Chilcott, Pierre-Fabre, Novartis, Roche, MSD. T Thomas: Selective interventions (fees for advisory activities or speaker's bureau): Amgen, Daiichi-Sankyo, BMS, GSK, Lilly, Merck, Novartis, Roche, Servier, Warner&Chilcott research support: Amgen, Chugaï, Lilly, Merck, Pfizer, Roche, Servier, Warner&Chilcott. S Rouanet: Roche France Employee. MC de Vernejoul: conference and/or research support and/or board membership: Amgen, Roche, Servier, Merck, Lilly.

P345

FREEDOM TRIAL: DENOSUMAB IS NOT ASSOCIATED WITH FRACTURE HEALING COMPLICATIONS IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS

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Objectives: A fracture provides an opportunity to intervene in patients with osteoporosis. However, concerns about potential fracture healing complications may be a barrier to timely initiation of therapy in this setting. In the FREEDOM trial, denosumab, a RANK Ligand inhibitor, significantly reduced the risk of new vertebral, hip and nonvertebral fractures compared with placebo over 3 years in women with osteoporosis.[1] In this prespecified analysis, all complications associated with the management or healing of nonvertebral fractures were assessed.

Materials/Methods: FREEDOM was a 3-year, randomized, double-blinded trial in postmenopausal women aged 60–90 years with low BMD. Women were assigned to denosumab 60 mg SC or placebo every 6 months, with daily elemental calcium and vitamin D. Nonvertebral fractures were radiographically confirmed. Investigators reported all complications associated with the management or healing of each nonvertebral fracture on specific case report forms. Delayed healing was defined as fracture healing not completed within 6 months post fracture. Fracture healing complications were also evaluated by time between fracture occurrence and denosumab administration.

Results: Of the 851 nonvertebral fractures (465 placebo, 386 denosumab) in 667 subjects documented in FREEDOM, 120 (26%) in the placebo group and 79 (21%) in the denosumab group underwent surgical intervention. Complications associated with the fracture or its surgical management occurred in 5.5% of placebo subjects and 1.7% of denosumab subjects ($p<0.01$). Fractures occurred evenly throughout the 6-monthly dosing intervals. There were 6 reports of delayed union (4 placebo, 2 denosumab) and 1 of non-union (placebo). No complications associated with delayed healing/non-union were reported for any nonvertebral fractures ($n=303$) where denosumab was administered within 6 weeks before or after fracture occurrence, including when denosumab was administered as close to the fracture as within 1 day.

Conclusions: Over 3 years, denosumab significantly reduced the risk of nonvertebral and hip fractures compared with placebo, while allowing fracture healing without increased complications, regardless of time of administration. Denosumab provides an opportunity to safely and conveniently address osteoporosis treatment needs before and after fracture occurrence.

Reference: Cummings NEJM 2009;361:756

Acknowledgement: Amgen Inc funded this study.

Disclosure of Interest: This study and the presentation were sponsored by Amgen Inc. SA: Consultant/speaker/advisory activities, Eli-Lilly, Roche, Amgen, MSD.JDA: Grant/research support, Amgen, Eli Lilly, GSK, Merck, Novartis, Pfizer, Procter & Gamble, Roche, Sanofi Aventis, Wyeth, Bristol-Myers Squibb; Consultant/speaker/advisory

activities, Amgen, Astra Zeneca, Eli Lilly, GSK, Merck, Novartis, Nycomed, Pfizer, Procter & Gamble, Roche, Sanofi Aventis, Servier, Wyeth, Bristol-Myers Squibb. SB: Grant/research support, Amgen; Consultant/speaker/advisory activities, Amgen. SC: Grant/research support, Amgen; Consultant/speaker/advisory activities, Amgen, Lilly. LdG: Grant/research support, Lilly, AMGEN, Merck Sharp & Dohme, Wyeth, Novartis, Roche, Aventis, Pfizer. NG: Grant/research support, Amgen. GL: Grant/research support, Amgen. SP: Speaker/advisory activities, Pfizer, Bayer Schering Pharma, Servier, Lilly, Daiichi-Sankyo, Roche, Warner Chilcott, Amgen, Arkopharma, Boehringer-Ingelheim; Research grants/consulting fees, Pfizer, Servier, Lilly, Daiichi-Sankyo, Amgen, Arkochim, Bayer Schering Pharma. KP: Grant/research support, Amgen. HR: Grant/research support, Roche and Lilly; Consultant/speaker/advisory activities, Roche, Lilly, Amgen, Servier, MSD, Novartis, Nycomed. CR: Grant/research support, Amgen; Consultant/speaker/advisory activities, Amgen. DU: none declared. ES: Consultant/speaker/advisory activities, Amgen, Merck, Novartis, Eli Lilly. CL, GM, PRH, AW: Employee and Stockholder, Amgen.

P346

RISK FACTORS FOR OSTEOPOROTIC HIP FRACTURES: ANTIOXIDANTS AND RADICALS

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Objectives: Proximal femoral fractures occur as the results of osteoporosis and decrease in bone strength by aging in both genders. The production of free radicals by osteoclasts increases the destruction of calcified tissue. An excessive increase in these radicals disturbs the prooxidant–antioxidant balance while antioxidant systems protect the organism against reactive oxygen species. The aim of our study was to determine the levels of total antioxidant status and free radicals for to associate them with hip fracture risk in different fracture types.

Materials/Methods: 24 patients (Group 1; 18 female/6 male, mean age 75.16±6.89 years) with femoral neck fractures, 38 patients (Group 2; 23 female/15 male, mean age 77.52±6.74 years) with intertrochanteric fractures of hip were included in the study. All fractures were due to low energy trauma, simple falls. BMD measurements were done with Lunar DXA. The measurements were performed on the intact side of the hip and obtained as femoral neck, wards, trochanteric and total BMD values. Total antioxidant status (TAS, mmol/L) was determined by Randox manuel kit, nitrite-nitrate levels (μmol/L) were done by Roche colorimetric kit and nitrotyrosine levels (nmol/L) were done ELISA (Hycult Biotech). Cortizol (μg/dL), Vitamin A (μmol/L) and Vitamin E (μmol/L) were measured by relevant methods with autoanalyzers.

Results: Neck, trochanter and total BMD values were in agreement for osteoporosis. There were no significant differences between the two groups for all BMD values. The mean and standard deviation values for TAS levels in Group 1 (1.26±0.13) was significantly higher than Group 2 (1.15±0.21), $p<0.037$. There were not any differences for cortisol, nitrite-nitrate and Vit E levels. Nitrotyrosine levels were increased in Group 2 (83.18±8.47) compared to Group 1 (81.50±8.06). Besides Vit A levels were decreased in Group 2 (1.05±0.43) compared to Group 1 (1.46±0.70).

Conclusions: The decreased levels of total antioxidant status and increased levels of nitrotyrosine of the patients with intertrochanteric hip fractures can indicate an insufficient antioxidant enzyme system and deficiency that may lead to a variety of nutritional and vascular disorders that all results were in agreement with the clinical severity.

Disclosure of Interest: None declared.

P347

UNDERCARBOXYLATED OSTEOCALCIN IN RELATION TO PLASMA GLUCOSE AND FAT MASS IN PATIENTS WITH TYPE-2 DIABETES MELLITUS: A CROSS-SECTIONAL STUDY

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Objectives: To study the relationships between undercarboxylated osteocalcin (unOC), other bone turnover markers (BTMs), serum glucose and adiponectin together with fat mass among patients with Type 2 diabetes mellitus (T2DM).

Materials/Methods: A total of 630 patients with T2DM [postmenopausal women (n=350; men (n=275); age range 50–79 years] were studied. Each patient completed a questionnaire and provided blood and urine samples. Anthropometric parameters, socioeconomic status, together with the measurements of serum unOC, BTMs [namely: