

# From EFOS to ExFOS. Any news with teriparatide prescription habits in Greece?

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## ABSTRACT

**Purpose:** Extended Forsteo Observational Study (ExFOS), a multinational, non-interventional, prospective, observational study to evaluate fracture outcomes, back pain, compliance and health-related quality of life in osteoporotic male and female patients treated with teriparatide(TPTD), has followed European Forsteo Observational Study (EFOS) on postmenopausal women, aiming to provide more data on the *effect of the extension of treatment duration from 18 to 24 months* and the new indications (*glucocorticoid induced and male osteoporosis*). We list alongside the results recorded in Greece.

**Methods:** Baseline characteristics of Greek participants in EFOS are juxtaposed with those of participants in ExFOS. Data regarding by sex analysis of the latter cohort (post-hoc analysis) is incorporated. Descriptive comparison of the Hellenic population of EFOS and ExFOS is attempted.

**Results:** ExFOS enrollment speed in Greece is 45% increased compared to EFOS. Enrollers are as elderly, exhibiting equally low bone density. Profile is somewhat different between sexes. As in EFOS, ExFOS patients complain of relatively frequent, severe back pain. Currently enrolled patients smoke more (male derived increase) but are more active (higher exercise rates and less need of arms assistance to rise). Noticeably, numerically fewer patients (especially in the female population) had fracture history, especially vertebral, compared to the Hellenic EFOS cohort. Approximately one in five patients, a fraction equivalent to that observed in EFOS, had no antiosteoporotic treatment whatsoever. A numeric decrease in calcitonin and an increase in bisphosphonates use, as prior antiresorptives, can be displayed.

**Conclusions:** Hellenic EFOS patients share similarities with female ExFOS patients but also have noticeable differences that may indicate a relative change towards prescription in less severely affected patients. Differences observed between male and female ExFOS TPTD users may reflect distinction in osteoporosis diagnosis and treatment for males. Data are interpreted in the context of an observational setting.

## INTRODUCTION

### EFOS (European Forsteo Observational Study)

European (8 countries), 3-year, prospective, observational program evaluated the long-term effectiveness of teriparatide, for a maximum **treatment duration of 18 months** and another **18 month follow up**, in a naturalistic setting.

\***In Greece**, 302 female patients enrolled in 31 investigative sites:  
-Enrollment: 05/Jul/2004 - 30/Sep/2005  
-Recruitment rate: 0.65 pts/site/month

### ExFOS (Extended Forsteo Observational Study)

European, prospective, non-interventional, observational study to evaluate fracture outcomes, back pain, compliance and health related QoL in patients prescribed teriparatide under **new indications** (24 m, male, GIOP) with maximum treatment 24 months, post-treatment follow-up of at least 18 months

\* **In Greece**: 439 patients (92.3% (405) female), 32 investigative sites:  
-Enrollment 16/Feb/2011 - 24/May/2012  
-Recruitment rate: 0.94 pts/site/month

## METHODS

Juxtaposing baseline Hellenic data of two "sibling" studies.

A post hoc by sex analysis for ExFOS has been implemented.

Conclusions are based on descriptive comparison as no statistical analysis could be applied.

### \*The Hellenic ExFOS Study Group:

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## RESULTS

Hellenic population	ExFOS total population	ExFOS males	ExFOS females	EFOS <sup>2*</sup>
Mean (SD) age (years)/N	70.1(9.8)/439	71.5 (10.3) /34	70.0(9.8) /405	70.0(8.5)
Mean (SD) BMI (kg/m <sup>2</sup> ) /N	26.7(4.3)/412	26.4 (4.6) /34	26.7 (4.3) /378	26.3(4.0)
<b>Menstrual history (women) /N</b>				
Mean time since menopause (years) /N	-	-	22.1(10.3) /385	24.4(9.0)
Mean fertile period (years) /N	-	-	34.6(5.6) /325	32.4(5.9)
Premature menopause/N	-	-	5.5% / 21	9.3%
<b>Fracture risk factors</b>				
Current smokers	12.1% /52	33.3% /11	10.4% /41	12.6%
No exercise	49.2% /209	61.8% /21	48.1% /188	71.5%
Hip fracture in biological mother	18.1% /57	14.8% /4	18.4% /53	16.6%
One or more falls in the preceding year	37.1% /153	50.0% /15	36.0% /138	40.7%
Assist with arms	41.3% /180	58.8% /20	39.8% /160	92.1%
<b>Prior Treatments</b>				
Prior antiosteoporotic treatments	80.2% /439	55.9% /19	82.2% /333	83.1%
• Calcitonin	23.2% /102	5.9% /2	24.7% /100	64.6%
• Bisphosphonates	59.0% /259	32.4% /11	61.2% /248	36.1%
Prior glucocorticoid use	8.9% /39	17.6% /6	8.1% /33	14.6%
<b>Quality of life variables</b>				
Back pain (in the previous year)	88.4% /388	76.5% /26	89.4% /362	97.4%
Moderate to severe pain in month previous to enrollment	80.9% /304	88.0% /22	80.4% /282	85.3%
Mean (SD) EQ-5D VAS (cm)	57.0(21.7) /421	56.9 (20.7) /33	57.0 (21.8) /388	54.2(24.9)

### Baseline bone health

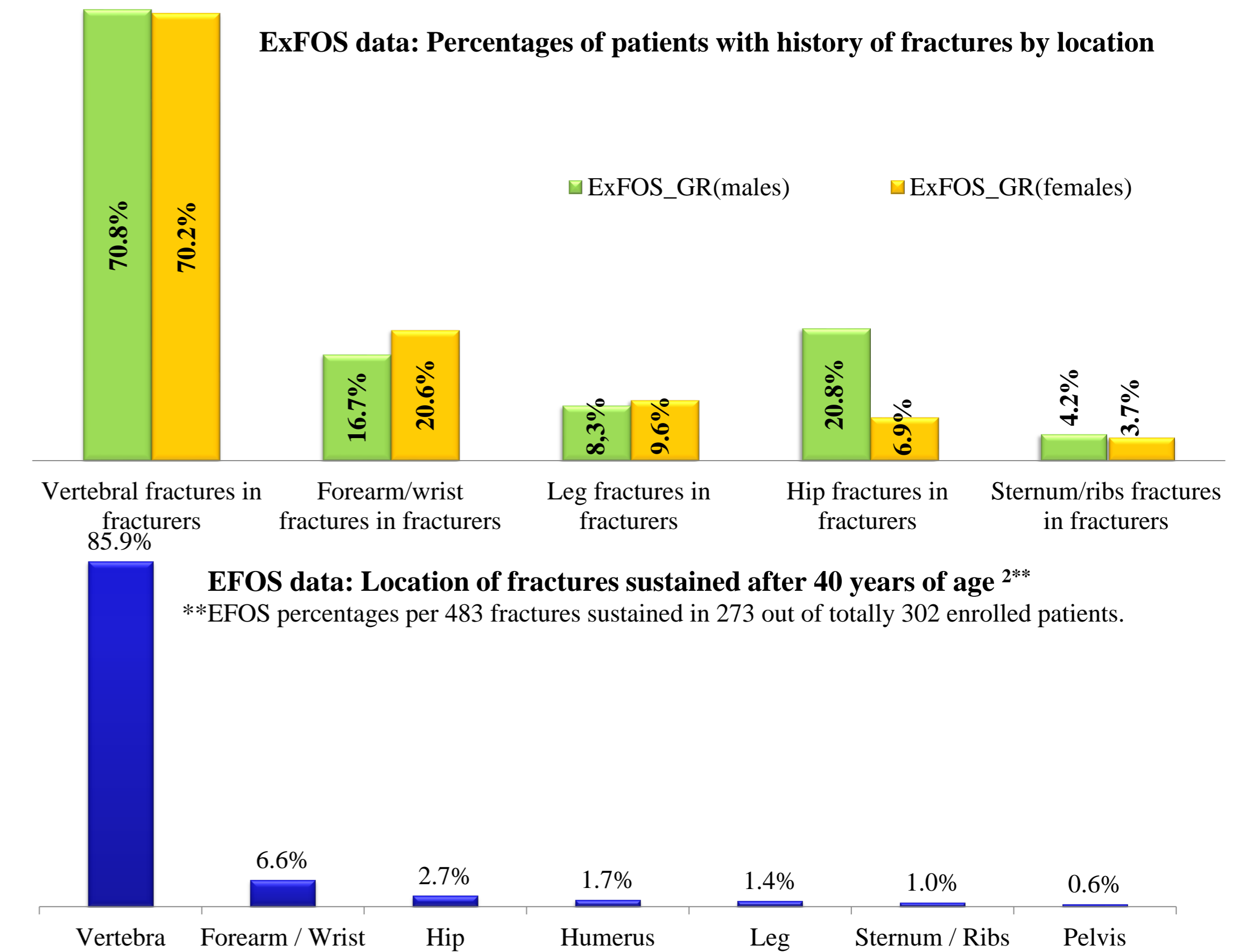
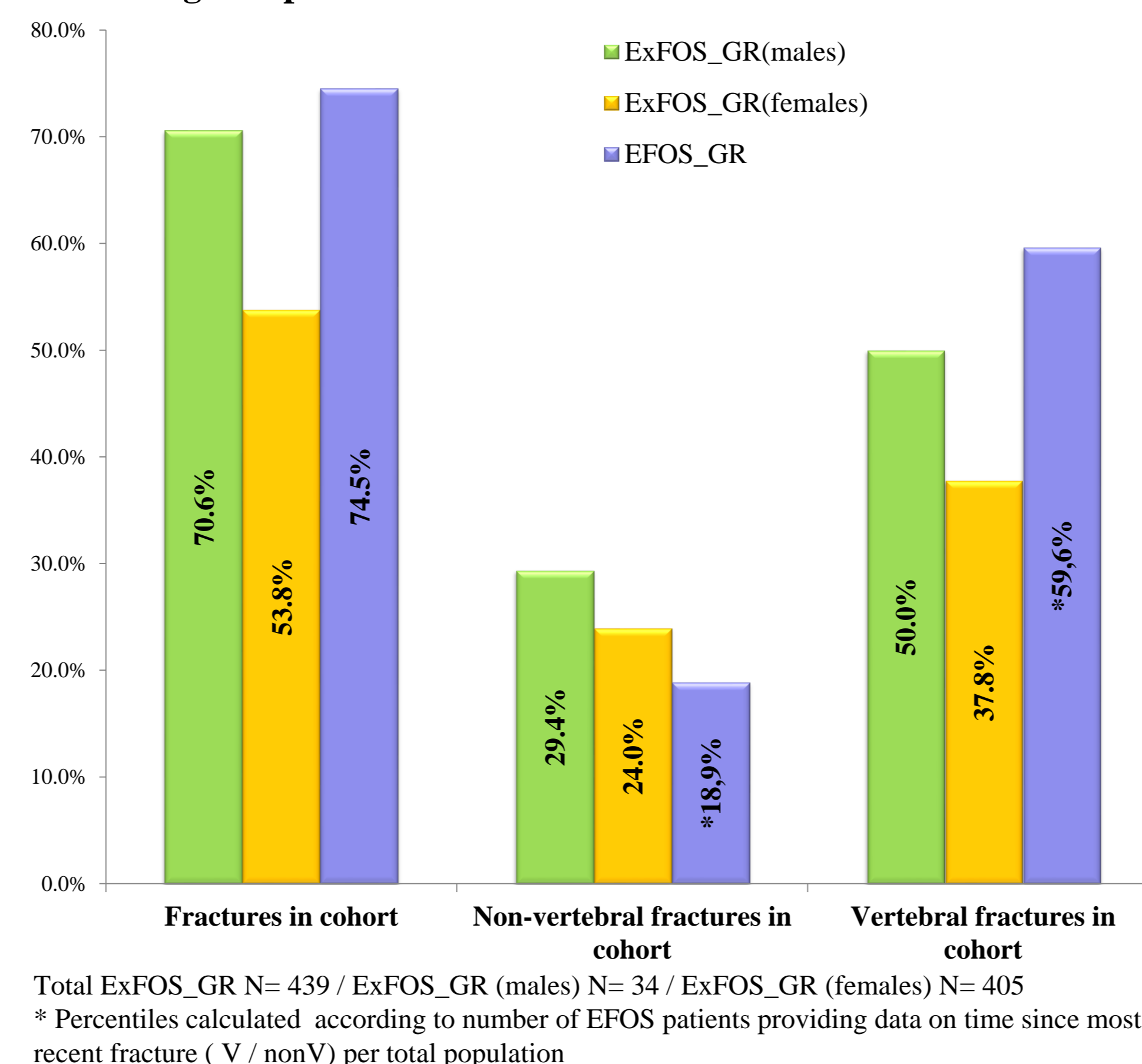
DEXA BMD values similar

Hellenic population	ExFOS ALL	ExFOS males	ExFOS females	EFOS <sup>2*</sup>
Mean (SD) DXA BMD Spine	-3.4(0.7) /280	-3.3(1.3) /17	-3.4(0.7) /263	-3.4(0.7)
Mean (SD) DXA BMD total hip*	-3.2(0.5) /82	-3.4(0.6) /7	-3.2(0.5) /75	-2.8(1.1)
Mean (SD) DXA BMD Femoral neck*	-2.8(1.2) /45	-3.0(0.4) /4	-2.8(1.2) /41	-3.1(0.8)

\*higher N included

**Fracture history** 74.5% in EFOS compared to 53.8% in ExFOS women and 70.6% in ExFOS men

### Percentages of patients with at least one fracture



## CONCLUSIONS

Hellenic EFOS patients share similarities with female ExFOS patients but also have noticeable differences that may indicate a relative change towards prescription in less severely affected patients.

Differences observed between male and female ExFOS TPTD users may reflect distinction in osteoporosis diagnosis and treatment for males. Data are interpreted in the context of an observational setting.

### LITERATURE

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- Karras et al, *Bone (Journal of the Hellenic Society for the Study of Bone Metabolism)*, vol. 20, no. 3, article 156, 2009