

From EFOS to ExFOS, active treatment phase. Similarities and differences of the Greek cohorts' results

K. Aloumanis¹, P. Kokkoris², A. Kleisiounis², E. Kofini¹, K. Karachalios¹, V. Drossinos¹, G. Kapetanios³, for the Hellenic ExFOS study group

¹Department of Medical Research, Pharmaserve Lilly SACI ²Private Medical office ³3rd Orthopedics University clinic, Papageorgiou General Hospital, Thessaloniki, Greece.

ABSTRACT

Introduction: Extended Forsteo® Observational Study (ExFOS), a multinational, non-interventional, prospective, observational study, designed to evaluate fractures, back pain (BP), adherence and health-related quality of life (QoL) in teriparatide (TPTD) treated patients, based on the extension of treatment duration (24 months) and the addition of new indications (glucocorticoid-induced and male osteoporosis) was compared with EFOS.

Methods/design: Baseline data showed that Hellenic EFOS patients share similarities and noticeable differences with female ExFOS patients¹. To further evaluate such similarities / differences between the two studies, we aimed to compare the active treatment results of the Greek cohorts between EFOS² (N=301, all female) and ExFOS (N=416, 92.1% female). No statistical comparisons between studies were performed.

Results: Approximately 80% of patients in both cohorts were on treatment one month before maximum treatment period. Lumbar T-score (mean±SD) increased from -3.46±0.67 (N=175) at baseline to -2.54±0.74 (N=120) at study end in EFOS and from -3.39±0.73 (N=263) to -2.36±0.63 (N=78) in ExFOS. QoL and BP parameters had similar improvements, as shown by examples depicted below:

		Baseline	3 m.	6 m.	12 m.	18 m.	24 m.
BP (in previous month)	ExFOS	86.2%	79.3%	72.2%	65.6%	59.2%	42.2%
	EFOS	93.2%	84.6%	77.8%	66.4%	64.2%	
BP frequency (every/almost every day)	ExFOS	43.8%	12.4%	6.6%	4.3%	4.7%	0%
	EFOS	39.9%	7.5%	3.9%	2.5%	2.2%	
BP severity (moderate/severe)	ExFOS	76.2%	50.4%	32.8%	20.9%	22.2%	18.6%
	EFOS	89.9%	69.4%	50.7%	42.4%	32.4%	
EQ-5D Mobility (some/extreme problems)	ExFOS	57.9%	38.9%	29.9%	22.5%	17.7%	16.2%
	EFOS	62.3%	36.7%	24.0%	18.3%	14.8%	
EQ-5D VAS	ExFOS	57	66	71	75	77	83
	EFOS	54	64	69	74	80	

Conclusions: Two similarly designed studies, in comparable Hellenic populations, yielded similar results that should be interpreted in the context of observational studies

INTRODUCTION

Extended Forsteo® Observational Study (ExFOS), a multinational, non-interventional, prospective, observational study, designed to evaluate fractures, back pain (BP), adherence and health-related quality of life (QoL) in teriparatide (TPTD) treated patients, based on the extension of treatment duration (24 months) and the addition of new indications (glucocorticoid-induced and male osteoporosis) was compared with EFOS¹⁻³.

METHODS

Baseline data showed that Hellenic EFOS patients share similarities and noticeable differences with female ExFOS patients¹.

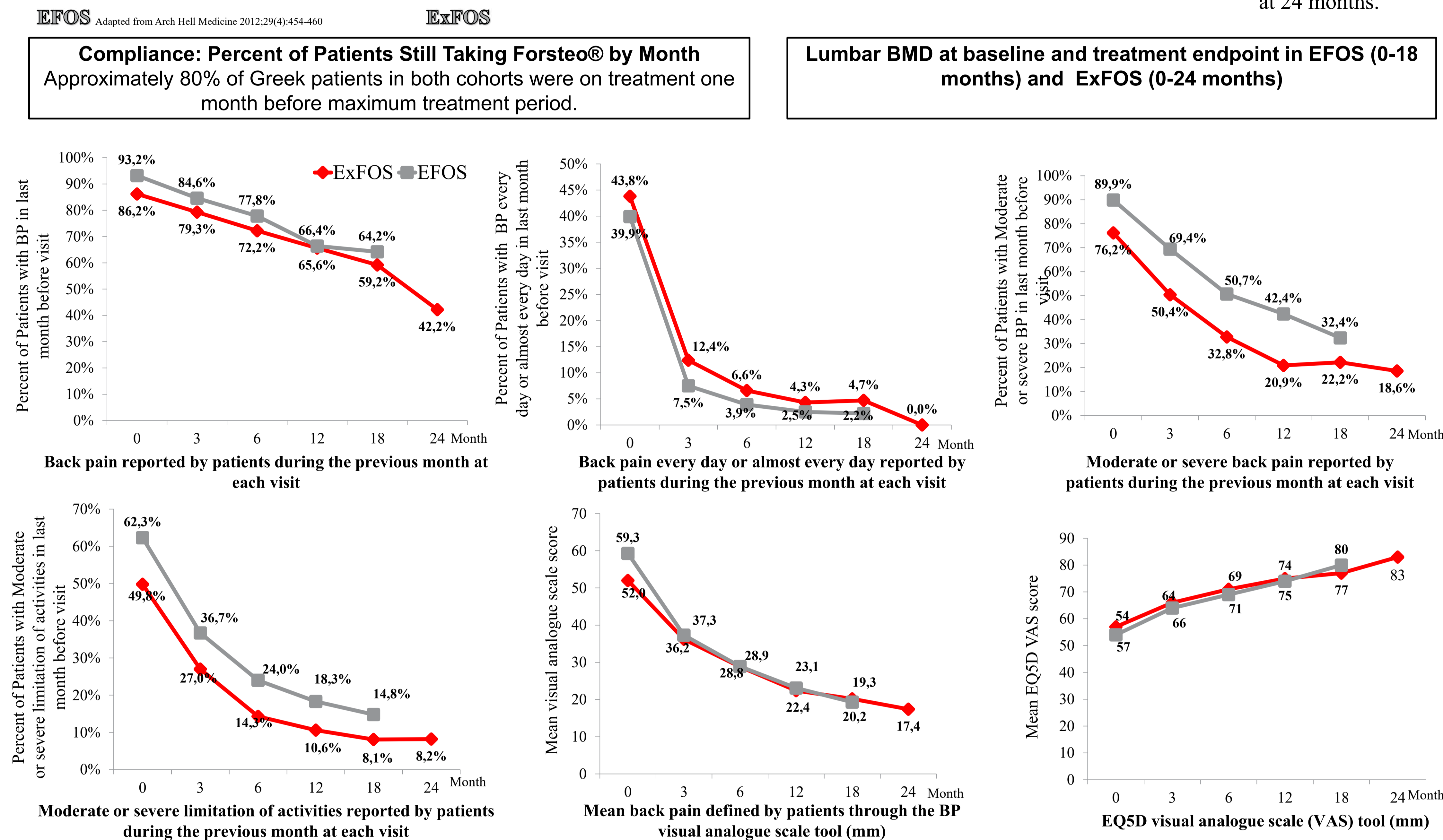
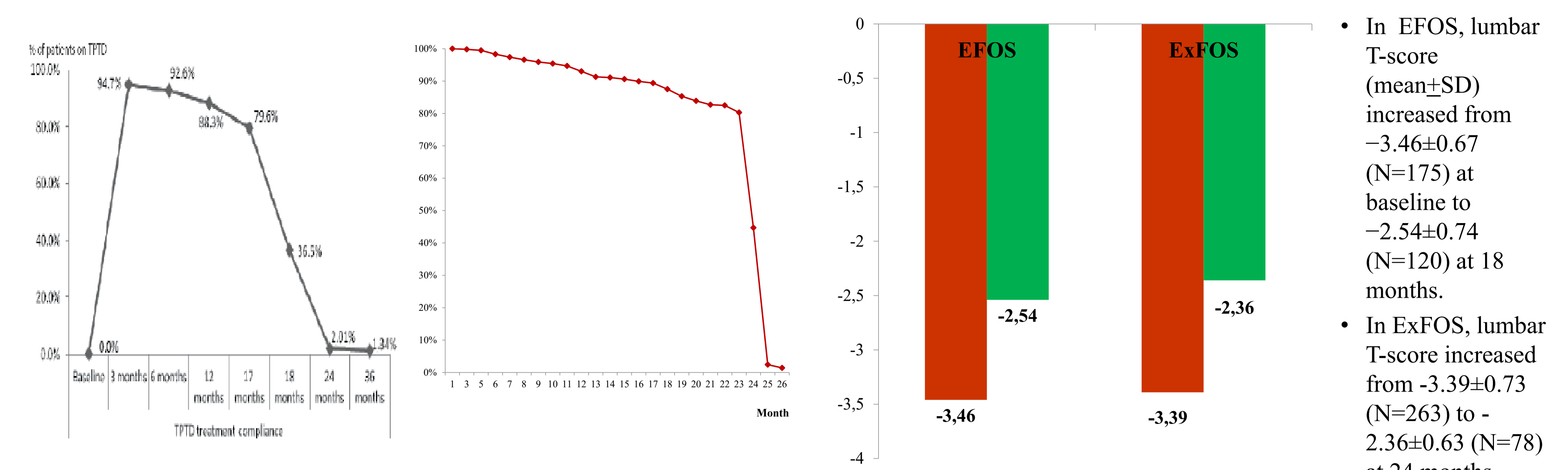
To further evaluate the effect of the similarities / differences between the two studies on the response to therapy, we aimed to juxtapose the active treatment results of the Greek cohorts between EFOS² (N=301, all female) and ExFOS (N=416, 92.1% female). No statistical comparisons were performed.

REFERENCES: ¹BMC Musculoskelet Disord. 2015;16:136 ²J Osteoporos. 2011;2011:510398. doi: 10.4061/2011/510398. Epub 2011 Sep 20, ³Archives of Hellenic Medicine. 2012;29(4):454-460

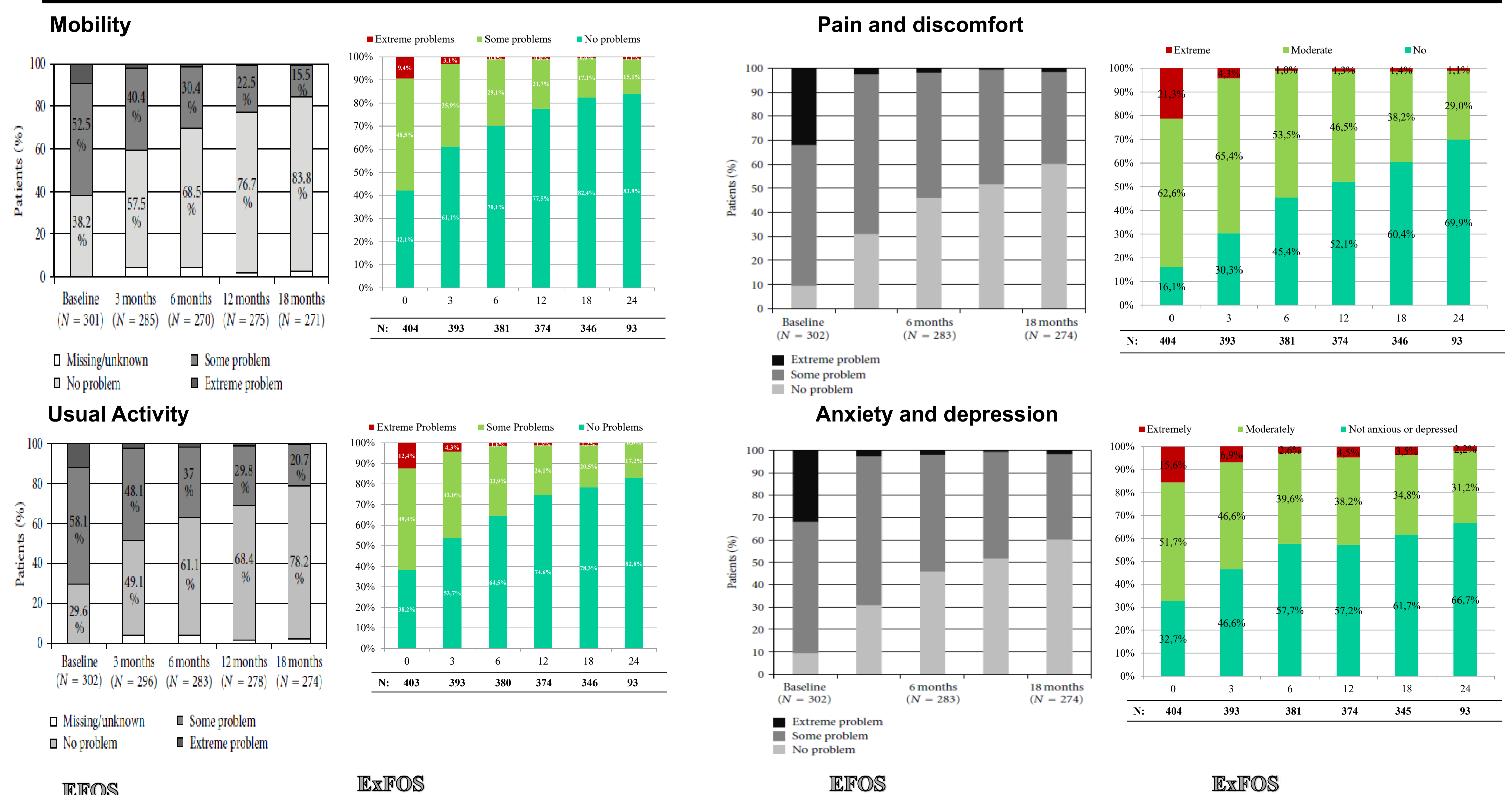
*The Hellenic ExFOS Study Group:

Adam A, Alexandridis T, Athanasakopoulos P, Bintas S, Dimopoulos N, Dionyssiotis Y, Georgountzos A, Giannadakis P, Gouvas G, Kapetanios G, Kaplanoglou T, Karagiannis A, Kleisiounis A, Kokkoris P, Kosmidis C, Kossyvakis K, Krallis N, Matsouka A, Matzaroglou C, Meleteas E, Milonas C, Papaioannou N, Papazisis Z, Repousis AP, Savvidis M, Temekonidis T, Trovas G, Tsakiri V, Tzoiou M, Tzoutzopoulos A, Vadoros G, Ziabaras K

RESULTS



EQ-5D parameters



CONCLUSIONS

The two studies have differences, for example new indications and extension of treatment period in ExFOS, but overall the design and execution of the studies is quite similar.

In both EFOS and ExFOS we record a parallel increase in BMD, a decrease in back pain parameters and an increase in patient mobility/activity. Additionally, Quality of Life parameters seem to be improving in a similar manner. Results that should be interpreted in the context of observational studies.

