

FLEXIQULE™

Chapter 12 **MANAGEMENT OF OSTEOARTHRITIS (OA) WITH THE PHARMA-STANDARD (PS) SUPPLEMENT FLEXIQULE™ (BOSWELLIA): A 6-MONTH REGISTRY. SAFETY AND LONG-TERM EFFICACY**

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A recent study has shown the efficacy of a new natural PS Supplement (FlexiQule™, including Boswellia as a main ingredient) in symptomatic arthrosis of the larger joints in otherwise healthy subjects.

The study indicated that most patients benefit from the regular management with FlexiQule™, improving quality of life, walking distance and most parameters linked to the WOM-AC score.

This registry study is assessing this new pharma-standard supplement FlexiQule™ (Boswellia in soft gel capsules) in the evolution and management of symptoms associated to osteoarthritis also managed with a 'standard management'

(SM). A comparison group of patients was managed only with the SM (according to the Merck Manual).

The 12-week registry included patients able to walk on a treadmill for a standardized walking test and to complete the WOMAC questionnaire (relative to the most common symptoms).

RESULTS

32 patients used the supplement and 34 acted as controls (SM). No safety problems were observed in 12 weeks; the Karnofsky scale was significantly improved in both groups: the variation (improvement) was higher ($p < 0.05$) in the supplement group.

The WOMAC score was decreased more in the supplement+SM group in comparison with controls (considering pain, stiffness and physical functions) ($p < 0.05$).

For social and emotional functions the decrease in score was also more evident in the FlexiQule™ group ($p < 0.05$). Both groups improved in pain-free and total walking distance at 12 weeks. Pain-free walking distance (treadmill) was higher ($p < 0.05$) with the supplement than in controls.

The improvement in total walking distance was also higher in the supplement group ($p < 0.05$) in comparison with SM.

The need for concomitant drugs use and for medical attention during the registry was reduced more with the supplement ($p < 0.05$).

Table 12.1. Variation in walking distance with FlexiQule™.

Pain-free walking distance	<i>Inclusion</i>	<i>3 months</i>	<i>5 months</i>
(Treadmill)			
Supplement	93.4;11.6 M	271.3;19.3	332;22
Controls	90.5;13.5	158.3;22.3	169;34
Total walking distance			
Supplement Group	164.3;23.2	322.3;22.3	378;29
Controls	158.3;18,4	240.2;19.3	288;33

In 12 weeks the difference between SM and the FlexiQule™ + SM was in favour of the management with the supplement for all target measurements.

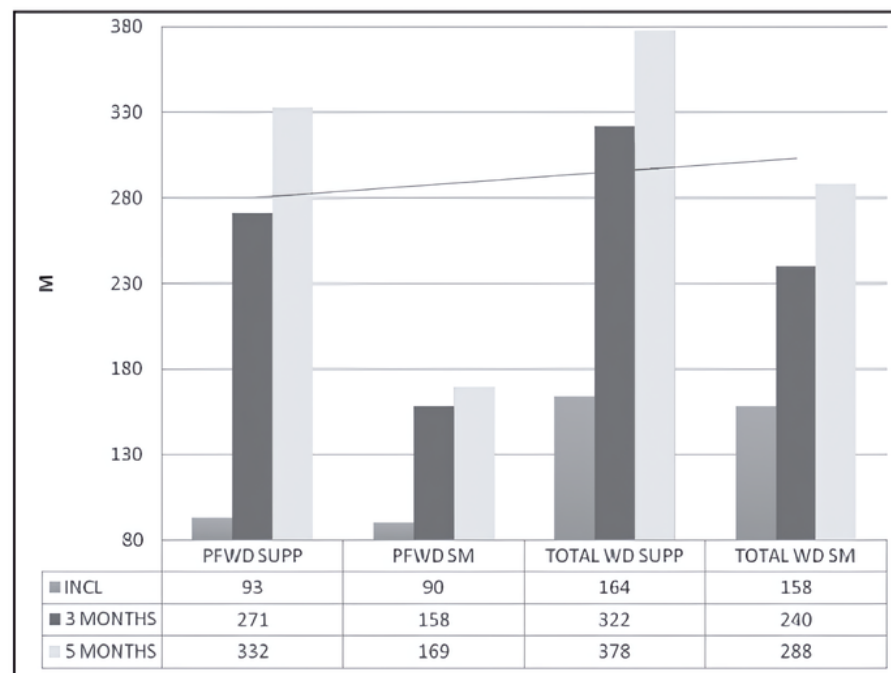


Figure 12.1. Variation in walking distance with FlexiQule™. The general improvement trend is shown. Variations are expressed in meters.

The present extension to 6 months included more patients (53 FlexiQule™ vs 58 controls are completing 5 months of supplementation) and data (still in elaboration at 5 months) confirmed a further improvement.

All subjects should complete a 6 months follow up in weeks.

In conclusion, even with a more prolonged supplementation, FlexiQule™ shows to be safe and well tolerated.

References

1. Belcaro G, Dugall M, Luzzi R, Ledda A, Pellegrini L, Hu S, Ippolito E. Management of osteoarthritis (OA) with the pharmaceutical supplement FlexiQule™ (Boswellia): a 12-week registry. *Minerva Gastroenterol Dietol.* 2015 Oct 22. (Epub ahead of print).