

Flexiqule+Centella asiatica; dose ranging. Osteoarthritis cartilage study. Extension study

S. Hu, G. Belcaro, M. Hosoi, M.R. Cesarone, M. Dugall

1. Irvine3 Labs, Pescara

2. Dept SMOBiotec, Ch-Pe University, Pescara

3. IA-PSS: International Agency for Pharma-Standard Supplements, Pescara-Geneve

ABSTRACT

The product Flexiqule C includes 150 mg of boswellia in each capsule (the daily dose was 300 mg/day) and 25 mg of ginger (daily dose of 50 mg/day).

In this extension, morphological study Centella Asiatica was added in this group in two different doses in a dose ranging evaluation:

- Group a: 50 mg/day (one daily dose).
- Group c; 300 mg/day in 3 doses.
- Group b included the SM (standard management) group.

Aim of the extension study was a dose ranging evaluation of the effects of centella asiatica on the joint cartilage.

Conclusions. This extension (dose ranging) study appears to indicate that a higher dose of CA may produce a significant more important and faster improvement in the articular cartilage (particularly in younger subjects) in association with the positive effects of Flexiqule on knee pain and inflammation.

The improvement in morphology (thickness of the cartilage at the articular surface) appears to be related to a better function in patients in a relatively short period of time. More prospective studies are needed for a longer period of time.

Key Words: cectella asiatica, collagen, knee cartilage, arthrosis, boswellia, ginger, knee

INTRODUCTION

The product Flexiqule C includes 150 mg of boswellia in each capsule (the daily dose was 300 mg/day) and 25 mg of ginger (daily dose of 50 mg/day).

In this extension, morphological study Centella Asiatica was added in this group in two different doses in a dose ranging evaluation:

- Group a: 50 mg/day (one daily dose)
- Group c; 300 mg/day in 3 doses.
- Group b included the SM (standard management) group.

Aim of the extension study was a dose ranging evaluation of the effects of centella asiatica on the joint cartilage.

METHODS

Methods are described in detail in Chapter 1 (Flexiqule+Centella Asiatica; Osteoarthritis Cartilage Study; Hu Shuh et al.)

In this preliminary report, only the thickness at the cartilage is shown with the relative Karnofsky scale (indicating the global physical capacity).

Results are shown at inclusion (the thickness is considered 100%) and after 6 months of supplementation.

Measurements were obtained with high resolution ultrasound (Preirus, Hitachi and a specific elastosonography software).

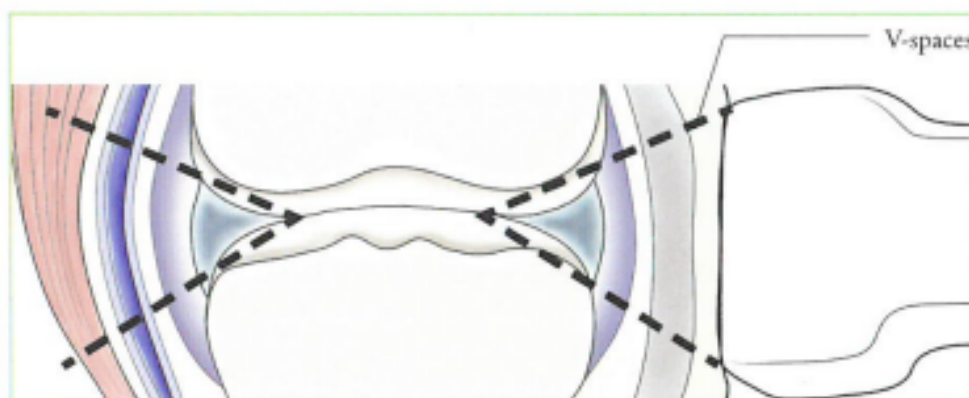


FIGURE 7.1. Localization of the ultrasound imaging at the knee V-space (the test is possible when no calcifications or important irregularity is present). The medial-interval surface is preferred for this test.



FIGURE 7.2. An irregular cartilage surface with significant differences in thickness (steps) visible on the scans. The thickness of the 'white' echogenic layer (cartilage) may be measured with precision, up to 0.02 mm. Periostium/cartilage irregularities, visible as 'steps'

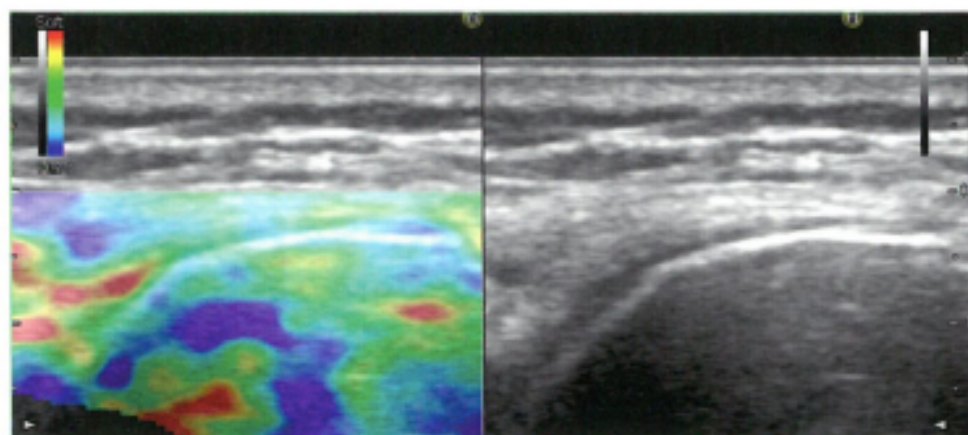


FIGURE 7.3. differences in density at the joint, and at its articular spaces can be evaluated (and measured) by high-resolution elastosonography. Densitometry-Elastosonography, Preirus, Hitachi.

Figures 7.1-7.3 show samples of the measurements sites and targets as described in Chapter 1.

RESULTS

There were no significant side effects or tolerability problems.

All included subjects completed the 6 months without problems.

The 3 supplement groups are shown in Table 7.I.

They included all males (BMI<25.5) and were strictly comparable for symptoms and their localization at the knee. They all used SM.

Table 7.II shows the variations in cartilage thickness at the knee.

The variations are expressed as a percent of the original value (considered 100% at inclusion). There was a more important increase with the higher dose of CA ($p<0.05$). Also, the Karnofsky scale indicated a better improvement with the high dose of CA ($p<0.05$).

TABLE 7.I. THE 3 SUPPLEMENT GROUPS OF THE EXTENSION STUDY INCLUDED ALL MALES (BMI<25.5) AND WERE STRICTLY COMPARABLE FOR SYMPTOMS AND THEIR LOCALIZATION AT THE KNEE (MAINLY ONE SINGLE KNEE).

All males

Groups		Number of cases	Age
A. PS Supplement	Flexiqule with ca 100mg	12	47.5;1.5
B. Standard Management	Controls	16	47.2;2
C. Controls2	Flexiqule with ca 300 mg	10	47.35;1.3

TABLE 7.II. THE VARIATION IN CARTILAGE THICKNESS. THE VARIATIONS ARE IN PERCENT OF THE ORIGINAL VALUE (CONSIDERED 100%).

Groups	Cartilage thickness inclusion and 6 months	Karnofsky (0-100%) scale inclusion and 6 months
FLX	100%	92.2;2
+CA 50 mg	+8.3%	93;0.8
SM controls	100%	93.1;1.2
6 months	+0.45%	94.3;0.6
FLX+	100%	90.2;1.1
Cent. As. 300 mg	22.7%	95.3;2*

Cartilage thickness (considered the most important target measurement) was increased, significantly more in the Flexiqule-C group with 300 mg/day of Centella Asiatica.

The increase was measured by high-resolution ultrasound at the knee, where the cartilage is visible. Table values express increase in % (from the initial thickness value = 100%).

*= better than controls.

CONCLUSIONS

This extension (dose ranging) study appears to indicate that a higher dose of CA may produce a significant more important and faster improvement in the articular cartilage (particularly in younger subjects) in association with the positive effects of Flexiqule on knee pain and inflammation.

The improvement in morphology (thickness of the cartilage at the articular surface) appears to be related to a better function in patients in a relatively short period of time. More prospective studies are needed for a longer period of time.