


OBJECTIVES

To conduct a randomized controlled double-blind clinical trial, to assess the efficacy of three different doses of BoNT-A intramuscular injections and possible adverse effects of this treatment in patients with persistent masticatory myofascial pain; in order to stablish a treatment protocol




100 volunteers

- 18 – 45 years
- Myofascial pain
- Contraceptive use
- Pain ≥ a 3m
- Previous treatments

Randomization

Ultrasonography

5 groups



C/BoNTA-L

10U T

30U M

C/BoNTA-M

20U T


50U M

C/BoNTA-H

25U T

75U M


C/SP

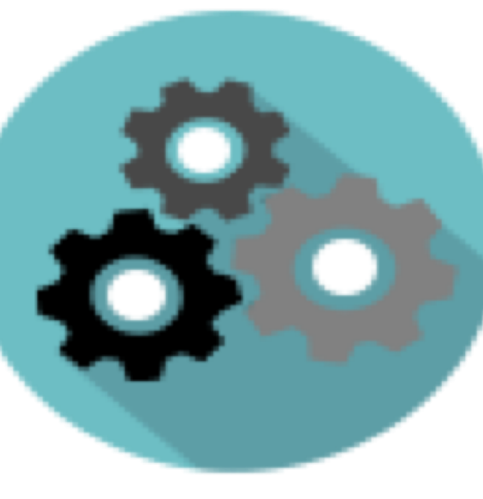


C/SS

0,4 T


1ml M





METHODS

Pain Preasure Threshold

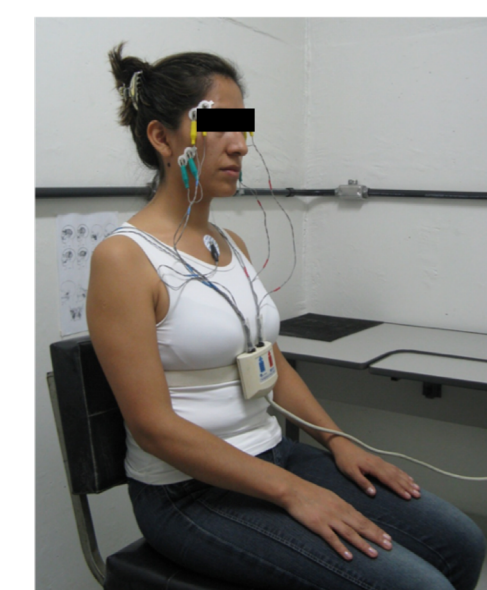


TD,MD, ME,TE


TE,ME, MD,TD

Eletromiography

MVC (5s)



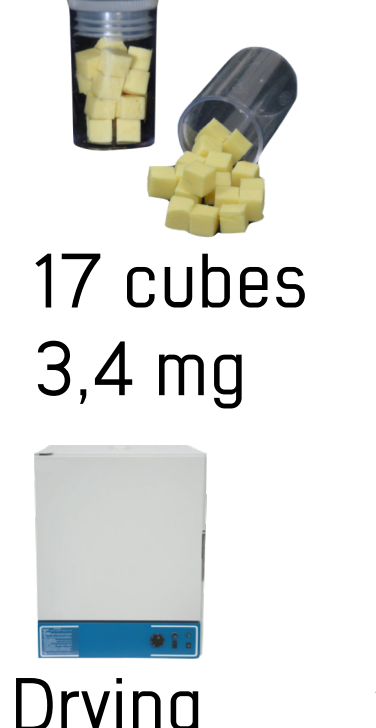
Ultrasonography



Relaxed

Contracted

Masticatory Performance



17 cubes 3,4 mg

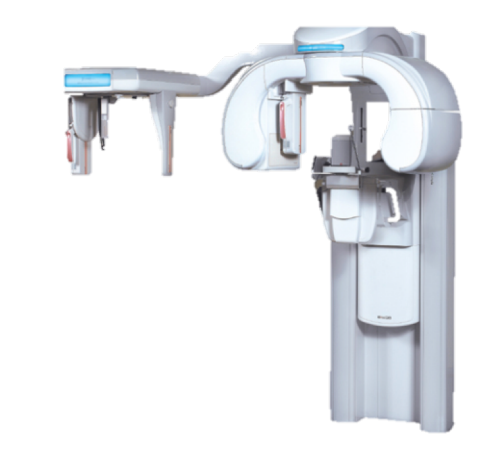
20 Cyclos

Desinfection

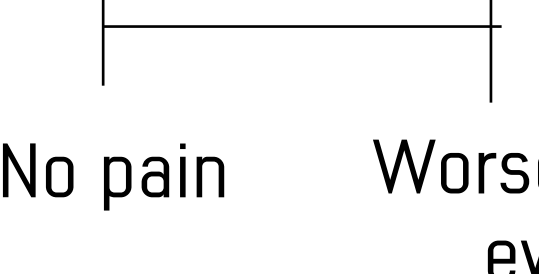
10 Sieves

Weighing

Cone Beam Tomography




Visual Analogue Scale




No pain

Worse pain ever




Evaluation Periods

7, 14, 21, 28, 90 and 180 days

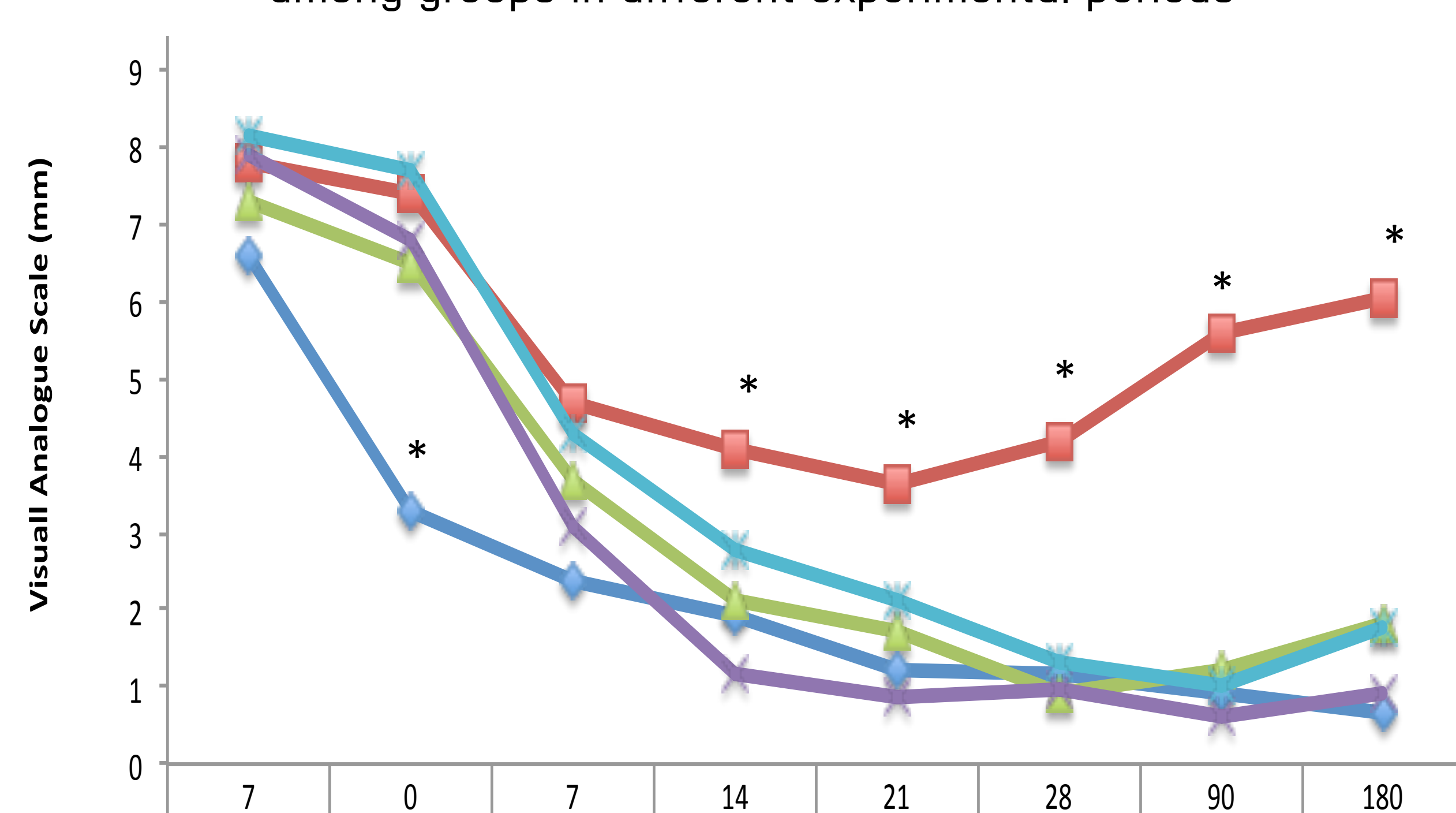


Linear mixed model test was used for comparisons between groups and evaluation periods (p<0.05).



RESULTS

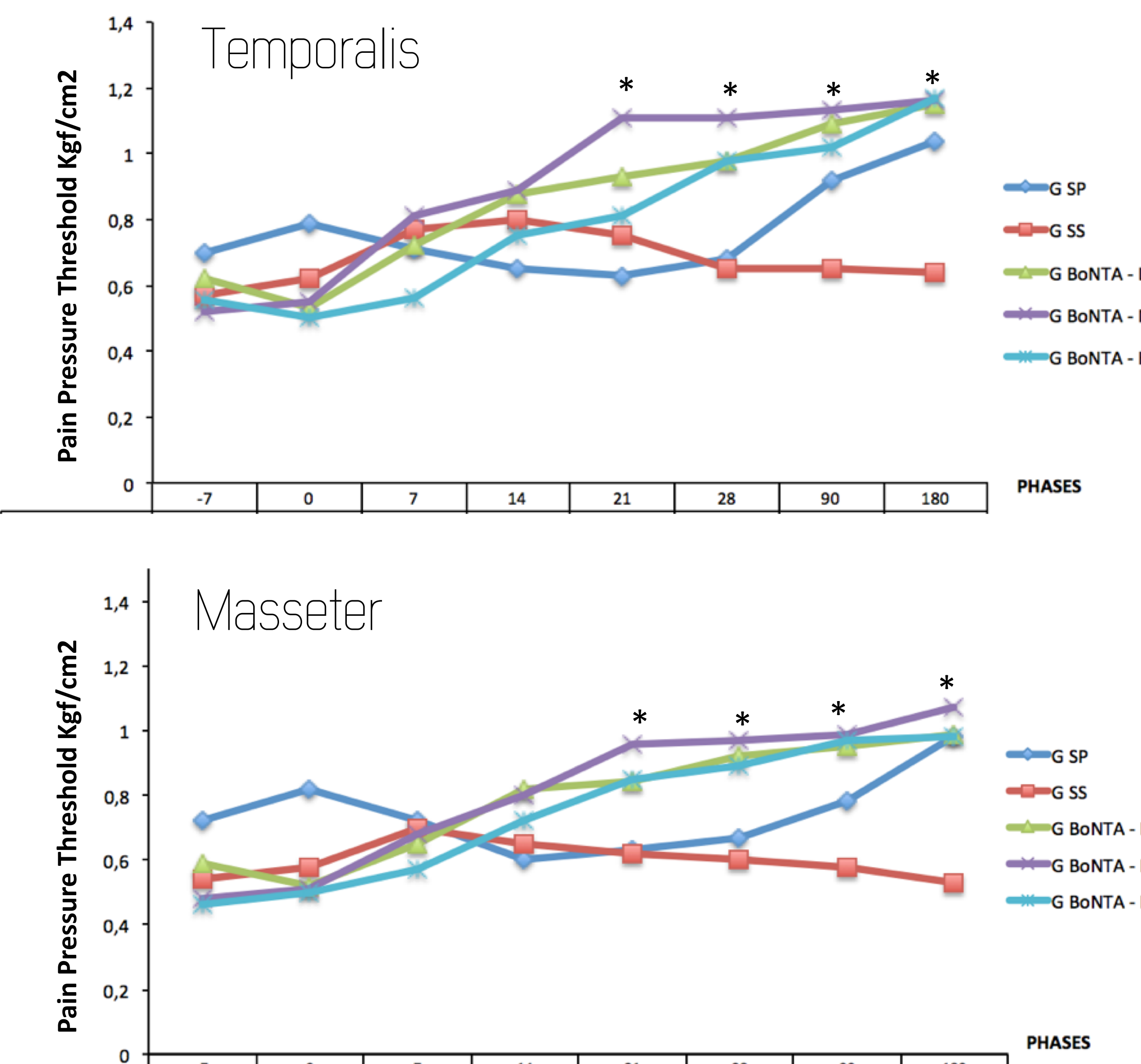
Figure 1. Visual Analogue Scale scores among groups in different experimental periods



Phases	7	0	7	14	21	28	90	180
G SP	6,58	3,29	2,35	1,92	1,24	1,17	0,94	0,65
G SS	7,78	7,4	4,7	4,07	3,63	4,16	5,58	6,05
G BoNTA-L	7,3	6,5	3,7	2,1	1,7	0,9	1,2	1,82
G BoNTA-M	7,9	6,8	3,09	1,191	0,87	0,97	0,6	0,91
G BoNTA-H	8,14	7,7	4,3	2,8	2,1	1,3	1	1,79

*p<0.05

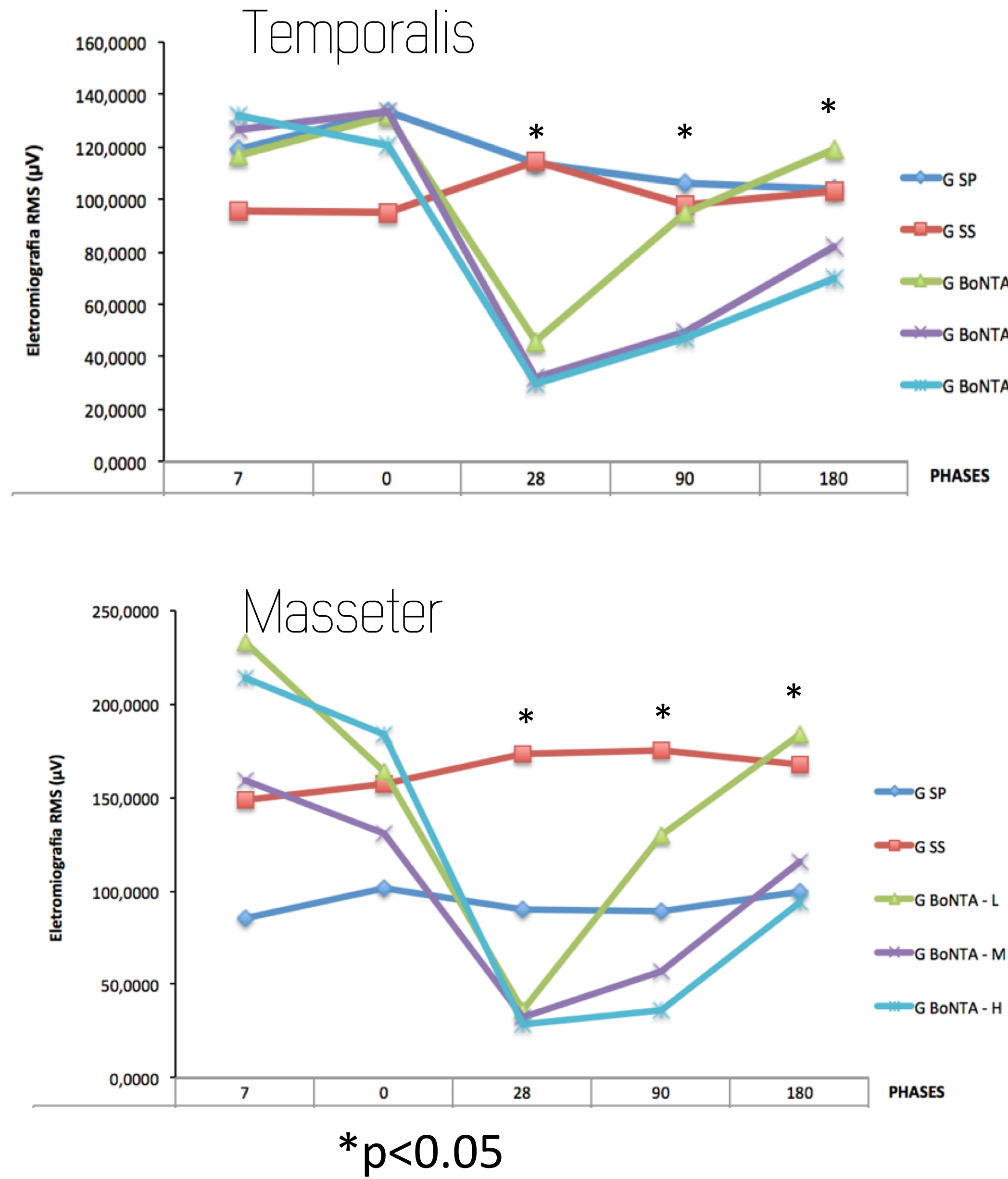
Figure 2. Pressure Pain Threshold scores among groups in different experimental periods



Phases	-7	0	7	14	21	28	90	180
G SP	0,65	0,75	0,8	0,7	0,6	0,7	0,9	1,1
G SS	0,6	0,6	0,7	0,8	0,7	0,6	0,6	0,6
G BoNTA-L	0,6	0,6	0,7	0,8	0,9	1,0	1,1	1,2
G BoNTA-M	0,6	0,6	0,7	0,8	0,9	1,0	1,1	1,2
G BoNTA-H	0,6	0,6	0,7	0,8	0,9	1,0	1,1	1,2

*p<0.05

Figure 3. Root Mean Square scores in maximum muscle contraction condition among groups in different periods



Phases	7	0	28	90	180
G SP	120,000	120,000	100,000	100,000	100,000
G SS	120,000	120,000	100,000	100,000	100,000
G BoNTA-L	120,000	120,000	100,000	100,000	100,000
G BoNTA-M	120,000	120,000	100,000	100,000	100,000
G BoNTA-H	120,000	120,000	100,000	100,000	100,000

*p<0.05

Table 1. Mean and standar desviation of muscle thickness evaluated in different periods

M	T	SS	BoNTA-L	BoNTA-M	BoNTA-H
CONTRACTED					
RT	0	2,45 (1,05) Aa	2,32 (0,71) Aa	2,13 (0,88) aA	1,89 (0,82) Aa
	30	2,45 (1,27) Aa	1,70 (0,65) ABb	1,40 (0,55) Bb	1,54 (0,71) Ba
	90	2,57 (1,51) Aa	1,70 (0,59) ABb	1,47 (0,62) Bb	1,41 (0,43) Ba
RM	0	11,70 (1,88) Aa	12,37 (1,75) Aa	11,90 (1,55) Aa	12,34 (1,68) Aa
	30	12,04 (2,11) Aa	11,75 (1,47) ABb	9,88 (1,83) Bb	10,44 (1,26) Ba
	90	12,09 (1,79) Aa	11,6 (1,70) ABb	10,49 (1,72) Bb	11,38 (1,67) Ba
LM	0	11,51 (1,80) Aa	12,83 (1,44) Aa	12,52 (1,71) Aa	12,39 (1,91) Aa
	30	11,72 (1,81) Aa	12,08 (2,11) Aa	11,10 (1,77) Ab	10,91 (1,56) Ab
	90	11,76 (1,68) Aa	12,01 (1,67) Aa	11,28 (1,64) Ab	11,22 (1,49) Aab
LT	0	2,49 (0,99) Aa	2,57 (0,80) Aa	2,26 (0,84) Aa	2,03 (0,57) Aa
	30	2,44 (0,97) Aa	1,68 (0,62) ABb	1,50 (0,54) Bb	1,59 (0,66) Bab
	90	2,58 (0,97) Aa	1,65 (0,64) Bb	1,42 (0,63) B b	1,41 (0,51) Bb

Uppercase in horizontal represent differences groups
Lowercase in vertical denote differences among evaluation periods

Table 2. Mean and standard deviation of the comminuted median particle sizes (mm) according to period and concentration groups

		Period					
Groups		Baseline	7 D	14 D	21D	28D	
BoNT-A							
High		5.9±0.8 Bab	6.4±0.6 Aab	6.6±0.5Aa	6.7±0.6 Aab	6.4±0.7 Aa	
Medium		5.9±0.9 Bab	6.8±0.5Aa	6.9±0.6Aa	6.8±0.7 Aa	6.6±0.6ABa	
Low		5.5±0.9 Bb	6.1±0.7 Ab	6.1±0.6Ab	6.1±0.8 Abc	6.2±0.4 Aa	
SS		6.2±0.7 Aa	5.8±0.7 Ac	5.8±0.8Ab	5.7±0.9 Ac	5.7±0.9 Ab	

Different uppercase letters in horizontal represent differences among evaluation periods
Different lowercase letters in vertical denote differences among groups

Table 3 . Median of coronoid apophis bone volume evaluated in different periods

Periods	Right				Left			
	SS	BoNTA-L	BoNTA-M	BoNTA-H	SS	BoNTA-L	BoNTA-M	BoNTA-H
Baseline	217.2aA	213.6aA	195.6aA	207.9aA	185.7aA	243.6aA	156.4aB	232.8aA
	(±77)	(±122.3)	(±118)	(±108.7)	(±25.5)	(±184.3)	(±76.2)	(±86.4)
90D	210.9aA	194aA	164.3aA	189.2bA	171.3aA	236.3aA	158.5aA	195.1bA
	(±50.6)	(±213.8)	(±135.9)	(±93.8)	(±61.1)	(±195.4)	(±54)	(±105.1)

Different lowercase in vertical represent significant differences among evaluation periods
Different uppercase in horizontal represent significant differences among groups