

From:
The Department of
Periodontology,
Dental Faculty,
Oslo, Norway

A CLINICAL EVALUATION OF THE EFFECT OF ASCOXAL T® ON PLAQUE FORMATION AND GINGIVITIS

by

JAN R. JOHANSEN

LEIV FLÖTRA

PER GJERMO

INTRODUCTION

Laboratory tests have established that salivary and gastric mucins are degraded by a mixture of ascorbic acid and hydrogen peroxide (*Robertson et al* 1941). When these two components are mixed, the ascorbic acid undergoes an oxidation-reduction reaction. The oxidation of the ascorbic acid (the Ascox reaction) reduced the viscosity of saliva (*Ericsson & Stjernström* 1951), and inhibited the growth of a number of bacteria, some fungi and viruses in vitro (*Ericsson & Lundbeck* 1955).

Berghagen et al. (1954) investigated the effect of the Ascox reaction in 7 patients with necrotizing ulcerative gingivitis. The patients were given a mouthwash containing ascorbic acid, sodium percarbonate and copper sulphate. The authors reported a considerable improvement of the clinical condition and a marked reduction in the oral bacterial flora. Their investigation suggested that this mouthwash might be used to improve oral hygiene in patients where regular toothbrushing was not possible.

To simplify the clinical use of this preparation Astra* introduced a tablet (Ascoxal®) containing 100 mg ascorbic acid, 70 mg sodium percarbonate

* Astra Läkemedel AB, Södertälje

and 0.2 mg copper sulphate. This tablet is dissolved in approximately 25 ml of water and used as a mouthwash.

The use of Ascoxal in the treatment of gingivitis has been reported by several investigators (*Classen*, 1960; *Muth*, 1960; *Rasch*, 1961; *Wade et al*, 1961 and *Clausen*, 1966). The findings varied from positive effects of the preparation to no effect at all.

Kristoffersen (1963) investigated the effect of Ascoxal on the rate and degree of plaque and calculus formation. The author found no statistically significant difference between a group using Ascoxal tablets and another group using a placebo for 30 days.

A chewable tablet (Ascoxal T[®]) has recently been marketed by Astra. The tablet insures a higher local concentration of the active components of the preparations.

Bergenholz et al (1967) found a statistically significant inhibition of plaque formation after one and three days use of Ascoxal T. The difference between the preparation and the placebo was more pronounced after three days which was the end of the experimental period.

The opinion that bacterial plaque is the main factor in the etiology of periodontal disease is well substantiated (World Workshop in Periodontics, 1966). Therefore, a preparation that might inhibit plaque formation would be of major importance in the prevention and treatment of periodontal disease.

This investigation was intended to clarify the effects of Ascoxal T on plaque formation and gingivitis.

PART I. THE EFFECT OF ASCOXAL T ON EXPERIMENTAL GINGIVITIS MATERIAL AND METHODS

Thirty-five junior dental students (males and females) volunteered to participate in this study. Their mean age was twenty-three years. No differentiation between the sexes was attempted since an earlier report had ruled out any possible sex difference in gingivitis and plaque scores in a comparable group of dental students (*Johansen*, 1969).

The Gingival Index (G.I.) (*Löe & Silness*, 1963) was recorded for each of the students. A thorough prophylaxis was done to remove calculus and plaque from all surfaces of all teeth. In order to study the effect of Ascoxal T on experimental gingivitis (*Löe et al*, 1965) the students were told to omit all oral hygiene measures for 15 days. Each student was given a coded supply of tablets to last during the experimental period. The code for

the active preparation and the placebo was only known by the manufacturer * and was not revealed until the end of the experiment. One tablet was chewed for one minute 4 times daily according to the manufacturer's directions. After three days the Plaque Index (P.I.) (*Silness & Løe, 1964*) was recorded. The P.I. and the G.I. were again recorded after eight, ten, fifteen, seventeen and twenty-one days. After recording the P.I. and the G.I. on the fifteenth day the students were told to resume their regular oral hygiene procedures and to continue using the tablets. During the experimental period the students were motivated to follow the procedures of the experiment by personal contacts with the authors.

In this investigation the same dentist did all of the examinations to obtain the G.I. scores while the P.I. registrations were performed by another dentist. This was done to eliminate any interexaminer error. The recorded data were transferred to punch cards which were control read before being treated in a computer at the Department of Mathematics, University of Oslo **. Student's t test were used to test for significant differences between the means. The entire experiment was conducted as a double blind study.

RESULTS

Tables I and II show the mean P.I. and G.I. values with standard deviation (S.D.) for the different surfaces of the teeth. Table III presents the mean P.I. for the different teeth after 15 days of no oral hygiene. Figures 1-4 are graphic illustrations of Tables I and II. When using the P.I. only the mesial surfaces are examined. Therefore, both the terms »mesial» and »approximal» are used in this report.

The Plaque Index. Plaque seemed to form in approximately equal amounts on all teeth. The upper incisors had a slightly lower mean plaque index than the other teeth. Throughout the experiment the approximal surfaces tended to show higher P.I. scores than the other surfaces.

The mean P.I. was consistently lower in the Ascoxal T (active) group than in the placebo group. This difference is statistically significant at three days for the lingual surfaces, at three and eight days for the approximal surfaces and the buccal surfaces. When all surfaces are grouped together the difference is statistically significant at three and eight days observation

* Astra Läkemedel AB, Södertälje, Sweden is gratefully acknowledged for the supply of Ascoxal T and placebo tablets.

** The programming and the statistical analysis were made by Amund R. Tinderholt, cand. real.

Table I.
Mean Plaque Index at various observation periods

		Observation periods in days													
		0		3		8		10		15		17		21	
Surfaces	Drugs	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.
Upper															
Buccal	Ascoxal T	No	0.2	0.25	1.2	0.47	1.3	0.29	1.6	0.30	0.1	0.10	0.1	0.20	
	Placebo	Registra-	0.6	0.39	1.5	0.37	1.5	0.36	1.8	0.29	0.1	0.21	0.2	0.20	
Lower		tion													
Buccal	Ascoxal T		0.2	0.21	1.1	0.39	1.3	0.52	1.6	0.33	0.1	0.11	0.2	0.18	
	Placebo		0.6	0.43	1.4	0.35	1.4	0.43	1.7	0.28	0.1	0.13	0.2	0.24	
Both	Ascoxal T		0.23**	0.21	1.17*	0.40	1.31	0.37	1.60	0.28	0.09	0.09	0.15	0.16	
	Placebo		0.61	0.36	1.45	0.32	1.46	0.37	1.72	0.24	0.12	0.13	0.21	0.19	
Upper															
Mesial	Ascoxal T		0.8	0.28	1.5	0.37	1.6	0.28	1.8	0.19	0.1	0.11	0.2	0.20	
	Placebo		1.2	0.32	1.7	0.34	1.8	0.25	2.0	0.27	0.2	0.26	0.3	0.24	
Lower															
Mesial	Ascoxal T		0.8	0.34	1.5	0.30	1.6	0.34	1.8	0.23	0.2	0.12	0.3	0.25	
	Placebo		1.3	0.31	1.8	0.30	1.7	0.32	1.9	0.19	0.3	0.29	0.4	0.27	
Both	Ascoxal T		0.81**	0.26	1.50*	0.31	1.62*	0.28	1.83	0.18	0.14	0.09	0.24	0.21	
	Placebo		1.28	0.28	1.77	0.30	1.77	0.26	1.94	0.21	0.23	0.24	0.34	0.23	
Upper															
Lingual	Ascoxal T		0.1	0.15	0.6	0.25	0.5	0.35	0.8	0.32	0.0	0.04	0.1	0.10	
	Placebo		0.1	0.15	0.8	0.34	0.6	0.28	1.0	0.25	0.1	0.08	0.1	0.15	
Lower															
Lingual	Ascoxal T		0.3	0.23	1.0	0.36	1.0	0.43	1.4	0.30	0.3	0.20	0.2	0.20	
	Placebo		0.4	0.24	1.3	0.36	1.2	0.31	1.4	0.28	0.2	0.15	0.4	0.28	
Both	Ascoxal T		0.18*	0.16	0.79*	0.29	0.75	0.29	1.11	0.28	0.14	0.10	0.15	0.11	
	Placebo		0.28	0.17	1.04	0.32	0.93	0.25	1.21	0.22	0.11	0.08	0.25	0.20	
All Sur-															
faces															
Upper	Ascoxal T		0.5	0.20	1.2	0.32	1.3	0.25	1.5	0.19	0.1	0.08	0.1	0.16	
	Placebo		0.8	0.27	1.4	0.32	1.4	0.26	1.7	0.24	0.1	0.16	0.2	0.19	
Lower	Ascoxal T		0.5	0.22	1.3	0.29	1.4	0.38	1.6	0.22	0.2	0.11	0.3	0.17	
	Placebo		0.9	0.25	1.6	0.29	1.5	0.31	1.7	0.20	0.2	0.18	0.3	0.23	
All Sur-															
faces															
Upper	Ascoxal T		0.51**	0.19	1.24*	0.29	1.33	0.29	1.59	0.19	0.13	0.08	0.20	0.16	
and															
Lower	Placebo		0.86	0.24	1.51	0.29	1.48	0.26	1.70	0.21	0.17	0.15	0.28	0.20	

* $0.01 \leq P \leq 0.05$ Significant** $P < 0.01$ Highly Significant

Table II.
Mean Gingival Index at various observation periods

Surfaces	Drugs	Observation periods in days													
		0		3		8		10		15		17		21	
		\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.
Upper															
Buccal	Ascoxal T	0.6	0.31	No	1.0	0.19	1.0	0.17	1.2	0.22	1.0	0.13	0.4	0.24	
	Placebo	0.5	0.37	Regi-	1.1	0.23	1.0	0.16	1.3	0.19	0.9	0.15	0.4	0.31	
Lower				stration											
Buccal	Ascoxal T	0.8	0.28		1.2	0.16	1.1	0.12	1.2	0.18	1.0	0.05	0.5	0.19	
	Placebo	0.8	0.33		1.3	0.25	1.1	0.13	1.3	0.17	1.0	0.12	0.4	0.28	
Both)	Ascoxal T	0.71	0.25		1.07	0.15	1.08	0.13	1.20	0.16	0.97	0.07	0.41	0.18	
	Placebo	0.63	0.31		1.18	0.22	1.06	0.11	1.27	0.16	0.97	0.11	0.38	0.27	
Upper															
Mesial	Ascoxal T	0.5	0.28		0.9	0.18	1.0	0.16	1.3	0.22	0.9	0.21	0.2	0.27	
	Placebo	0.5	0.37		1.1	0.19	1.1	0.24	1.3	0.19	0.9	0.20	0.3	0.28	
Lower															
Mesial	Ascoxal T	0.5	0.35		1.0	0.15	1.0	0.13	1.2	0.21	0.9	0.13	0.2	0.17	
	Placebo	0.5	0.35		1.1	0.15	1.2	0.18	1.3	0.20	0.8	0.21	0.2	0.14	
Both	Ascoxal T	0.54	0.28		0.97*	0.15	1.01*	0.11	1.23	0.17	0.90	0.13	0.22	0.19	
	Placebo	0.46	0.34		1.09	0.15	1.13	0.18	1.26	0.18	0.85	0.16	0.25	0.19	
Upper															
Lingual	Ascoxal T	0.6	0.37		1.0	0.26	0.9	0.21	1.0	0.25	0.7	0.27	0.2	0.16	
	Placebo	0.6	0.42		0.9	0.29	1.0	0.21	1.1	0.30	0.7	0.23	0.3	0.22	
Lower															
Lingual	Ascoxal T	0.9	0.25		1.1	0.20	1.1	0.19	1.2	0.17	0.9	0.21	0.3	0.20	
	Placebo	0.8	0.39		1.2	0.27	1.1	0.15	1.3	0.20	1.0	0.14	0.3	0.23	
Both	Ascoxal T	0.74	0.28		1.06	0.19	1.00	0.17	1.08	0.18	0.78	0.21	0.25	0.15	
	Placebot	0.69	0.37		1.05	0.26	1.06	0.16	1.21	0.21	0.86	0.13	0.30	0.19	
All Sur-															
faces															
Upper	Ascoxal T	0.6	0.27		1.0	0.17	1.0	0.13	1.2	0.17	0.9	0.17	0.2	0.20	
	Placebo	0.5	0.35		1.1	0.19	1.1	0.19	1.2	0.17	0.9	0.14	0.3	0.25	
Lower	Ascoxal T	0.7	0.27		1.1	0.13	1.1	0.11	1.2	0.13	0.9	0.09	0.3	0.15	
	Placebo	0.6	0.31		1.1	0.18	1.1	0.11	1.3	0.16	0.9	0.12	0.3	0.15	
All Sur-															
faces															
Upper	Ascoxal T	0.63	0.25		1.02	0.14	1.02	0.10	1.19	0.13	0.89	0.12	0.27	0.16	
and															
Lower	Placebo	0.56	0.31		1.10	0.18	1.10	0.14	1.25	0.15	0.88	0.10	0.29	0.18	

* $0.01 \leq P \leq 0.5$ Significant
 ** $P < 0.01$ Highly Significant

Table III.
Mean Plaque Index for the different teeth after 15 days of no oral hygiene

		Right side						Left side							
		Molars		Premolars		Front teeth		Front teeth		Premolars		Molars			
Upper jaw	Ascoxal T	1.9	1.8	1.6	1.6	1.5	1.4	1.3	1.2	1.3	1.3	1.5	1.5	1.7	1.9
	Placebo	2.0	1.9	1.8	1.8	1.5	1.6	1.5	1.4	1.6	1.6	1.6	1.6	1.7	1.9
Haderup's System		7	6	5	4	3	2	1 ± 1	2	3	4	5	6	7	
Lower jaw	Placebo	1.9	1.9	1.8	1.7	1.7	1.6	1.8	1.8	1.7	1.6	1.6	1.5	1.8	1.8
	Ascoxal T	1.7	1.6	1.5	1.5	1.7	1.7	1.8	1.7	1.7	1.6	1.6	1.5	1.6	1.7

time. After oral hygiene measures were reinstated there was no statistically significant difference between the two groups (Table I).

The Gingival Index. The gingival scores were lower for the Ascoxal T group during the first 15 days. At 8 and 10 days this difference is statistically significant for the approximal surfaces, but not for any other surfaces alone, or grouped together. When oral hygiene was resumed, there was no difference between the experimental and the control groups (Table II).

PART II. THE EFFECT OF ASCOXAL T AS AN ADJUVANT TO ORAL HYGIENE MEASURES IN AIR FORCE RECRUITS

The purpose of the second part of this study was to investigate the effects of Ascoxal T on plaque formation when the drug was used as an adjuvant to regular oral hygiene measures. Furthermore, an attempt was made to evaluate the effect of Ascoxal T in reducing gingivitis.

MATERIAL AND METHODS

Fifty soldiers from The Royal Norwegian Air Force volunteered to take part in this clinical trial. Their mean age was 22 years.

All soldiers were examined in a regularly equipped dental office. Again the same dentist as in Part I scored P.I. and the other dentist scored G.I. The soldiers were given numbered bottles containing Ascoxal T or a placebo. The randomization of the active tablets and the placebo tablets by numbers

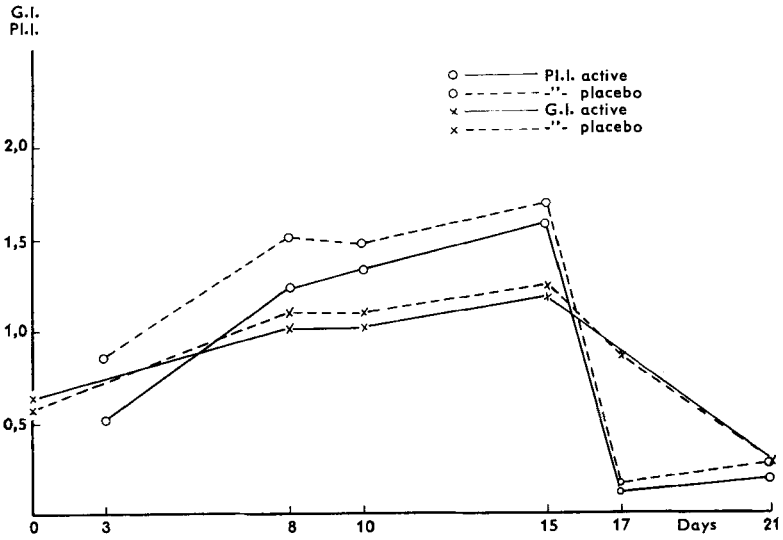


Fig. 1. Mean Pl. I. and G. I. at various observation periods in experimental gingivitis. All surfaces.

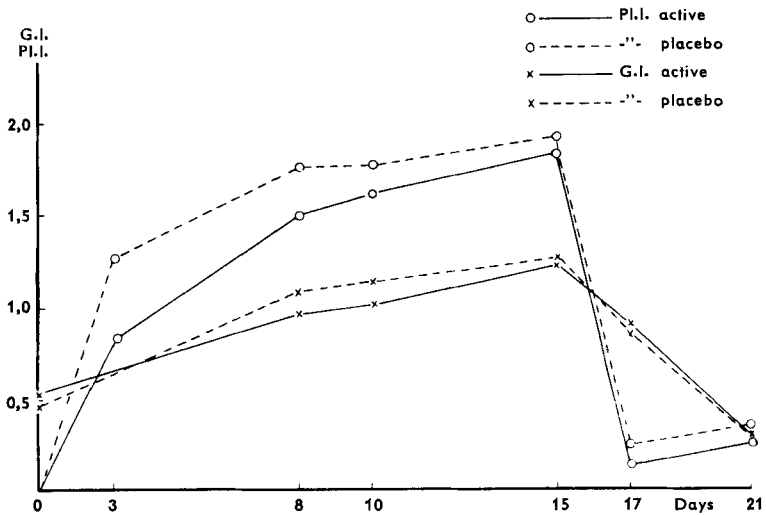


Fig. 2. Mean Pl. I. and G. I. at various observation periods in experimental gingivitis. Approximal surfaces.

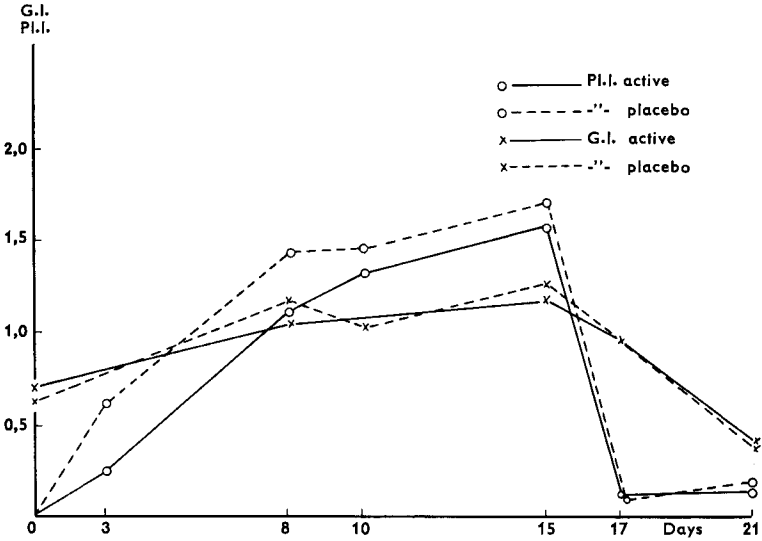


Fig. 3. Mean Pl. I. and G. I. at various observation periods in experimental gingivitis. Buccal surfaces.

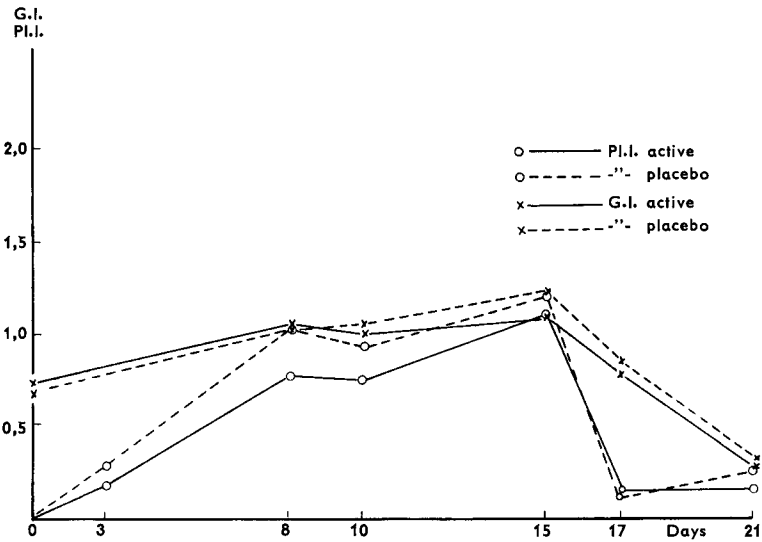


Fig. 4. Mean Pl. I. and G. I. at various observation periods in experimental gingivitis. Lingual surfaces.

Table IV.
Mean Plaque Index at various observation periods

Surfaces	Drugs	Observation periods in weeks									
		0		1		2		3		4	
		\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.
Upper Buccal	Ascoxal T	0.9	0.53	0.5	0.29	0.6	0.33	0.8	0.36	0.6	0.34
	Placebo	1.1	0.50	1.0	0.51	0.9	0.47	0.9	0.50	0.9	0.53
Lower Buccal	Ascoxal T	1.1	0.54	0.7	0.46	0.7	0.51	0.8	0.51	0.7	0.43
	Placebo	1.3	0.52	1.1	0.47	1.0	0.36	1.1	0.39	1.0	0.43
Both	Ascoxal T	1.00	0.52	0.65**	0.35	0.66*	0.40	0.80	0.42	0.65*	0.38
	Placebo	1.19	0.49	1.07	0.47	0.96	0.40	1.01	0.43	0.96	0.47
Upper Mesial	Ascoxal T	1.3	0.51	1.0	0.39	0.9	0.35	1.1	0.42	1.0	0.40
	Placebo	1.5	0.43	1.4	0.47	1.2	0.47	1.3	0.43	1.3	0.43
Lower Mesial	Ascoxal T	1.5	0.44	1.1	0.35	1.1	0.41	1.2	0.43	1.0	0.36
	Placebo	1.6	0.36	1.5	0.39	1.3	0.31	1.4	0.39	1.3	0.34
Both	Ascoxal T	1.39	0.44	1.07**	0.35	0.98*	0.36	1.16	0.41	1.01*	0.36
	Placebo	1.55	0.37	1.42	0.41	1.26	0.37	1.34	0.40	1.29	0.38
Upper Lingual	Ascoxal T	1.0	0.47	0.7	0.42	0.6	0.34	0.7	0.36	0.6	0.35
	Placebo	1.1	0.32	0.9	0.32	0.8	0.32	0.9	0.32	0.8	0.33
Lower Lingual	Ascoxal T	1.5	0.34	1.3	0.40	1.3	0.52	1.2	0.38	1.2	0.42
	Placebo	1.6	0.33	1.4	0.37	1.3	0.39	1.3	0.34	1.2	0.44
Both	Ascoxal T	1.28	0.35	0.97*	0.37	0.89	0.40	0.93	0.34	0.92	0.35
	Placebo	1.36	0.30	1.18	0.30	1.02	0.32	1.07	0.31	1.04	0.35
All Surfaces											
Upper	Ascoxal T	1.1	0.46	0.8	0.32	0.8	0.32	0.9	0.36	0.8	0.34
	Placebo	1.3	0.39	1.2	0.40	1.0	0.40	1.1	0.38	1.1	0.38
Lower	Ascoxal T	1.4	0.39	1.1	0.36	1.1	0.43	1.1	0.41	1.0	0.36
	Placebo	1.5	0.35	1.4	0.36	1.2	0.28	1.3	0.34	1.2	0.34
All Surfaces											
Upper and Lower	Ascoxal T	1.26	0.41	0.94**	0.33	0.87*	0.36	1.02	0.38	0.90*	0.34
	Placebo	1.41	0.36	1.27	0.37	1.13	0.33	1.19	0.36	1.14	0.34

* $0.01 \leq P \leq 0.05$ Significant
 ** $P < 0.01$ Highly Significant

Table V.
Mean Gingival Index at various observation periods

Surfaces	Drugs	Observation periods in weeks									
		0		1		2		3		4	
		\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.	\bar{X}	S.D.
Upper Buccal	Ascoxal T	1.2	0.28	1.1	0.21	1.0	0.14	1.1	0.22	1.1	0.30
	Placebo	1.2	0.22	1.1	0.18	1.1	0.18	1.1	0.18	1.1	0.18
Lower Buccal	Ascoxal T	1.4	0.33	1.2	0.25	1.2	0.26	1.2	0.29	1.3	0.31
	Placebo	1.4	0.29	1.2	0.23	1.2	0.21	1.3	0.24	1.3	0.20
Both	Ascoxal T	1.27	0.29	1.15	0.22	1.12	0.19	1.17	0.25	1.20	0.29
	Placebo	1.30	0.24	1.18	0.19	1.17	0.18	1.19	0.19	1.20	0.17
Upper Mesial	Ascoxal T	1.3	0.30	1.2	0.28	1.2	0.28	1.3	0.29	1.3	0.34
	Placebo	1.4	0.33	1.2	0.30	1.2	0.30	1.3	0.32	1.3	0.32
Lower Mesial	Ascoxal T	1.2	0.37	1.2	0.26	1.1	0.19	1.2	0.24	1.2	0.27
	Placebo	1.3	0.31	1.2	0.22	1.1	0.20	1.2	0.22	1.2	0.23
Both	Ascoxal T	1.28	0.32	1.20	0.26	1.16	0.22	1.23	0.25	1.28	0.28
	Placebo	1.34	0.28	1.21	0.23	1.18	0.23	1.22	0.24	1.25	0.25
Upper Lingual	Ascoxal T	1.4	0.23	1.3	0.24	1.2	0.29	1.3	0.25	1.3	0.32
	Placebo	1.4	0.20	1.3	0.24	1.2	0.35	1.2	0.32	1.4	0.27
Lower Lingual	Ascoxal T	1.5	0.25	1.5	0.27	1.5	0.27	1.6	0.27	1.6	0.28
	Placebo	1.5	0.22	1.4	0.22	1.3	0.23	1.5	0.24	1.4	0.26
Both	Ascoxal T	1.48	0.21	1.39	0.22	1.35	0.24	1.44	0.23	1.47	0.25
	Placebo	1.43	0.19	1.35	0.20	1.26	0.27	1.34	0.25	1.39	0.24
All Surfaces											
Upper	Ascoxal T	1.3	0.24	1.2	0.22	1.2	0.21	1.2	0.22	1.3	0.28
	Placebo	1.3	0.23	1.2	0.21	1.2	0.23	1.2	0.24	1.3	0.24
Lower	Ascoxal T	1.4	0.29	1.3	0.23	1.2	0.20	1.3	0.24	1.3	0.25
	Placebo	1.4	0.25	1.2	0.19	1.2	0.15	1.3	0.18	1.3	0.17
All Surfaces											
Upper and Lower	Ascoxal T	1.33	0.26	1.24	0.21	1.20	0.19	1.27	0.22	1.31	0.25
	Placebo	1.35	0.22	1.24	0.19	1.20	0.18	1.24	0.20	1.27	0.20

* $0.01 \leq P \leq 0.05$ Significant

** $P < 0.01$ Highly Significant

was made by the manufacturer. The dosage was that used in Part I, i.e. 1 tablet 4 times daily.

In this experiment care was taken to avoid any influence by the examiners on the daily routine of oral hygiene in the recruits. Obviously, some influence must be anticipated, but an effort was made to keep this at a minimum.

Both Pl.I. and G.I. were again recorded after one, two, three and four weeks. A »double blind» approach was followed throughout the procedures.

When the recorded data had been transferred to punch cards which were control read, the code for the active and the placebo numbers was obtained from the manufacturer, and an analysis of the data was made as mentioned before.

RESULTS

Tables IV and V show the mean Pl.I. and G.I. scores with standard deviations (S.D.) for the different surfaces of the teeth. Figs. 5—9 are graphic illustrations of the tables. Note the difference in scale from Figs. 1—4.

The Plaque Index. The Pl.I. in the Ascoxal T group was consistently lower than in the placebo group. This difference was significant after one week for the lingual surfaces. The difference was highly significant after one week for the approximal surfaces, significant after 2 and 4 weeks. The buccal surfaces parallel the approximal surfaces in scores. When all surfaces were combined, the difference between the active and the placebo group was also highly significant after one week and significant after 2 and 4 weeks (Table IV).

Attention should be focused at the difference between the two groups at the start of the experiment, Pl.I. = 1.26 in the active group versus Pl.I. = 1.41 in the placebo group ($p = 0.2$), in the evaluation of these differences.

The Gingival Index. There was no statistically significant difference in G.I. between the two groups at any observation interval ($0.2 < p < 1.0$).

A group of soldiers with established gingivitis ($G.I. \geq 2$) on one or more surfaces at the start of the observations was considered separately (Fig. 9). Ascoxal T did not affect the Gingival Index of this group to any distinguishable extent ($0.80 > p > 0.30$).

DISCUSSION

At some observation intervals Ascoxal T showed a statistically significant inhibition of plaque formation in both Part I and Part II of this investigation. The difference in plaque scores between the groups was not statistically significant after 10 days in Part I. This might possibly be explained by an

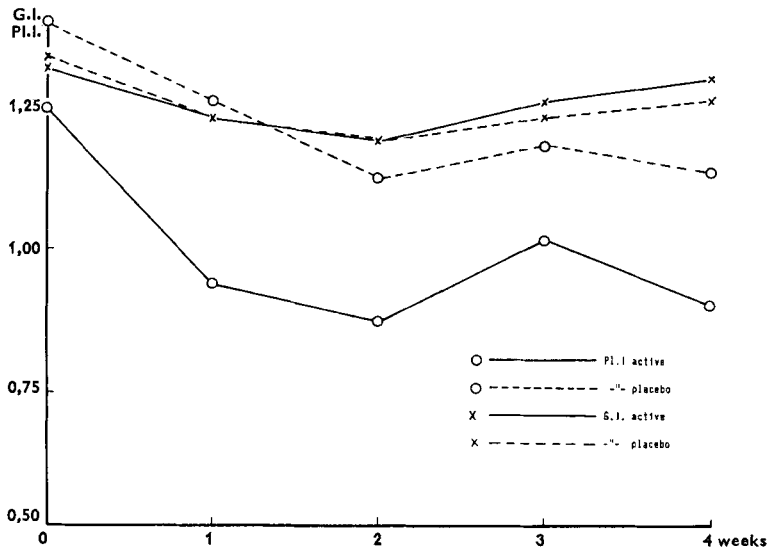


Fig. 5. Mean Pl. I. and G. I. at various observation periods in military recruits. All surfaces.

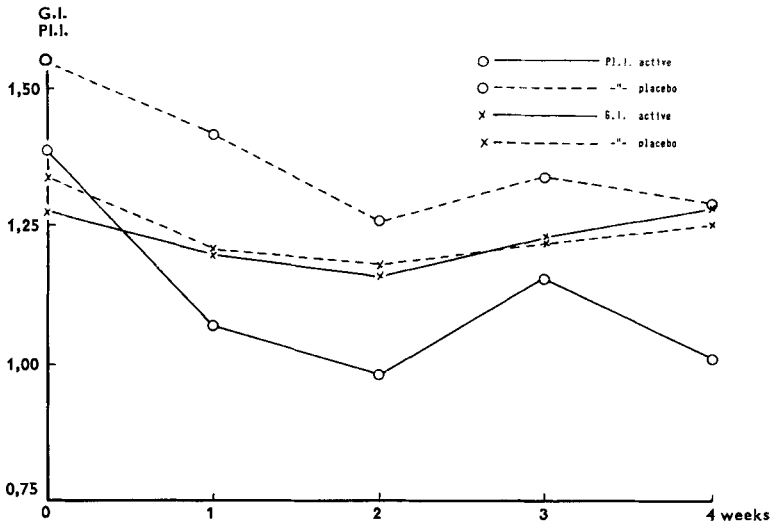


Fig. 6. Mean Pl. I. and G. I. at various observation periods in military recruits. Approximal surfaces.

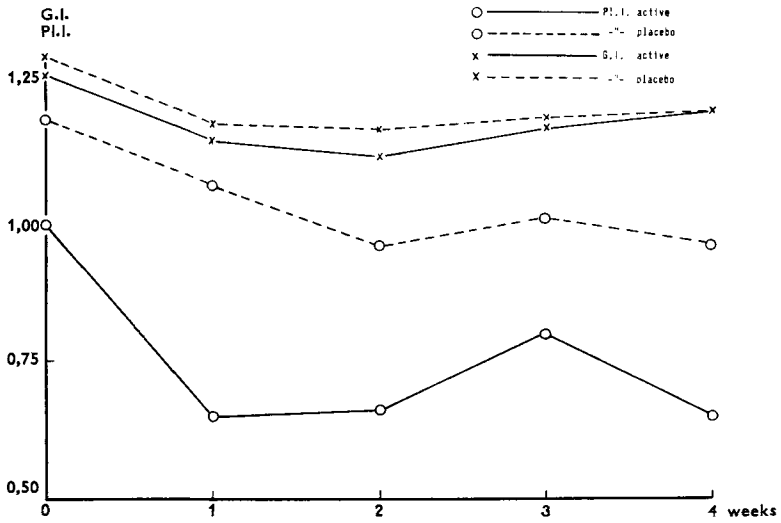


Fig. 7. Mean Pl. I. and G. I. at various observation periods in military recruits. Buccal surfaces.

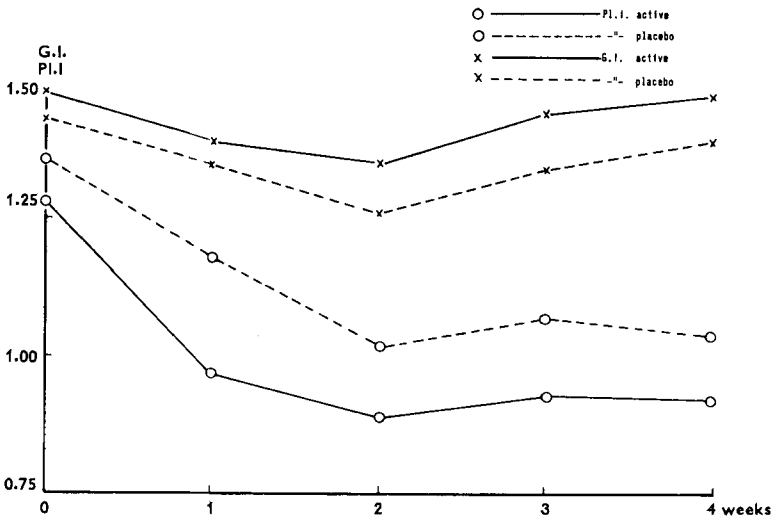


Fig. 8. Mean Pl. I. and G. I. at various observation periods in military recruits. Lingual surfaces.

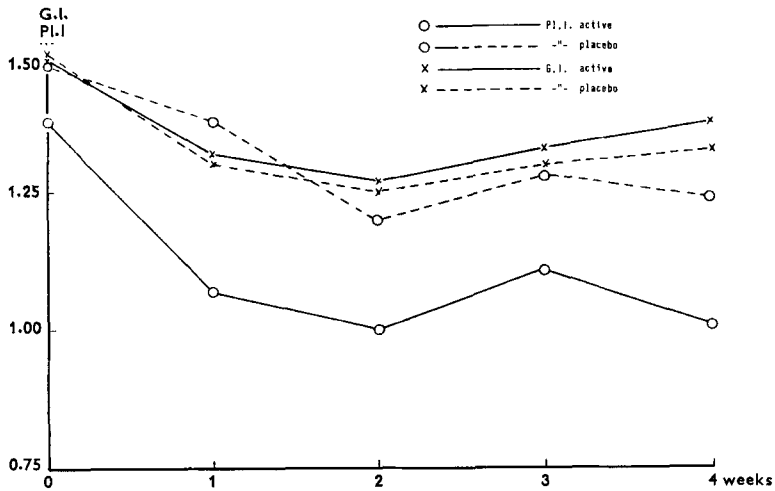


Fig. 9. Mean P.I. and G.I. at various observation periods in military recruits with established gingivitis. (G.I. \geq 2). All surfaces.

inherent limitation of the P.I. as a recording tool when plaque scores reach high values. (Mean P.I. = 1.59 vs 1.70).

Apparently the G.I. scores do not differ for the two groups in both parts of the investigation. Although there was less gingivitis in the experimental group this was not statistically significant. One might expect that less plaque formation should be accompanied by a proportional reduction in gingivitis. This did not occur in this study. A possible explanation is that the G.I. scoring system was not sensitive enough to reveal the differences since most of these patients had low G.I. scores and the detection of differences in these ranges is clinically more difficult than observing differences of scores at the higher ranges. Also, the preparation may affect certain bacteria which are important in plaque formation but have little to do with the development of the inflammatory tissue response. This hypothesis might be tested by qualitative bacterial studies of the plaque at various time intervals. Finally, the tablets may inhibit plaque formation by affecting various salivary components other than bacteria which contribute to plaque formation e.g. salivary mucins or proteins.

SUMMARY

The effect of Ascoxal T® on plaque formation and gingivitis was investigated in a double blind study in dental students and military recruits.

The results indicated:

Part I. Experimental gingivitis in dental students:

Ascoxal T showed a statistically significant inhibition of plaque formation after 3 and 8 days of no oral hygiene, but not after longer observation intervals.

Ascoxal T had no statistically significant effect on the progression of experimental gingivitis.

Ascoxal T had no statistically significant effect on plaque formation or gingival conditions when regular oral hygiene measures were reinstated.

Part II. The effect of Ascoxal T as an adjuvant to oral hygiene measures in military recruits.

Ascoxal T had a statistically significant effect on the amount of plaque on the teeth when it was used in addition to regular oral hygiene measures ($0.01 < p \leq 0.05$). If $p < 0.01$ was chosen as the significance level, this effect disappeared.

There was no statistically significant effect of Ascoxal T on the G.I. in the recruits. Soldiers with one or more surfaces scoring G.I. ≥ 2 at the start of the experiment showed no statistically significant reduction in their mean scores after four weeks ($0.3 < p < 0.7$).

No undesirable side effects of Ascoxal T were reported by any of the participants in the study.

RÉSUMÉ

ÉVALUATION CLINIQUE DE L'ACTION DE L'ASCOXAL T® SUR LA FORMATION DE PLAQUE ET SUR LES GINGIVITES

L'action de l'Ascoxal T sur la formation de plaque et sur les gingivites a été étudiée dans un test doublement aveugle chez des étudiants en art dentaire et des recrues militaires.

Les faits suivants ressortaient des résultats:

Partie no I. Gingivite expérimentale chez des étudiants en art dentaire:

L'Ascoxal T présentait une action inhibitrice statistiquement significative sur la formation de plaque après 3 jours et après 8 jours d'absence de soins d'hygiène bucco-dentaire, mais non dans les cas où les intervalles entre les observations étaient plus longs.

L'Ascoxal T ne présentait pas d'action statistiquement significative sur le développement des gingivites expérimentales.

L'Ascoxal T ne présentait pas d'action statistiquement significative sur la formation de plaque et sur l'état de la gencive lorsque les soins réguliers d'hygiène bucco-dentaires étaient repris.

Partie no II. Action de l'Ascoxal T comme adjuvant des soins d'hygiène bucco-dentaire chez les recrues militaires.

L'Ascoxal T avait une action statistiquement significative sur la quantité de plaque présente sur les dents lorsqu'on l'utilisait en plus des soins réguliers d'hygiène bucco-dentaire ($0,01 < p \leq p, 05$). Si $p < 0,01$ était choisi comme niveau de significativité, cette action disparaissait.

L'Ascoxal T ne présentait pas d'action statistiquement significative sur l'indice gingival chez les recrues. Les soldats ayant un indice gingival (GI) ≥ 2 au niveau d'au moins une surface au début de l'expérience ne présentaient pas de réduction statistiquement significative en se qui concernait leurs valeurs moyennes au bout de quatre semaines ($0,3 < p < 0,7$).

Aucun de ceux qui participaient à cette étude n'a rapporté d'effet secondaire indésirable de l'Ascoxal T.

ZUSAMMENFASSUNG

EINE KLINISCHE AUSWERTUNG DER WIRKUNG VON ASCOXAL T[®] AUF PLAQUE-FORMATION UND GINGIVITIS

Die Wirkung von Ascoxal T auf Plaque-Formation und Gingivitis wurde in einer doppelten Blinduntersuchung bei Studenten des Zahnmedizin und Rekruten ermittelt.

Die Resultate zeigten:

Teil I. Experimentelle Gingivitis bei Studenten des Zahnmedizin: Ascoxal T zeigte eine statistisch signifikante Inhibition von Plaque-Formation nach 3 und 8 Tagen ohne Mundhygiene, aber nicht nach längeren Observationsintervallen.

Ascoxal T hatte keine statistisch signifikante Wirkung auf das Fortschreiten von experimenteller Gingivitis.

Ascoxal T hatte keine statistisch signifikante Wirkung auf Plaque-Formation oder gingivale Kondition, sobald die übliche Myndhygiene wieder angewandt wurde.

Teil II. Die Wirkung von Ascoxal T als ein Adjuvans zu mundhygienischen Massnahmen bei Rekruten.

Ascoxal T hatte eine statistisch signifikante Wirkung auf die Menge von Zahnplaque, sobald es zusätzlich zu üblichen Mundhygiene angewandt wurde ($0,01 < P \leq 0,05$). Diese Wirkung verschwand bei einem Signifikanzniveau von $p < 0,01$.

Es ergab sich keine statistisch signifikante Wirkung von Ascoxal T auf den gingivalen Index bei den Rekruten. Bei Soldaten, die zu Beginn des

Experiments einen gingivalen Index ≥ 2 hatten, zeigte sich nach 4 Wochen keine statistisch signifikante Reduktion der durchschnittlichen Werte ($0.3 < p < 0.7$).

Bei keinem der Untersuchten traten unangenehmen Nebenwirkungen von Ascoxal T auf.

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Address:

*Department of Periodontology,
Dental Faculty,
Geitmyrsvn. 69,
Oslo 4, Norway*