Chlorhexidine gel versus internal implant bacterial contamination: a proof-of-concept human study.

Poster n° 7513

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Background and aim:

Among several factors influencing the implant survival rate, microorganisms can play a central role. During surgery bacteria may colonize the surfaces of implants causing tissues inflammation near the implant-abutment interface. To reduce this phenomenon several local antiseptics were used after surgical procedures (Chlorexidine digluconate) in order to decrease bacterial load. Microorganisms developing inside the implant body are similar to that of subgingival biofilm with the same species (i.e. Porphyromonas gingivalis). Chlorhexidine used to reduce the oral bacterial load has a limited time action to plaque formation inside the implants. Aim: The aim of this randomized, controlled, double-blind human study was to evaluate by microbiologic qualitative and quantitative analysis the presence of a specifical periodontal pathogens, Porphyromonas gingivalis, related to the use or not of CHX gel at implant-abutment interface.

Img.1: Gel (A or B) was put on internal connection and cover screw at implant placement. (T0)

Img.2: Soft tissue healing around healing abutment at 10 weeks.

Img.3: Soft tissue healing after healing abutment removal. (10 weeks)

Img.4: paper point taking off the gingival fluid on natural tooth. (control)

Img.5: paper point taking off the gingival fluid on implant. (test)

Img.6: replacement of healing abutment. (rx 10 weeks)
Group B

Img.7: replacement of healing abutment. (rx 10 weeks)
Group A

Img.8: Healing abutment

Img.9: paper point

Results:

Randomization gave 4 patients in group A (placebo) and 7 in group B (CHX test). Both groups showed no clinically visible plaque, suppuration or bleeding on probing. Plaque and bleeding score values were less than 25% at T0 and T1 in patients of both groups. The worst 4 values of group B were selected and compared in order to even out the sample. Except one, all samples showed several colonies of Porphyromonas gingivalis: group A showed the highest value of bacteria while group B the less one. Data concerning colonization evidenced significant statistical differences between the two groups ($p < 0.05$).

Conclusions:

The present results demonstrated significant statistical differences between the two groups: plaque collected from group A showed more colonies of Porphyromonas gingivalis if compared with group B.

This human study confirmed the primary role of Chlorhexidine in inhibiting the bacterial plaque formation, as documented in 30 years of Literature.

This could explain how to prevent, or reduce, the early inflammation at the abutment-fixture interface and consequent crestal bone loss around implant.

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Materials and Methods:

This study (n°2342) was approved by the local Ethics Committee on 23/07/2015. Following predetermined inclusion and exclusion criteria, 11 patients of 36 (between 29 and 75 years) who needed a single implant supported crown restoration were enrolled and randomly divided into two groups. Starting from implant insertion (Cortex classic, Shalomi, Israel) phase (T0) and during all clinical and surgical stages a 0.20% chlorhexidine gel (Plak®Gel; Polifarma Benessere Srl, Roma, Italia) or a placebo gel was used differently as indicated by randomization chart. At 8 weeks the second stage surgery was performed placing the healing abutment (T1). At 10 weeks the first screw was replaced with a new one and collected, together with saliva and gingival fluid samples, to perform microbiological analysis. Gingival fluid was collected from implants and tooth and TaqMan-PCRs were carried out to quantify the amount of Porphyromonas gingivalis. The results, expressed as mean $\pm$ SD were treated with inferential statistics.

samples	2	4	6	10
copies/	2	43,6	36,8	53,6
	10	37,1	42,9	36,2
	14	63,3	58	38
copies/ml	2000	43600	36800	53600
	10000	37100	42900	36200
	14000	63300	58000	38000
mean value	8,67E+03	4,80E+04	4,59E+04	4,26E+04
SD	6,11E+03	1,36E+04	1,09E+04	9,57E+03

Tab.1: quantitative analysis of Porphyromonas gingivalis (TaqMan-PCRs). Group A

	1	7	8	11
copies/	46	49,6	66	32,5
	51	39,6	72	53,5
	29	13,8	60,1	33,3
copies/ml	46000	49600	66000	32500
	51000	39600	72000	53500
	29000	13800	60100	33300
mean value	4,20E+04	3,43E+04	6,60E+04	3,98E+04
SD	1,15E+04	1,85E+04	5,95E+03	1,19E+04

Tab.2: quantitative analysis of Porphyromonas gingivalis (TaqMan-PCRs). Group B

Graph 2

Graph1: shows the mean values of all the study samples; the one indicated with A or B show the values choose for statistical analyses.

Graph2: graphical representation of statistical differences between the two groups ($p < 0.05$).