

# **Prospective randomised cross-over study for the Oral quality of life in mandibular edentulous patients with a two versus four locator-retained overdenture**

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Running title: Oral quality of life in patients with a locator-retained overdenture

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Key words: oral quality of life, locator-retained overdenture, intraindividual comparison, two versus four locator

## **Purpose:**

The aim of the study is to compare the oral health related quality of life (OHRQoL) in a prospective, randomized cross-over trial in patients with locator-retained overdentures in the mandibular with two or four locator.

## **Materials and Methods:**

In 30 mandibular edentulous patients four implants (ICX-plus implants (medentis medical GmbH, Dernau, Germany)) have been placed intraforaminal. Eight weeks after transgingival healing it was decided randomly if two or four of the implants have been incorporated in the prosthesis. After three months a switch of the retention concepts has been done. The patients with a two implant-retained overdenture got four implants incorporated. Whereas the other patients, with a four implant-retained overdenture, got taken out two locator of retention. After three more months all four implants have been retained in the locator-retained overdenture in every patient. To measure OHRQoL of the patients the oral health impact profile (OHIP- 14 G) was used.

## **Results:**

A considerable increase in OHRQoL could be seen in all patients after the prosthetic supply of the implants and a statistically significant difference of OHRQoL could be seen comparing the OHIP-14 G scores after implementation of two implants with the OHIP-14 G scores after implementation of four implants. Patients showed a higher OHRQoL after incorporation of four implants in the overdenture as compared to OHRQoL after incorporation of only two implants.

## **Conclusion:**

Patients with implant retained-overdentures proved to benefit in their OHRQoL in comparison with a conventional denture. The number of incorporated implants in the locator-retained overdenture did influence the increase of OHRQoL statistically significantly with an advantage of four implants.

## **Introduction:**

Retention and stability of complete dentures are important factors for successful restorations of mandibular edentulous patients. Both, improved denture retention and stability, facilitate the restorations of oral functions such as mastication and speech, as well as an increase of patient comfort and self-confidence(1). In recent years dental implants have enjoyed great success in edentulous patients and improved patients satisfaction (2), prosthetic outcomes of complete dentures(3), preservation of bone resorption (4) and neuromuscular adaption (5).A limiting factor of wide spread acceptance of implant supported overdentures continue to be the high costs and the invasive nature of implant surgeries(6). But in comparison with implant fixed prosthetic supplies implant-retained overdentures represent a cost-effective treatment in the rehabilitation of the edentulous mandible(7).Therefore different concepts of treatments of mandibular edentulous patients have been carried out.In the study of Zitzmannet al. (2005) four implants intraforaminal in the edentulous mandible lead to an improvement in perceived chewing ability of the patients compared with patients with a conventional denture, but at substantially higher costs (6).Long-term results of Balagueret al. (2013) suggest that three-implant mandibular overdentures have an equivalent survival rate to four-implants(8). However, according to the McGill consensus statement at present a two implant-retained overdenture is considered to be the treatment of choice for restoration of edentulous mandibles,(9, 10). But there is evidence that the implant overdenture is superior only in those situations with less than adequate mandibular ridge height(11).Whereas functional and psychological parameters can be achieved with two implants, whilst stabilization with four implants improves prosthesis retention, chewing ability and pain reduction in the long term (12).Arguments for implant-retained overdentures with a single implant are the lower costs and a minimal tissue trauma(13).

Roccuzzoet al. (2012) performed a systematic review to assess the optimal number of implants for removable reconstructions comparing solutions with one versus two and two versus four implants. They did not conclude that bone loss, patients satisfaction, or number of complications is significantly related to the number of implants supporting the overdenture. (14).

But not only the number of implants differ in the treatment concepts, also the possible prosthetic restorations and attachment systems are discussed controversially(15, 16).However, in edentulous patients with extremely resorbed mandibles the use of short endosseous implants in combination with an overdenture was recommended as the first choice of treatment byStellingsmaet al. (2013) (17).Comparing different designs of implant-retained overdentures and fixed full-arch implant-supported prosthesis on stress distributions computed tomography-based three-dimensional finite element analysis confirmed that the use of fixed implant dentures and removable dentures, retained by unsplinted implants in the edentulous mandible, reduced stress in

the peri-implant bone tissue, mucosa and implant/prosthetic components(18).

Studies with an intraindividual comparison of different treatments could help to answer the question of the number of implants needed to improve oral health related quality of life in patients with an edentulous mandible.

The aim of the study is to compare the oral health related quality of life (OHRQoL) in a clinical prospective, randomized intraindividual cross-overtrial in patients with locator-retained overdentures in the mandibular retained by two or four implants.

### **Materials and Methods:**

The prosthesis of the mandible of the edentulous patients was newly made in all 30 patients because of the age of the former provision before four implants have been placed intraforaminal (examination date = E1). For implantation 120ICX-plus implants (medentis medical GmbH, Dernau, Germany) with the diameter of 3,45 mm and a length between 6,5 mm -12 mm were used. None of the patients had an allergy against antibiotics and therefore every patient got orally two gram of amoxicillin, as a single administration for prophylaxis, one hour preoperatively. In all patients the implants have been placed transgingival by the same physician. After implantation the prosthesis was adjusted to the implants and patients could wear these prosthesis for the healing period of eight weeks. The supply of the prosthesis after the healing phase was randomly allocated to the patients. In 15 patients two implants (group I) and in the other 15 patients four implants (group II) have been first incorporated in the prosthesis (examination date = E2). No blinding was done. The prosthetic supraconstruction was done in the Department of Prosthodontics of the same prosthodontics and locator-retainment was chosen as prosthetic supply. In group I, where first only two implants have been incorporated into the locator-retained overdenture, the two posterior placed implants have been used for retention. After three months a switch of the retention concepts was done in all patients. The patients of group I with a two implant-retained overdenture got all four implants incorporated. The patients of group II with four implant-retained overdenture have been taken out two implants of retention (examination date = E3). After three more months (six month after the prosthetic loading) all four implants in the 30 patients (group I and group II) have been retained in the locator overdenture (examination date = E4). Follow-up after one year was the endpoint of data shown (examination date = E5). Further examinations are planned every year until the fifth year after the first loading (data are not shown).

To measure OHRQoL of the patients the oral health impact profile (OHIP-14 G) and a Visual Analog Scale (VAS) (10 pointscale) was used and has been completed through the patients during every investigation (E1 –

E5). The Oral Health Impact Profile in short form consisting of 14 items (OHIP-14), developed by Slade (19) and translated into German by John *et al.* (2006) (20), was used to determine the degree of impact of the different oral diseases on seven dimensions (two items per dimension) (Table 2). The questions can be answered with a Likert scale: "never" = 0, "barely" = 1, "sometimes" = 2, "often" = 3 and "really often" = 4. An analysis can be made of either the total score or the score for each subscale. The maximum score for the complete OHIP-14 is 56 and in each of the dimension the maximum score is 8. The OHIP-14 G, as a standardized characterisation of the subjective side of the OHRQoL, was used as a snap-reading method to determine oral pain and psychosocial effects of OHRQoL. For each of the OHIP questions, individuals were asked how frequently they had experienced the impact of OHRQoL in the last month. The OHIP-14 was chosen for its wide coverage, good psychometric properties and ease of use in a clinical setting. A substantial normative data set for the UK exists also for this short form version, which allowed comparisons with normal population data. A comparison of the OHRQoL to the different times (E1- E5) and in the different groups (I and II) was evaluated (21).

#### Statistical analysis

The study protocol was approved by the local ethic committee (873.254.10 (7263)) and a written informed consent was obtained for each patient. Data collection, data management, and data analysis were performed with statistical software package SPSS® version 21. As primary analysis, the within subject differences in oral health related quality of life (OHIP-14 G score) at the end of each implementation period (score at examination date E4 minus score at examination date E3) are compared between the randomized groups using a two-sided Mann-Whitney-U-test. A pre-test to identify potential carry-over effects is performed by comparing the total sum of OHIP-14 G scores examined at date E3 and E4 between randomized groups by the two-sided Mann-Whitney-U-test. Descriptive methods are used for the analysis of secondary outcomes. For the primary analysis a p-value  $\leq$  0.05 was considered as statistically significant. P-values of secondary analyses are given for descriptive reasons and are considered as explorative.

#### **Results:**

Thirty patients (20 (67%) woman, 10 (33%) men) were included in the study with the average age of patients of 62 years ( $\pm$  9 years; min: 46 years; max: 82 years). 21 (70%) of the patients have been fully edentulous, four (13%) patients had an implant retained prosthetic restoration in the maxilla and five (17%) patients have been dentated partially in the maxilla. In the early healing phase two implants were lost, both in patients with

generalized horizontal and vertical bone atrophy. Both patients were randomly distributed into group II. For these two patients a three (first three month of implant loading) versus two implant (second three month of implant loading) incorporation model was used for the locator-retained overdenture. Therefore an implant survival rate of 98.3% was achieved after one year (E5) of follow-up. All prostheses were successfully in function and prosthodontics maintenance was restricted to a minimal loss of retention. Comparing the two patient groups no difference between gender, sex, alcohol consumption and smoking habits could be seen (Table I).

A considerable difference of OHIP-14 G could be seen in the patients (group I together with group II) comparing the different times of the treatment (Friedman Test:  $p \leq 0.001$ ). Thereby the OHRQoL was improving with implant treatment after loading of the implants in both groups. Also a marked difference of OHIP-14 of the seven dimensions could be seen in the patients (group I together with group II) comparing the different times (E1-E5) of the treatment (Friedman Test dimension I: functional limitation  $p = 0.004$ ; dimension II: physical pain  $p = \leq 0.001$ ; dimension III: psychological discomfort  $p = \leq 0.001$ ; dimension IV: physical disability  $p = \leq 0.001$ ; dimension V: psychological disability  $p = \leq 0.001$ ; dimension VI: social disability  $p = \leq 0.001$ ; dimension VII: handicap  $p = \leq 0.001$ ).

The primary analysis (Table II) identifies a statistically significant decrease in the OHIP-14 G score if four implants were incorporated in the overdenture as compared to two implants only ( $p=0.026$ ). A median OHIP-14 G score of 7 was observed three months after incorporating two implants in both groups whereas the median OHIP-14 G score decreased to 2 and 3 in group I and II, respectively, three months after incorporating four implants. The pre-test did not indicate any relevant carry-over effects ( $p=0.744$ ). The within subject differences in the OHIP-14 G score at the end of each implementation period are illustrated in Figure III. Subjects who started with two implants show an increase in quality of life (lower OHIP-14 G score) after incorporation of four implants whereas subjects who started with four implants show a decrease in quality of life (higher OHIP-14 G score) after taking out two implants of retention. A similar result could be seen comparing the VAS at E3 and E4, patients with two implants incorporated in the locator-retained overdenture (median [Q1; Q3] = 5.6 [4.0; 7.0]) showed a lower OHRQoL than patients with four implants incorporated in the locator-retained overdenture (8.6 [Q1: 8.0; Q3: 10.0]) (Mann-Whitney-U-test;  $p \leq 0.001$ ). Looking at the VAS no differences of OHRQoL between the groups could be detected. The pre-test did not indicate any relevant carry-over effects ( $p = 0.653$ ).

The study compared the intraindividual OHRQoL in patients with four implants in the edentulous mandible

retaining in each of the patients the overdenture for three month with two implants and for three months with all four implants. The primary criterion of outcome was the number of implants needed to improve the OHRQoL. It could be seen that the OHRQoL increased significantly through the implant treatment after the prosthetic supply. The number of implants had a significant influence on patients OHRQoL by using locator. Patients wearing a four implant-retained overdenture had a higher OHRQoL compared with patients with a two implant-retained overdenture.

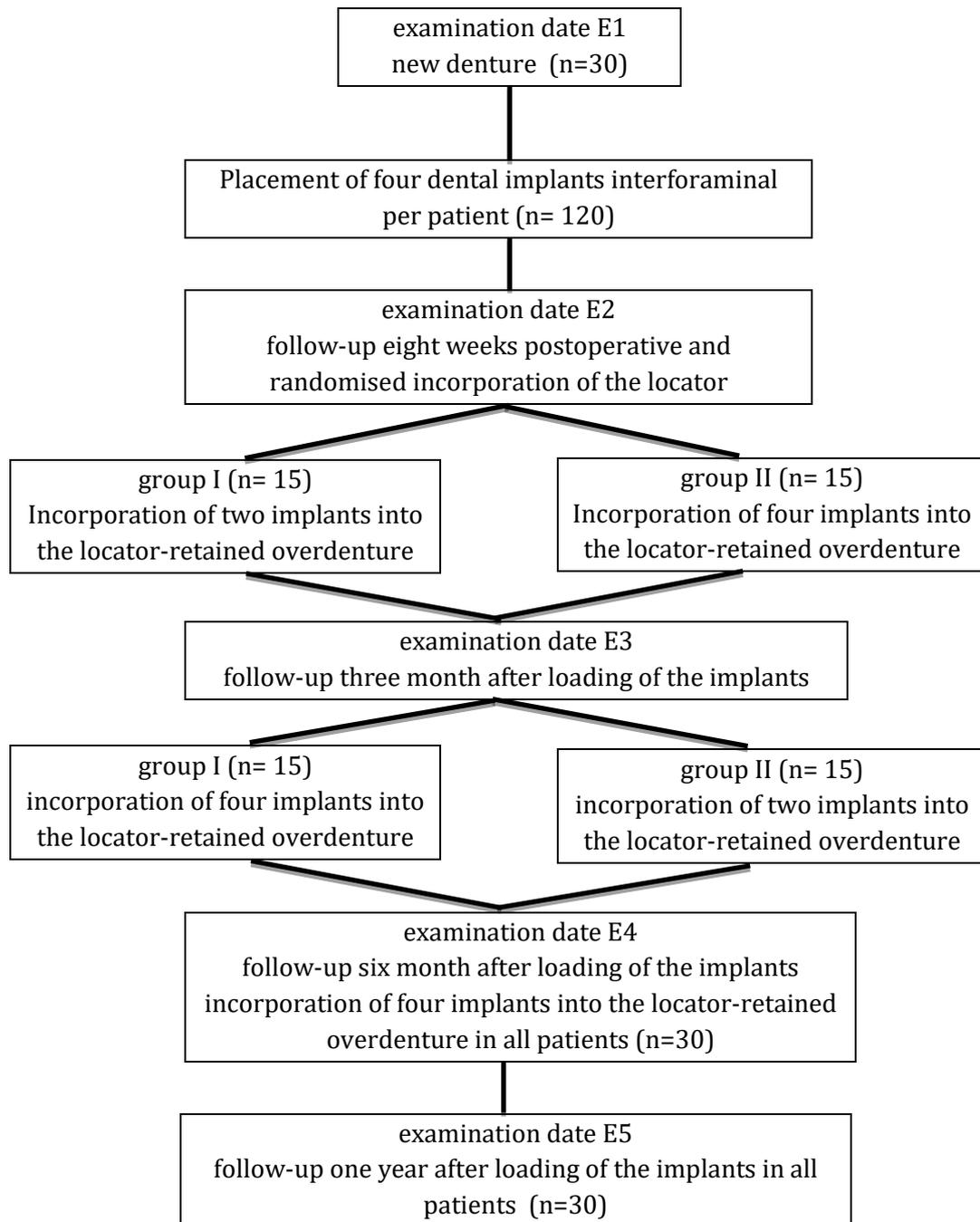
Compared to a conventional denture implant treatments in mandibular edentulous patients had a positive impact on the OHRQoL according to other studies (1, 3, 22, 23). If the numbers of implants in the edentulous mandible affect the improvement of the OHRQoL in implant-retained overdentures still is discussed controversially (14, 24). One problem of the discussion might be that not only the number of implants differs in the patient samples, but also the prosthetic supply. Implant-retained soft tissue supported overdentures on two implants are often used with locators (25), ball (25, 26), or bar (26) attachments. Implant-retained overdentures on at least three or four implants can be used as well as soft tissue supported, or with a complete implant supported fixed prosthesis (18, 27). In most studies where OHRQoL has been tested OHRQoL is only one set of questions between many others. Cost effectiveness of the treatment, positive effects on oral structures, like bone height stability (11), neuromuscular adaptation (5) or prosthetic complications are often also evaluated. Therefore studies are difficult to compare with each other. The present study focused only on patient's satisfaction wearing the implant-retained overdenture. To achieve this goal sufficiently an intraindividual comparison of patients OHRQoL was used as the study design, which has not been described before. Over time a significant difference could be evaluated between patients wearing the overdenture retained with two or four implants. The OHRQoL increased switching from two to four implants and a decrease could be seen switching from four to two implants. In contrast to the results of Meijer *et al.* (2009), where 30 patients have been treated with two IMZ implants and 30 patients with four IMZ implants in the edentulous mandible without a difference of OHRQoL between the groups (28). As well as De Kok *et al.* (2011) who compared 20 patients and their satisfaction with two versus four implants in the edentulous mandible and could not see any difference between the treatment groups (27). But if the patient's satisfaction expressed in their OHRQoL increase with a four implant-retained overdenture, advantages and disadvantages of two versus four implants in the edentulous mandible for retainment of the overdenture should be reexamined. Decision making in any dental treatment should be undertaken always in agreement with the patient, and based on the best available evidence (29). Universally, in implant treatments economical factors often play an essential role. If the increase of OHRQoL outweighs the higher costs and the larger surgical

intervention of a four-implant treatment has to be decided by the patients themselves. Therefore it is important to be able to justify, how many implants should be used for support or retention of the prosthesis in each individual case(24).

**Acknowledgments:**

The study was supported by medentis medical GmbH, Dernau, Germany.

**Figure I:** flow diagram on patient enrollment, intervention and follow-up.

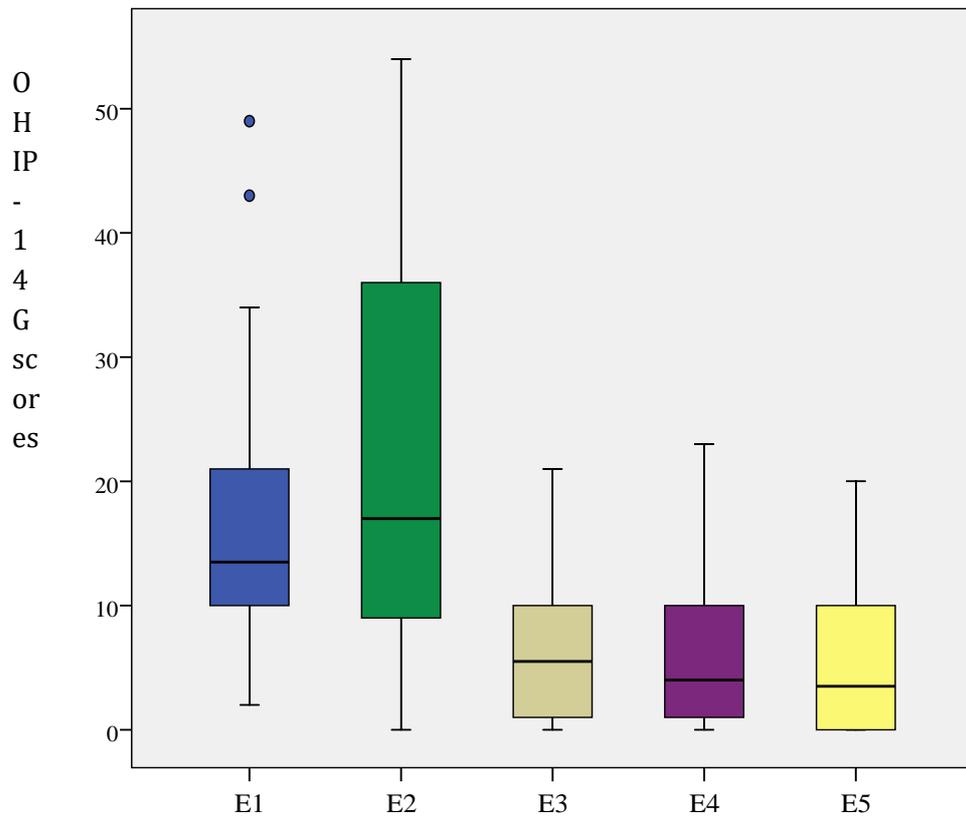


	<b>all patients (n=30)</b>	<b>group I (n = 15)</b>	<b>group II (n = 15)</b>
<b>gender</b>	20 (67%) woman, 10 (33%) man	9 (60%) woman, 6 (40%) man	11 (73%) woman, 4 (27%) man
<b>age (mean, SD, max, min)</b>	62 ± 9; min: 46 years, max.: 82 years	63 ± 8; min: 51 years, max.: 75 years	61 ± 9; min: 46 years, max.: 82 years
<b>alcohol consumption</b>	14(47%) never 12 (40%) ≤ two times a week 1 (3%) ≥ two times a week 3 (10%) daily	9 (60%) never 4 (27%) ≤ two times a week 0 (0%) ≥ two times a week 2 (13%) daily	5 (33%) never 8 (53%) ≤ two times a week 1 (7%) ≥ two times a week 1 (7%) daily
<b>smokingbehavior</b>	16 (53%) nonsmokers 8(27%) active smokers 6(20%) former smokers	10 (67%) nonsmokers 2 (13%) active smokers 3 (20%) former smokers	6 (40%) nonsmokers 6 (40%) active smokers 3 (20%) former smokers
<b>prostheticrestaurati on of the maxilla</b>	24 (80%) edentulous 2 (7%) implant retained- overdenture 4 (13%) partially edentulous	13 (87%) edentulous 1 (7%) implant retained- overdenture 1 (7%) partially edentulous	11 (73%) edentulous 1 (7%) implant retained- overdenture 3 (20%) partially edentulous

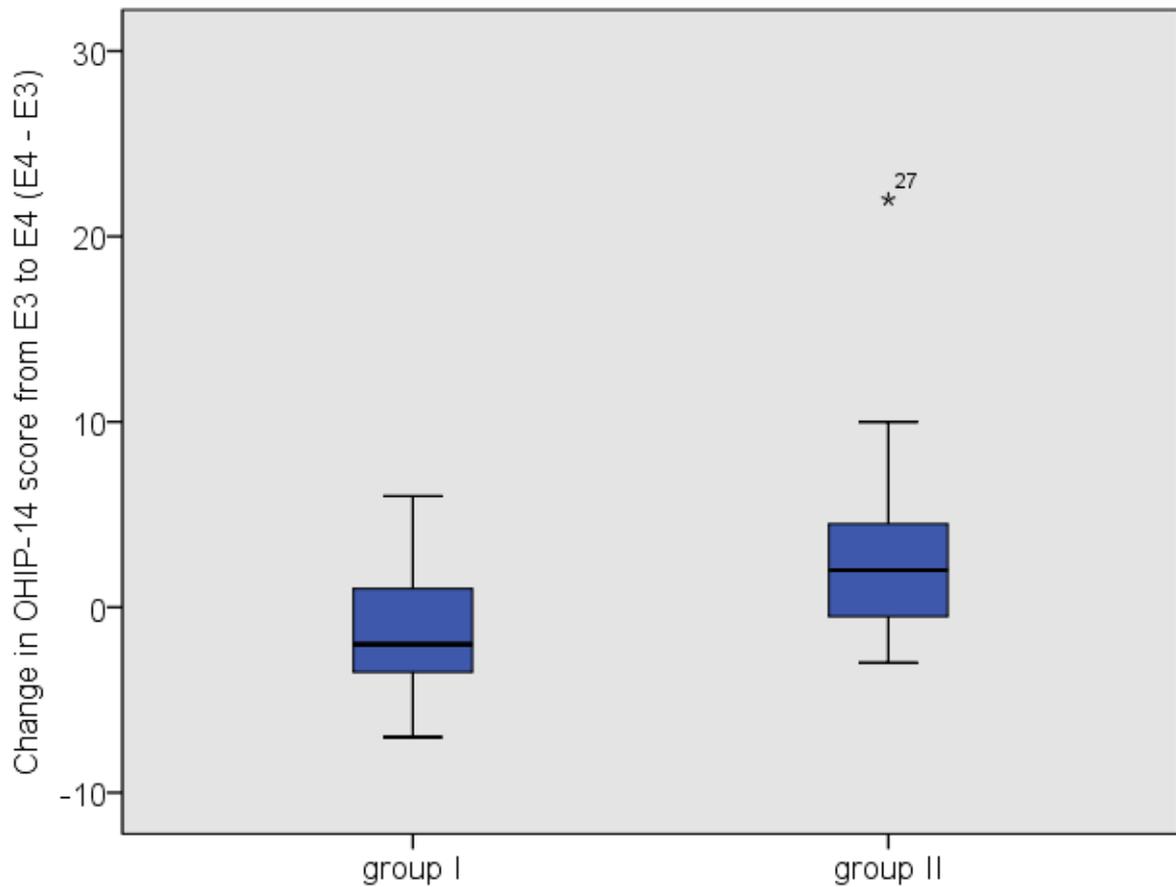
**Table I:** Gender, age (mean; standard deviation = SD; maximum = max; minimum = min), alcohol consumption, smoking behaviour and prosthetic restoration of the maxilla of all patients, splitted into the different groups of patients (group I: incorporation of two for the first three month of loading and four implants for the second three months of loading; group II: incorporation of four implants into the overdenture for the first three months of loading and two implants for the second three months of loading)

	median [Q1; Q3]		p <sup>1</sup>
	group I (N=15)	group II (N=15)	
OHIP-14 G at E3	7 [0; 11]	3 [1; 7]	
OHIP-14 G at E4	2 [0; 10]	7 [2; 13]	
Change in OHIP-14 G from E3 to E4	-2 [-4; 2]	2 [-1; 6]	0.026

**Table II:** Median and quartiles of the OHIP-14 G scores at the different investigation times (E3 = after the first three months of loading; E4 = after the second three months of loading) in the two patient groups (group I = first three month incorporation of two implants in the locator-retained overdenture, second three months incorporation of all four implants in the locator-retained overdenture; group II = first three month incorporation of four implants in the locator-retained overdenture, second three months incorporation of two implants in the locator-retained overdenture).<sup>1</sup> Mann-Whitney-U-test



**Figure II:** OHIP-14 G scores (minimum = 0; maximum = 56) at different investigation times (E1 = preoperative; E2 = after the healing period and before loading of the implants; E3 = after the first three months of loading; E4 = after the second three months of loading; E5 = one year after loading)



**Figure III:** Change in OHIP-14 G scores from investigation time E3(after the first three months of loading) to investigation time E4 (after the second three months of loading) in the two patient groups (group I = first three months incorporation of two implants in the locator-retained overdenture, second three months incorporation of all four implants in the locator-retained overdenture; group II = first three months incorporation of four implants in the locator-retained overdenture, second three month incorporation of two implants in the locator-retained overdenture)

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