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The role of dental implant abutment design on the aesthetic outcome: preliminary 3-month post-loading results from a multicentre split-mouth randomised controlled trial comparing two different abutment designs

Key words *abutment design, aesthetics, dental implants*

Purpose: To evaluate whether there are aesthetic and clinical benefits to using a newly designed abutment (Curvomax), over a conventional control abutment (GingiHue).

Materials and methods: A total of 49 patients, who required at least two implants, had two sites randomised according to a split-mouth design to receive one abutment of each type at seven different centres. The time of loading (immediate, early or delayed) and of prosthesis (provisional crowns of fixed prosthesis) was decided by the clinicians, but they had to restore both implants in a similar way. Provisional prostheses were replaced by definitive ones 3 months after initial loading, when the follow-up for the initial part of this study was completed. Outcome measures were: prosthesis failures, implant failures, complications, pink esthetic score (PES), peri-implant marginal bone level changes, and patient preference.

Results: In total, 49 Curvomax and 49 GingiHue abutments were delivered. Two patients dropped out. No implant failure, prosthesis failure or complication was reported. There were no differences at 3 months post-loading for PES (difference = -0.15, 95% CI -0.55 to 0.25; *P* (paired *t* test) = 0.443) and marginal bone level changes (difference = -0.02 mm, 95% CI -0.20 to 0.16; *P* (paired *t* test) = 0.817). The majority of the patients (30) had no preference regarding the two abutment designs; 11 patients preferred the Curvomax, while five patients preferred the GingiHue abutments (*P* (McNemar test) = 0.210).

Conclusions: The preliminary results of the comparison between two different abutment designs did not disclose any statistically significant differences between the evaluated abutments. However the large number of missing radiographs and clinical pictures casts doubt on the reliability of the results. Longer follow-ups of wider patient populations are needed to better understand whether there is an effective advantage with one of the two abutment designs.

Conflict of interest statement: *This research project was originally partially funded by Biomax (Andover, MA, USA), the manufacturer of the Curvomax abutments evaluated in this investigation. Biomax, under pressure from some investigators, asked to modify the original agreed protocol. In a following phase, Zimmer-Biomet (Palm Beach Gardens, Florida, USA), the manufacturer of the implants and the GingiHue abutments, took over the funding of this project. Data belonged to the authors and the sponsors did not interfere with the publication of results.*

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Introduction

Implant-supported prostheses are an effective and reliable treatment for replacing missing teeth. The success of implant-supported prostheses is mainly based on the ability of the bone to integrate and stabilise dental implants[1]. This process is generally known as "osseointegration". Literally thousands of new dental implant designs, materials and surface technologies are continuously developed in an attempt to further improve the outcome of implant therapy. There are many trials comparing different implant systems made from various materials and of different design, and surface characteristics[2]. Less scientific attention was given to the role of the abutment morphology on the clinical outcome, with special reference to the aesthetic outcome. It is obvious that the morphology, the material and the colour of the abutment, being the connection and the transition between the intrabony portion (the implant) and the oral portion (the prosthesis), plays an important role in the maintenance of peri-implant tissue health and to ensure good aesthetics. While this issue is subject to an aggressive commercial marketing, with many manufacturers and clinicians claiming the superiority of their products over the competition, reliable scientific evidence is still scarce and does not disclose any clinical visible differences[3-8].

A currently emerging idea is the concept of "less metal, more tissue". Two recent randomised controlled trials (RCTs), tested the hypothesis of whether the thickness and the aesthetics of soft tissues around abutments can be enhanced by using a less flared and concave abutment design; however their clinical results failed to prove it, since no differences were observed when compared with conventional abutments[4,5,9]. According to the same concept a new abutment was designed (Curvomax, Biomax, Vicenza, Italy; Fig 1) to allow more space for peri-implant soft tissues so as to facilitate their maintenance and decrease the risk of recession. Another commercially available abutment (GingiHue, Zimmer-Biomet, Palm Beach Gardens, Florida, USA; Fig 2), is characterised by a more conventional design, which could act as gold standard control.

The aim of this pragmatic, multicentre, randomised controlled trial (RCT) of split-mouth design, was to evaluate whether there are some aesthetic and clinical benefits to using the newly designed Curvomax abutment over a conventional control GingiHue abutment used in similar clinical condition with the same implant system (T3 tapered DCD implants, Zimmer-Biomet). This is the first report presenting the clinical outcome at 3 months post-loading. Further reports were originally agreed at the completion of the 1 and 5 years post-loading follow-ups. The present article is reported according to the CONSORT statement for improving the quality of reports of parallel-group randomised trials (http://www.consort-statement.org/) and the extension checklist for reporting within person randomised trials[10].

Materials and methods

This study was designed as a pragmatic multicentre RCT of split-mouth design, with each patient receiving two implants to support one abutment of each type (Curvomax and GingiHue), which were randomly allocated. When possible, blinded assessments were carried out by independent outcome assessors.

Any partially edentulous patient requiring at least two implants, being 18 years or older, and able to understand and sign a written informed consent form, was eligible for this trial. Implants could be placed in adjacent sites. Broad inclusion criteria were used, including any type of bone, any location, whether or not the patient was a smoker, immediate post-extractive implants, and immediate, early or delayed loading procedures, etc. Pre-operative radiographs (periapical, panoramic, CT scans or other radiographic examinations at the operators' discretion), together with clinical inspections, were used to determine bone volumes, which had to allow the placement of at least two implants of at least 8.1 mm long and 4.1 mm wide. Exclusion criteria were:

- Unable to commit to a 5-year follow-up;
- Less than 3.0 mm of soft tissue height above the future implant site as measured at screening with an endodontic file inserted into the mucosa until the bone was felt;
- General contraindications to implant surgery;
- Immunosuppressed or immunocompromised;
- Irradiated in the head and/or neck area;

Fig 1 Test abutment: Curvomax (Biomax, Vicenza, Italy) 4.0 mm diameter with either a 1.0 mm or a 2.0 mm collar height concavity, platform 3.8 mm. The reduced platform of the abutment induced a minor horizontal platform switching of 0.15 mm (see Figures 3a, 3b and 3d).

Fig 2 Control abutment: GingiHue IAPP452G straight (Biomet 3i) with 2.0 mm collar height, profile 5.0 mm and platform 4.1 mm.

- Uncontrolled diabetes;
- Pregnancy or nursing;
- Untreated periodontitis;
- Poor oral hygiene and motivation;
- Substance abuse;
- Psychiatric problems or unrealistic expectations;
- Acute/purulent infection in the area intended for implant placement;
- Treated or under treatment with intravenous amino-bisphosphonates;
- Referred only for implant placement if the follow-up cannot be done at the treatment centre;
- Participation in other studies, if the present protocol could not be followed properly.

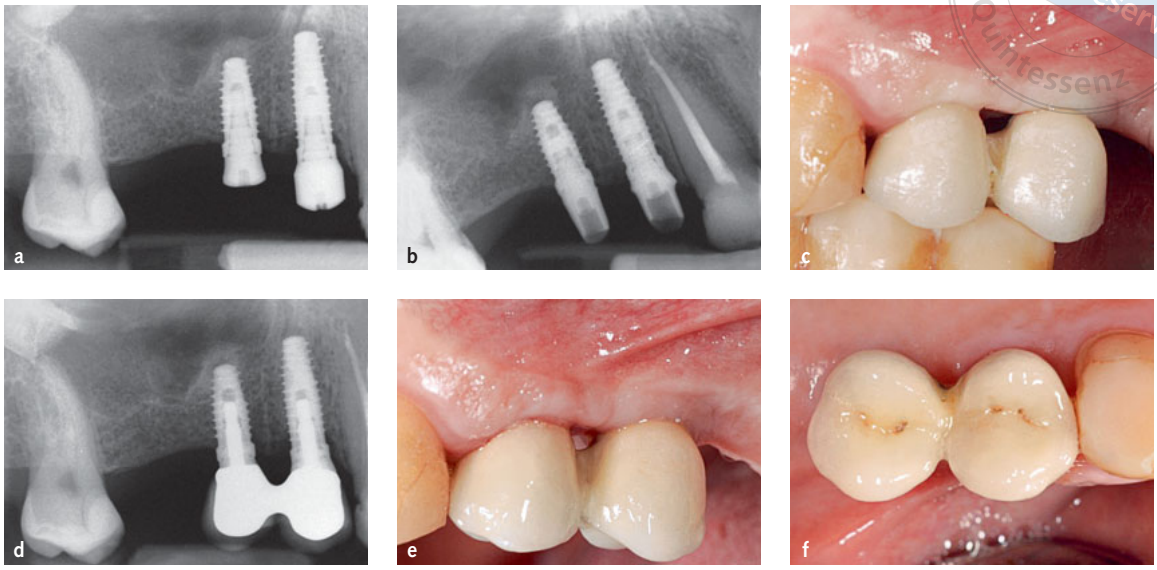
All patients received thorough explanations and signed a written informed consent form prior to being enrolled on the trial to document that they understood the scope of the study (including procedures, follow-up evaluations, and any potential risks involved), were allowed an opportunity to ask questions pertaining to this study, and were apprised of treatment alternatives. The study was open to qualifying patients with no regard to sex or race.

Patients were recruited and treated in seven Italian private practices by experienced operators (Drs Cardaropoli, Delli Ficorelli, Fabianelli, Gobbato, Mascellani, Mazzocco and Scutellà). Each practitioner should have enrolled and treated 10 patients in this trial. All the follow-up visits were conducted at the respective treating centres. Originally, 11 centres agreed to participate in the study, but four centres failed to provide any patient data.

After consent was given, and in cases where more than two sites required single implants, the surgeon selected two implant sites among those with the most similar characteristics and indicated one area as site no. 1, and the other as site no. 2. Patients were categorised into one of three groups according to what they declared: non-smoker, moderate smoker (up to 10 cigarettes per day), and heavy smoker (more than 10 cigarettes per day).

Clinical procedures

Both implants were inserted during the same surgical session and were to be restored simultaneously with similar types of prostheses (Figs 3a to f). Patients received prophylactic antibiotic therapy: 2 g of amoxicillin (or 600 mg clindamycin, if allergic to penicillin) 1 h prior to surgery and then rinsed for 1 min with chlorhexidine 0.2%. All patients were treated under local anaesthesia (Articain with adrenaline 1:100.000). When needed, tooth extractions were performed as atraumatically as possible, in an attempt to preserve the buccal alveolar bone. Extraction sockets were carefully cleaned of any remnants of granulation tissue. Afterwards, crestal or slightly palatal incisions flaps were elevated, and both implant sites were prepared as recommended by the implant manufacturer. Bone quality was subjectively categorised into hard, medium and soft. Countersinking was used in hard bone. Two tapered dental implants (T3 tapered BNST implants, Zimmer-Biomet) with an internal hexagon connection (CERTAIN), made of titanium grade 4 with a media-blasted surface for



Figs 3a to f Treatment sequence of one of the patients treated by Dr Fabianelli: a) periapical radiograph just after implant placement showing two implant in position 15 (Curvomax) and 14 (GingiHue); b) periapical radiograph at delivery of the provisional prosthesis; c) provisional prosthesis in place; d) periapical radiograph at delivery of the definitive prosthesis, 3 months after initial loading; e) vestibular and f) occlusal clinical views of the definitive prosthesis at 3 months post-loading used for the aesthetic evaluation.

coarse 10+ micron topography, along with a dual acid-etched 1-3 micron peek-to-peek surface and a 0.01-0.1 μ discrete crystalline deposition (DCD) of calcium phosphate nano-particles, were placed. Only 4.0 mm diameter implants were used, but operators were free to choose 8.5 mm, 10.0 mm, 11.5 mm and 13.0 mm lengths, according to clinical indications. Implants were placed with the neck flush to the crestal bone level, with the exception of post-extractive implants. These were placed 2.0 mm below the palatal bone level and more palatally/lingually. In the case of post-extractive implants, and in the presence of a residual gap between the implant surface and the bone wall, the gap was filled with granules of anorganic bovine bone (Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland). Buccal walls were also horizontally augmented, at the surgeons' discretion, using anorganic bovine bone and collagen resorbable membranes (Bio-Gide, Geistlich Pharma AG). If both implants were not immediately loaded, those in aesthetic areas were submerged and those in non-aesthetic areas were not submerged. An envelope corresponding to the patient recruitment number containing details of which type of healing abutment to place for implant site no. 1 was disclosed. The other implant received the other type of healing abutment. Curvo Healing abutments, with the same concavity height of 1.0 mm or 2.0 mm as the final abutment, were used for the Curvomax abutments (Fig 1); and Standard Healing abutments were used for the GingiHue abutments (Fig 2). Flaps were sutured and baseline periapical radiographs of the study implants were taken. If bone levels around the study implants were hidden or difficult to estimate, a second radiograph was obtained.

A 400 mg dose of ibuprofen (or 1 g paracetamol, in the case of allergy to ibuprofen, or stomach problems) was prescribed two to four times a day during meals, if required. Postoperative antibiotics were prescribed only to patients subjected to bone augmentation procedures: 1 g amoxicillin twice a day for 6 days. Patients allergic to penicillin were prescribed 300 mg clindamycin twice a day for 6 days. Patients were instructed to use chlorhexidine 0.12% mouthwash for 1 min twice a day for 2 weeks and to avoid brushing and trauma on the surgical sites. Within 10 days, all patients were recalled and sutures were removed.

Impressions were taken and the same prosthetic procedures were implemented in the same patient for both implants. Within 1 week, provisional cemented acrylic prostheses were delivered, together with the study abutments and the final metal framework. Periapical radiographs of the study implants were then

taken. Two weeks after the delivery of provisional prostheses, a pick-up impression of the final metal framework on the study abutments was taken and, within 2 weeks, definitive metal-ceramic prostheses were delivered and cemented with a provisional zinc oxide-eugenol base cement (Temp-Bond, Kerr Dental, Orange, CA, USA). Three months after initial loading, periapical radiographs, as well as vestibular and occlusal pictures of the study implants – including one adjacent tooth per side – were taken.

Patients were enrolled on an oral hygiene maintenance programme, with recall visits at least every 6 months for the entire duration of the study.

Outcome measures

This study tested the null hypothesis that there were no differences in the clinical outcomes between the two abutment types against the alternative hypothesis of a difference. Outcome measures were:

- Prosthesis failure (primary outcome measure): inability to place or replacement of the prosthesis with a new prosthesis for any reason.
- Implant failure (primary outcome measure): implant failure was defined as implant mobility and/or any infection dictating implant removal or mechanical failure rendering the implant unusable, such as implant fracture or deformation of the implant-abutment connection. The stability of each implant was measured manually by tightening the abutment screw at delivery of definitive prostheses.
- Any complications and adverse events (primary outcome measure) were recorded and reported according to implant types.
- Aesthetic evaluation (primary outcome measure) of the vestibular and occlusal clinical pictures, including the two adjacent teeth of the definitive prostheses, was taken 3 months after loading, and performed on a computer screen. The aesthetic evaluation was carried out using the pink esthetic score (PES)[11]. In brief, seven variables were evaluated: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiencies, soft tissue colour and texture. A 0 to 1 to 2 scoring system was used, 0 being the lowest and 2 being the highest value, with a maximum achievable score of 14 per implant.
- Peri-implant marginal bone level changes (secondary outcome measure): periapical radiographs were made with the paralleling technique at implant placement (Fig 3a), at initial loading (Fig 3b), and at delivery of the definitive prostheses 3 months after loading (Fig 3d). Radiographs were scanned in TIFF format with a 600 dpi resolution, and stored on a personal computer. Peri-implant marginal bone levels were measured using the ImageJ (National Institutes of Health, Maryland, USA) software. The software was calibrated for every single image using the known length of the implant. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm. Reference points for the linear measurements were: the coronal margin of the implant collar and the most coronal point of bone-to-implant contact. The mesial and distal measurement of each implant was averaged and a mean calculated at implant level, and then at group level.
- Patient preference (primary outcome measure) assessed at 3 months after loading. Patients were blinded to abutment allocation, as were the assessors. The local assessor showed both implants to the patient using a well-lit mirror, and asked them which of the prostheses they preferred. Possible answers could be: "the prosthesis in implant site number 1"; "the prosthesis in implant site number 2"; "I like both prostheses the same"; or "I dislike both prostheses".

At each centre, a local, blind outcome assessor recorded all clinical outcome measures, with the exception of complications, which were evaluated by the clinicians responsible. The abutment type was not recognisable when assessing implant stability, but it could be recognised on radiographs. Dr Luca Sbricoli, a single independent, experienced assessor, evaluated the periapical radiographs and clinical pictures.

Methodological aspects

At the protocol formulation stage, there were no clinical data on the aesthetics outcome of the abutments under investigation, meaning a reliable sample size

calculation could not be performed. Therefore, it was decided to include 110 pairs. Each of the 11 original centres had to treat 10 patients. Unfortunately, only seven centres actually contributed to this trial and the majority of them did not provide the agreed 10 patients.

Eleven computer-generated restricted random lists were created. Only one investigator (Dr Esposito), who was not involved in the selection and treatment of the patients, knew the random sequence and had access to the random list stored on a password-protected portable computer. The random codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. The envelope corresponding to the patient recruitment number was only opened after both implants were placed and the indication was given to the clinician regarding whether to place a Curvomax or a GingiHue provisional or definitive abutments in the implant in position no.1. The other site received the other abutment type. Therefore, treatment allocations were concealed to the investigators in charge of enrolling and treating the patients.

All data analysis was carried out according to a preestablished analysis plan. A practitioner with expertise in statistics (Dr Trullenque-Eriksson) analysed the data. Differences in the proportion of patients with prosthesis/implant failures, complications, or preference (dichotomous outcomes) were compared using the exact McNemar test. Differences between the groups for continuous outcomes (mean marginal bone level changes, aesthetics assessed by the clinician) were compared using a paired *t* test. Comparisons between the various follow-up endpoints and the baseline measurements were made by paired *t* tests, to detect any changes in mean marginal bone level changes for each study group. Differences between centres for continuous outcomes were analysed with the Kruskal-Wallis test. For categorical outcomes comparing two groups, the Fisher's exact test was used. When the contingency table was larger than 2 × 2, the Fisher-Freeman-Halton exact test of independence was used instead. All statistical comparisons were conducted at the 0.05 level of significance.

Results

Four of the 11 clinicians failed to supply any data. In total 94 patients were screened for eligibility, but 45 patients were not recruited for the following reasons: 12 patients were affected by untreated periodontitis: eight for compromised health conditions/uncontrolled diabetes; six were unable to regularly attend the controls; six for suppuration at future implant sites; five because they were treated with endovenous bisphosphonates; four had bruxism (even though this was not an exclusion criteria); one did not want to participate in the trial; one for alcohol abuse; one for pregnancy, and for another patient no reason was given. All patients had their sites treated according to the allocated interventions. Two patients dropped out before the 3 months after loading follow-up: one patient was involved in a severe car accident after the delivery of provisional crowns (Dr Delli Ficorelli) and one patient's Alzheimer's disease worsened after delivery of the provisional crowns (Dr Fabianelli). The data of all remaining patients were included in the statistical analyses, with the exception of:

Dr Scutellà (seven patients)

- Curvomax:
  - Radiograph at implant insertion (seven patients);
  - Radiograph at initial loading (four patients);
  - Radiograph at 3 months after loading (three patients);
  - Clinical pictures at 3 months after loading (four patients.
- GingiHue:
  - Radiograph at implant insertion (seven patients);
  - Radiograph at initial loading (three patients);
  - Radiograph at 3 months after loading (two patients);
  - Clinical pictures at 3 months after loading (four patients).

Dr Mazzocco (five patients)

- Curvomax:
  - Radiograph at loading (two patients).
- GingiHue:
  - Radiograph at loading (two patients).

Dr Gobbato (10 patients)

- Curvomax:
  - Radiograph at 3 months after loading (10 patients);
  - Clinical pictures at 3 months after loading (one patient).
- GingiHue:
  - Radiograph at 3 months after loading (10 patients);
  - Clinical pictures at 3 months after loading (one patient).

Dr Delli Ficorelli (five patients)

- Curvomax:
  - Radiograph at implant insertion (five patients);
  - Radiograph at initial loading (four patients);
  - Radiograph at 3 months after loading (four patients);
  - Clinical pictures at 3 months after loading (four patients).
- GingiHue:
  - Radiograph at implant insertion (four patients);
  - Radiograph at initial loading (four patients;)
  - Radiograph at 3 months after loading (three patients);
  - Clinical pictures at 3 months after loading (three patients).

Dr Mascellani (six patients)

- Curvomax:
  - Radiograph at implant insertion (one patient);
  - Radiograph at 3 months after loading (six patients);
  - Clinical pictures at 3 months after loading (two patients).
- GingiHue:
  - Radiograph at implant insertion (one patient);
  - Radiograph at 3 months after loading (six patients);
  - Clinical pictures at 3 months after loading (two patients).

Dr Cardaropoli (10 patients)

- Curvomax:
  - Clinical pictures at 3 months after loading (two patients).
- GingiHue:
  - Clinical pictures at 3 months after loading (two patients).

Dr Fabianelli (six patients)

- Curvomax:
  - Clinical pictures at 3 months after loading (one patient).
- GingiHue:
  - Clinical pictures at 3 months after loading (one patient).

The following deviations from the research protocol were observed:

- Dr Scutellà: Treated seven patients instead of 10. In addition, treated one patient six times and one twice, but only data from the first treatment were included in the study. In one of the included patients, one implant was loaded immediately and the other conventionally.
- Dr Mazzocco: Treated five patients instead of 10.
- Dr Delli Ficorelli: Treated five patients instead of 10.
- Dr Mascellani: Treated six patients instead of 10.
- Dr Fabianelli: Treated six patients instead of 10.

Patients were recruited and implants were inserted from January 2014 to June 2015. The follow-up for all the remaining patients was 3 months post-loading. There were 30 females and 19 males (ranging in age from 39 to 89), with a mean age of 61 years at the time of implant placement In total, 42 (85.7%) patients declared they were non-smokers, two (4.1%) were moderate smokers (up to 10 cigarettes per day) and five (10.2%) were heavy smokers. The main recipient site and implant characteristics, divided by study group, are presented in Table 1. In total, 49 abutments of each type were placed. There were no apparent significant baseline imbalances between the two groups.

Up to 3 months post-loading, no implant or prosthesis failed, and there were no complications reported.

Table 1 Recipient site and implant characteristics of the 49 patients originally included.

		Curvomax abutments (n = 49)	GingiHue abutments (n = 49)
Bone quality	Hard bone	8 (16.3%)	9 (18.4%)
	Medium bone	36 (73.4%)	36 (73.5%)
	Soft bone	5 (10.2%)	4 (8.2%)
Jaw	Maxilla	25 (51%)	22 (44.9%)
	Mandible	24 (49%)	27 (55.1%)
Implant position	Canine sites	1 (2%)	3 (6.1%)
	Premolar sites	23 (46.9%)	20 (40.8%)
	Molar sites	21 (42.9%)	23 (46.9%)
	Incisor sites	4 (8.2%)	3 (6.1%)
Post-extractive implants		4 (8.2%)	4 (8.2%)
Augmented post-extractive implants		8 (16.3%)	9 (18.4%)
Implant length (mm)	8.5	9 (18.4%)	5 (10.2%)
	10.0	24 (49%)	23 (46.9%)
	11.5	11 (22.4%)	16 (32.7%)
	13.0	5 (10.2%)	5 (10.2%)
Loading	Immediate loading	2 (4.1%)	3 (6.1%)
	Early loading	0	0
	Delayed loading	47 (95.9%)	46 (93.9%)
Prosthesis type	Single crown	9 (18.4%)	
	Fixed prosthesis joining both implants	40 (81.6%)	

Table 2 PES scores at delivery of definitive prostheses (3 months after loading) by groups and by different aesthetic domains; standard deviation is in parenthesis.

	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
Curvomax = 33	1.30 (0.59)	1.00 (0.71)	1.88 (0.33)	1.61 (0.56)	2.00 (0)	1.97 (0.17)	1.97 (0.17)	11.73 (1.70)
GingiHue = 34	1.29 (0.76)	1.26 (0.57)	1.88 (0.41)	1.65 (0.54)	2.00 (0)	1.94 (0.24)	1.97 (0.17)	11.94 (1.71)
Mean difference (SD) N = 33	0.03 (0.95)	-0.24 (0.71)	0.00 (0.35)	-0.03 (0.31)	0 (0)	0.03 (0.17)	0 (0)	-0.15 (1.12)
P (paired *t* test)	0.856	0.058	1.000	0.572	1.000	0.325	1.000	0.443

Three months after loading, the average total PES score (Table 2), assessed by a blind assessor, was 11.73 ± 1.70 for Curvomax and 11.94 ± 1.71 for GingiHue implants, the difference being not statistically significant (difference = -0.15, 95% CI -0.55 to 0.25; P (paired *t* test) = 0.443).

At implant placement (baseline) the difference in bone levels was not statistically significant (difference in mm = -0.02, 95% CI -0.08 to 0.05; P (paired *t* test) = 0.594): 0.14 ± 0.22 mm for Curvomax abutments, and 0.15 ± 0.22 mm for GingiHue abutments (Table 3). Both groups gradually lost statistically significant amounts of peri-implant marginal bone at 3 months after loading. Three months after loading, Curvomax abutments lost an average of 0.34 ± 0.43 mm of peri-implant bone compared with 0.38 ± 0.39 mm with the GingiHue abutments (Table 3). Marginal bone level changes were not statistically significant different for Curvomax compared with GingiHue abutments at 3 months (-0.02 mm, 95% CI -0.20 to 0.16; *P* (paired *t* test) = 0.817; Table 3) after loading.

After delivery of the definitive crowns 3 months after initial loading, patients were asked by the local blind outcome assessors about their preference regarding the prostheses: Thirty patients declared that

Table 3 Mean radiographic peri-implant marginal bone levels and changes between abutment types and time periods.

	Implant placement	3 months post-loading*	Baseline – 3 months after loading
	N Mean (SD) 95% CI	N Mean (SD) 95% CI	N Mean (SD) 95% CI
Curvomax	36 0.14 (0.22) 0.06 to 0.21	24 0.43 (0.48) 0.22 to 0.63	20 0.34 (0.43) 0.14 to 0.54 *P* (paired *t* test) = 0.002*
GingiHue	37 0.15 (0.22) 0.08 to 0.22	26 0.51 (0.47) 0.32 to 0.70	21 0.38 (0.39) 0.20 to 0.55 *P* (paired *t* test) < 0.001*
Difference (SE) (95% CI)	36 -0.02 (0.19) -0.08 to 0.05 *P* (paired *t* test) = 0.594	24 -0.08 (0.42) -0.26 to 0.10 *P* (paired *t* test) = 0.344	20 -0.02 (0.38) -0.20 to 0.16 *P* (paired *t* test) = 0.817

*All changes from baseline are statistically different. SD = Standard deviation; CI = Confidence interval.

Table 4 Comparison between the seven centres up to 3 months after loading. The Fisher-Freeman-Halton exact test of independence was used to compare categorical outcomes.

	Scutellà 7 patients	Mazzocco 5 patients	Gobbato 10 patients	Delli Ficorelli 5 patients	Mascellani 6 patients	Cardaropoli 10 patients	Fabianelli 6 patients	*P*-value
Peri-implant marginal bone loss (N Mean SD)								
Curvomax	- 	5 0.20 0.27	- 	- 	- 	10 0.49 0.51	5 0.18 0.29	*P* (Kruskal Wallis) = 0.433
GingiHue	- 	5 0.42 0.41	- 	1 0.70 	- 	10 0.35 0.42	5 0.32 0.38	*P* (Kruskal Wallis) = 0.735
Pink esthetic score (N Mean SD)								
Curvomax	3 13 1.73	5 11.40 1.52	9 11.78 1.64	- 	4 11.00 2.58	8 12.00 1.69	4 11.25 1.50	*P* (Kruskal Wallis) = 0.730
GingiHue	3 13.33 1.16	5 11.40 1.67	9 12.11 1.36	1 14 	4 10.75 2.99	8 12.13 1.55	4 11.50 1.29	*P* (Kruskal Wallis) = 0.387
Patients preference (N)								
Curvomax	7 $(7)_a$	2 $(5)^{a,b}$	5 $(9)^{a,b}$	4 $(4)^a$	0 $(6)^b$	7 $(10)^{a,b}$	5 $(5)^a$	*P* (Fisher's exact test) = 0.002*
GingiHue	0 $(7)_a$	2 $(5)^a$	4 $(9)^a$	0 $(4)^a$	3 $(6)^a$	2 $(10)^a$	0 $(5)^a$	
The same	0 $(7)_a$	1 $(5)^a$	0 $(9)^a$	0 $(4)^a$	3 $(6)^a$	1 $(10)^a$	0 $(5)^a$	

a,b Each subscript letter denotes a subset whose column proportions do not differ significantly from each other.
*Statistically significant difference.

they were the same, 11 patients preferred the Curvomax and five preferred the GingiHue abutments (*P* (McNemar test) = 0.210).

The comparison between the seven centres is presented in Table 4. At 3 months after loading, no statistically significant differences were found between the centres, with the exception of more patients, in some centres, preferring Curvomax abutments (*P* = 0.002).

Discussion

This study was aimed at evaluating whether or not two different abutments placed and restored under similar clinical conditions had similar clinical performances. No statistically significant differences were observed between the two abutment types. No failures or complications were reported. Also, the aesthetic outcome and the peri-implant marginal bone

loss were very similar between the two abutment types. The majority of patients had no preference for one abutment type over the other. Therefore, it can be concluded that the clinical outcomes of the two different abutment designs is similar, leaving it in the clinician's hands to choose the preferred one.

When comparing the outcomes between different centres, no significant statistically differences emerged, meaning that all centres also achieved similar results, independent of the type of abutment used. However, in some centres patients preferred Curvomax over the GingiHue abutments, and the difference between centres was statistically significant. Since no differences were observed for aesthetics assessed by a blind centralised measurer, it cannot be excluded that patients might have been influenced by their particular practitioner's own opinions.

The few other RCTs that tested a similar hypothesis[4,5,9] failed to show any statistically significant differences, suggesting that little changes in abutment shapes may not have a major impact on the aesthetic outcome, even though all the published trials, including this present one, are most likely underpowered to detect a difference, it any. There are some additional trials comparing zirconia with titanium abutments with the idea of improving aesthetics[12], and others comparing standard vs customised zirconia abutments with the idea of being able to leave less submucosal cement to prevent peri-implantitis[13], and another comparing pink veneered vs zirconia abutments with the idea of improving aesthetics[14,15]. However, again such improvements could not be verified, with the exception of one trial[15], which showed a better aesthetic using pink veneered zirconia abutments, assessed with spectrophotometry. It remains unclear, however, if the human eye can perceive such a difference.

It is interesting to observe that despite the fact osseointegrated dental implants have been in use for more than 50 years and that thousands of scientific publications have been devoted to this subject, there is still a lack of sufficient reliable evidence to help clinicians choose the ideal abutment design/material/surface preparation.

The main limitations of the present study were the small sample size, the short follow-up duration, and the numerous radiographs and clinical pictures either nor taken or lost during the course of the study, which further reduced the sample size. Unfortunately, the planned sample size could not be achieved due to too many centres agreeing to participate in the trial and that never delivered any data, and by the reduced recruitment ability of the majority of the participating centres. A longer follow-up of this sample population was planned and is currently ongoing. Longer follow-ups are definitively needed since they might disclose clinically relevant differences, which may only appear after several years in function.

Regarding the generalisation of these preliminary results, due to the pragmatic nature of the present study design, other operators treating patients with similar procedures should obtain similar results.

Conclusions

The preliminary results of the comparison between two different abutment designs did not disclose any statistically significant differences between the evaluated abutments. However, the large number of missing radiographs and clinical pictures casts doubt on the reliability of the results. Longer follow-ups of wider patient populations are needed to better understand whether there is an effective advantage to using one of the two abutment designs.

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