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A comparison of two dental implant systems in partially edentulous patients: 1-year post-loading results from a pragmatic multicentre randomised controlled trial

Key words *dental implant, effectiveness, laser treated surface*

Purpose: To compare the clinical effectiveness of two implant systems: Way Milano and Kentron (Geass, Pozzuolo del Friuli, UD, Italy).

Materials and methods: A total of 64 patients requiring at least two single crowns or partial fixed dental prostheses supported by a maximum of three implants had their sites randomised according to a split-mouth design to receive both implant systems at six centres. Patients were followed up for 1 year after initial loading. Outcome measures were: prosthesis/implant failures; any complication; peri-implant marginal bone level changes; and clinician preference.

Results: In total 71 Way Milano and 73 Kentron implants were placed. Six patients dropped-out before the 1-year follow-up, but all remaining patients were followed up to 1 year post-loading. No Way Milano implant failed, whereas three Kentron implants failed before loading. Two complications were reported, one for each implant type. There were no statistically significant differences for prosthesis/implant failures (difference in proportions = 0.05, $P = 0.25$; 95% CI -0.02 to 0.13) and complications (difference in proportions = 0, $P = 1.0$, 95% CI -0.07 to 0.07) between the implant systems. Three operators preferred Way Milano implants whereas the other three had no preference. At implant placement (baseline) bone levels were higher for Way Milano implants (0.27 mm) than for Kentron implants (0.41 mm). Both groups gradually lost statistically significant amounts of peri-implant marginal bone at 4 months after loading and at 1 year after loading. One year after loading, Way Milano implants lost an average of 0.73 mm peri-implant bone compared with 0.84 mm of Kentron implants. Marginal bone level changes were not statistically significant different for Way Milano compared to Kentron implants at 4 months (-0.16 mm, 95% CI -0.30, 0.01; $P = 0.0606$) and 1 year (-0.09 mm, 95% CI -0.26, 0.09; $P = 0.3407$) after loading.

Conclusions: No statistically significant differences were observed between the two implant types, although three Kentron implants failed versus none of the Way Milano type. Longer follow-up of wider patient populations are needed to better understand whether there is an effective advantage with one of the two implant designs.

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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 to further improve the outcome of implant therapy. There are many trials comparing different implant systems made of various materials, and having different design and surface characteristics[2]. Dental implants are the subject of aggressive commercial marketing, with many manufacturers and clinicians claiming the superiority of their products over the competition. However, the claimed clinical superiority of any of these implant systems or implant characteristics has so far not been clearly confirmed by any well designed and conducted clinical trial[2], with one exception that showed only a small significant difference between two different implant designs on marginal bone loss[3]. Nevertheless, several implant characteristics, such as the micro- and macro-morphology, are believed to and actually could influence the clinical outcome of dental implants. Therefore, many different implant surfaces and implant designs have been developed and are currently used.

One of the leading ideas was to enlarge the implant surface available to increase the bone-to-implant contact. Another hypothesis is that cell behaviour could be influenced by different types of surface morphologies and characteristics. The increase of the implant surface can be obtained by having it roughened. There are several methods for producing surface roughness[4]; for example, implant surfaces can be blasted with various types of powders (alumina, hydroxyapatite, etc). Another mean to roughen an implant surface is by use of a laser beam. Depending on the type of laser used, laser-treated surfaces can yield roughness that is extremely ordered and uniform in contrast to blasting or plasma spraying that produce surfaces of random irregularity. Some authors suggested that cells participating in the osseointegration process may behave differently on implant surfaces with strictly regular and ordered superficial roughness characteristics[5]. One of the lasers, able to produce an 'ordered' rough surface characterised by a series of craters with a specific diameter and interspacing, is the pulsed, diode-pumped solid state (DPSS) source laser in a Q-Switch output mode or Q-Switch output rate. The laser-beam evaporates the material from the surface and this 'cold' ablation allows the creation of reproducible surfaces with a series of ordered pits without altering the physicochemical characteristics of the titanium. Such surface treatment was commercially named SYNTHEGRA (Geass, Pozzuolo del Friuli, UD, Italy; Figs 1a and 1b). The choice of the specific surface pattern with a hemispherical porosity of 20 μm diameter and 30 μm interspace was based on an *in vitro* study that suggested that this surface pattern seemed to trigger greater viability and proliferation in human osteoblast-like cells[6].

The aim of this pragmatic multicentre randomised controlled trial (RCT) of split-mouth design was to compare the clinical effectiveness of a recently designed implant system (Way Milano, Geass) when compared to its predecessor (Kentron; the Way Milano implant is an evolution of the Kentron implant). This is the second report in a series presenting clinical outcome at 1 year post-loading. A previous publication reported the results at 4 months post-loading[7]. A further report on this study will be published after the completion of 5-year follow-up. 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/).

Materials and methods

Any partially edentulous patient requiring at least 2 single implant-supported crowns or 2 partial fixed dental prostheses supported by a maximum of 3 implants (1 single implant-supported crown and 1 partial bridge in the same mouth were accepted), 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, but implants supporting the same prosthesis had to be of the same type. This study was designed as a pragmatic trial in order to reflect more the clinical reality. In fact, broad inclusion criteria were used, including factors such as any type of bone, any loca-

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tion and smokers. Clinicians were allowed to choose among several treatment options (e.g. flapless placement; crestal sinus lifting; immediate post-extractive implants; minor augmentation procedures at implant placement to fill possible gaps at immediate post-extractive implants or at implant fenestrations; immediate, early or delayed loading; submerged or non-submerged placement, etc) at their discretion if the implants in the same mouth could be subjected to similar procedures.

Preoperative radiographs (intraoral, panoramic, CT scans or other radiographic examinations at discretion of the operators) together with clinical inspections were used to determine bone volumes, which had to allow the placement of at least two implants being at least 9 mm long and 3.8 mm wide. Exclusion criteria were:

- general contraindications to implant surgery
- immunosuppressed or immunocompromised
- irradiated in the head and neck area
- uncontrolled diabetes
- pregnant or nursing
- poor oral hygiene and motivation
- untreated periodontitis
- substance abusers
- psychiatric problems or unrealistic expectations
- acute/purulent infection in the area intended for implant placement
- unable to commit to 5-year follow-up
- treated or under treatment with intravenous amino-bisphosphonates
- lacking antagonistic occlusal surfaces for the study implants at implant loading
- needing major bone grafting procedures, including sinus lift with lateral approach at implant placement (minor augmentation procedures such crestal sinus lift and augmentation at immediate implant in post-extractive sites, were allowed)
- participating in other studies, if the present protocol could not be properly followed.

The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to. All patients received thorough explanations and signed a written informed consent form prior to being enrolled in 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 without regard to sex or race. For patients having more than two eligible implant sites, the operator chose the two sites with the most similar characteristics at the screening visit.

Patients were recruited and treated in six Italian private practices by experienced operators (Drs Blasone, Calvo, Favaretto, Felice, Marin, Stacchi); each dentist should have treated 12 patients. All the follow-up visits were conducted at the respective treating centres. Originally seven centres agreed to participate in the study, but one centre did not provide any patient data.

After consent was given, and in cases where more than two areas required implant rehabilitation, the surgeon selected two partially edentulous areas among those that had the most similar characteristics and indicated one area as site number 1 and the other as site number 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).

The investigated devices were commercially available, tapered, titanium, grade 4, self-tapping dental implants with internal connection (Way Milano system versus Kentron system, Geass). The Way Milano system is an evolution of the Kentron system, which is characterised by micro-threading all the way to the implant neck, conical internal hexagonal connection with platform switching, and a laser treated implant surface (Synthegra) (Figs 1a to 1c). The Kentron system is characterised by an unthreaded collar, smooth for 1.7 mm in the coronal portion, a surface blasted with alumina, and a flat internal hexagonal connection (Figs 2a to 2c). Operators were free to choose implant lengths (9, 10, 11, 12, 13 or 15 mm) and diameters (3.8, 4.5 or 5.5 mm) according to clinical indications and their preferences.

Clinical procedures

Both implant types were inserted during the same surgical session and later restored simultaneously with similar types of prostheses. Patients received prophylactic antibiotic therapy: 2 g of amoxicillin (or clinda-

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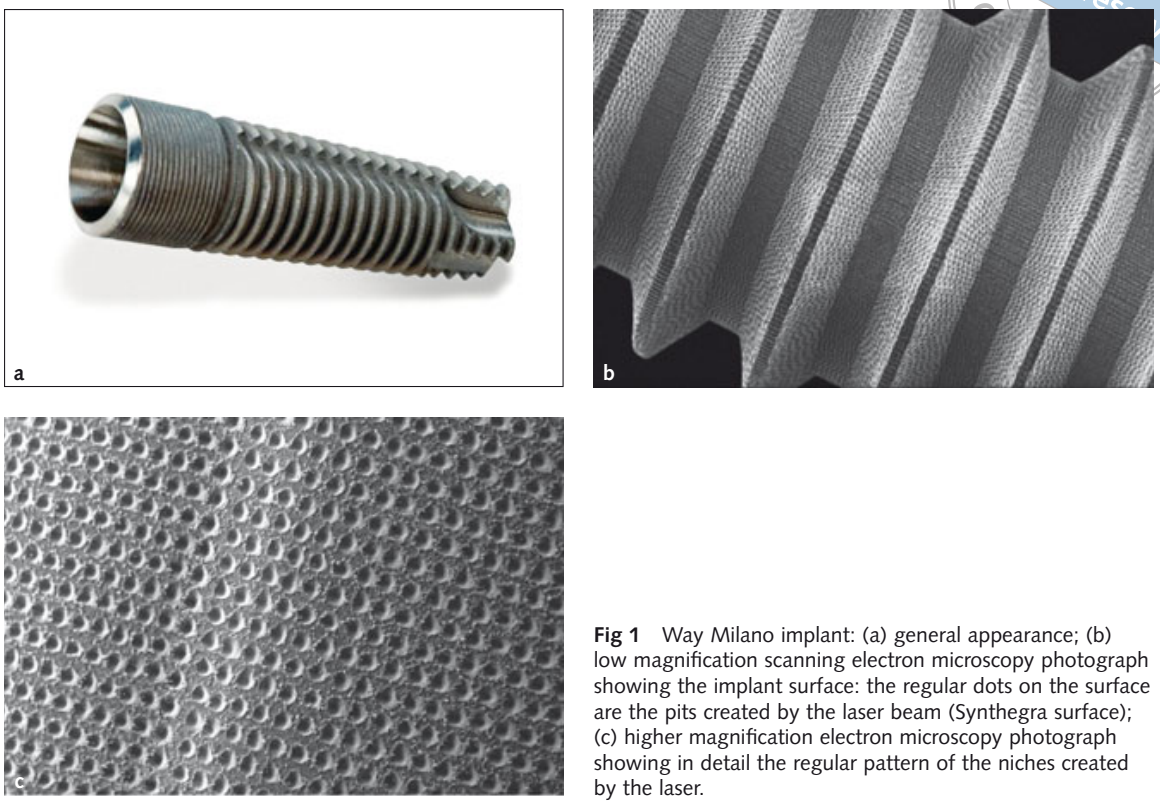

Fig 1 Way Milano implant: (a) general appearance; (b) low magnification scanning electron microscopy photograph showing the implant surface: the regular dots on the surface are the pits created by the laser beam (Synthegra surface); (c) higher magnification electron microscopy photograph showing in detail the regular pattern of the niches created by the laser.

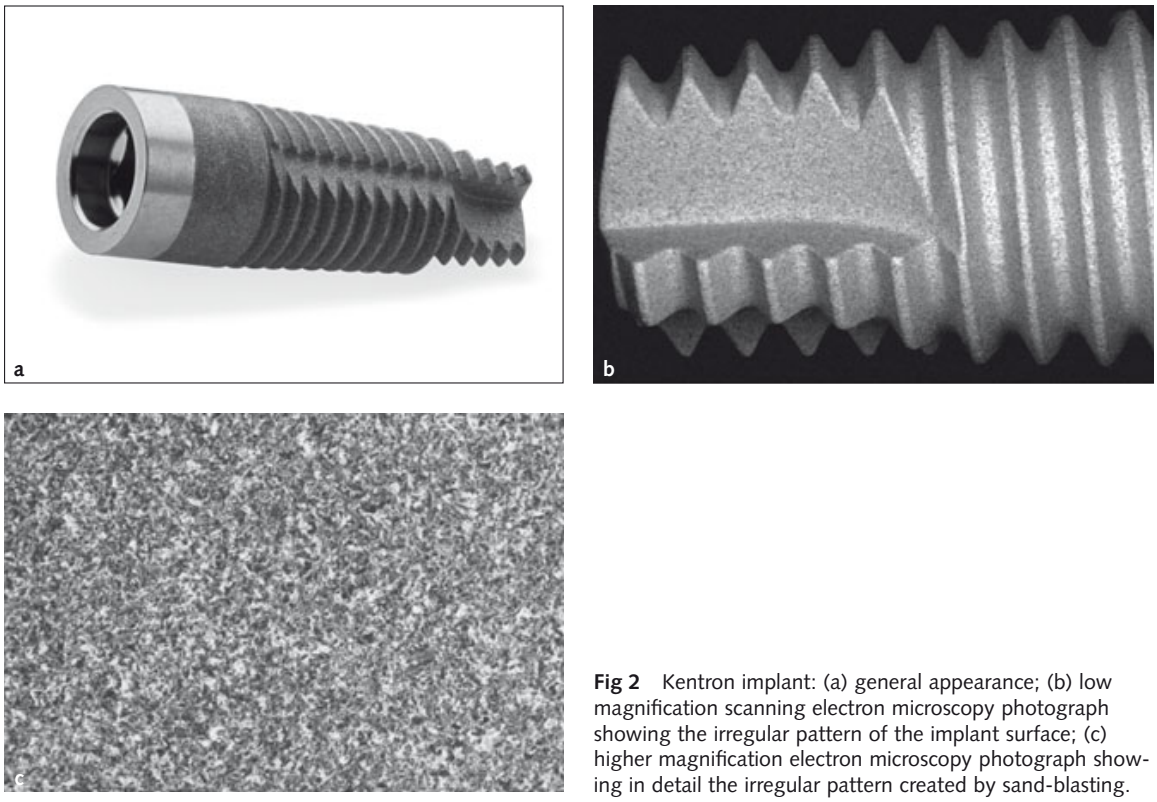

Fig 2 Kentron implant: (a) general appearance; (b) low magnification scanning electron microscopy photograph showing the irregular pattern of the implant surface; (c) higher magnification electron microscopy photograph showing in detail the irregular pattern created by sand-blasting.

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mycin 600 mg if allergic to penicillin) 1 h prior to surgery and rinsed for 1 min with chlorhexidine 0.2%. All patients were treated under local anaesthesia (Articain with adrenaline 1:100000). Tooth extractions, when needed, were performed as atraumatically as possible, attempting to preserve the buccal alveolar bone. Extraction sockets were carefully cleaned from any remnants of granulation tissue. Operators started preparing implant site number 1. When beginning to prepare implant site number 1, the decision to elevate or not the flap was left to the individual clinician. The standard implant site preparation procedure that was used was the one recommended by the implant manufacturer. In brief, the round bur or lance drill was used to prepare the cortical entrance, followed by the 2.1-mm diameter twist drill with drill stop at 800 rpm, by the 2.5-mm diameter twist drill with drill stop at 600 rpm, and drills in sequence up to the corresponding diameter of the implant to be inserted (3.8, 4.5, 5.5 mm) with drill stop at 400 rpm. In cases of hard bone, a drill of the same diameter but shorter by 1 mm could have been used to widen the implant site, pushing it down until the initial part of the coloured notch was level to the bone. In cases of soft bone, a final drill of one smaller size than the conventional procedure was used to under-prepare the implant site. During implant site preparation, bone quality was subjectively assessed and divided into hard, medium and soft. At this point the operator was informed whether the implant to be placed was Way Milano or Kentron by opening the sequentially numbered sealed envelope corresponding to patient recruitment number. Implants were placed with the neck flush to the crestal bone level with the exception of post-extractive implants that were placed 2 mm below the palatal bone level and more palatally/lingually.

Once the implant(s) were placed in site number 1 the same procedure was repeated to place implant(s) in site number 2; the only difference was that the implants were of the other system.

If surgeons decided to fill bone-to-implant gaps at post-extractive sites, to perform horizontal bone augmentation procedures at exposed threads or to lift the sinus crestally, they were only allowed to use either autogenous bone harvested from intraoral locations or small granules of Bio-Oss (Geistlich Pharma, Wolhusen, Switzerland) at their discretion. If they decided to use a barrier they had to use a resorbable one (BioGide, Geistlich Pharma).

Clinicians were free to decide whether to load the implants immediately (only if an insertion torque >35 Ncm was obtained), to submerge or to leave them non-submerged for the healing period. However, both implant types in the same mouth had to be treated with similar procedures and all implants had to be loaded within 4 months after their placement. Just after implant placement, intraoral radiographs (baseline) were obtained with the paralleling technique. If bone levels around the study implants were hidden or difficult to estimate, a second radiograph was obtained. Ibuprofen 400 mg was prescribed to be taken 2 to 4 times a day during meals, as long as required. Patients were instructed to use chlorhexidine 0.2% mouthwash for 1 min twice a day for 2 weeks and to avoid brushing and trauma on the surgical sites. Postoperative antibiotics were prescribed to patients subjected to bone augmentation procedures: amoxicillin 1 g twice a day for 6 days. Patients allergic to penicillin were prescribed clindamycin 300 mg twice a day for 6 days. Within 1 week, all patients were recalled and checked.

Clinicians were also free to choose screw-retained or cemented restorations with provisional cement, to load the implants directly with definitive restorations, and whether to use metal-ceramic or metal-composite restorations (single crowns could be also in full ceramic), however the same procedures had to be implemented in the same mouth.

Four months after loading, intraoral radiographs of the study implants were taken and all implants were tested for stability: partial fixed prostheses were removed and a torque of 15 Ncm was applied to the individual implants, whereas stability of implant-supported crowns could be tested using the handles of two instruments. The same procedures were repeated 1 year after initial loading.

Patients were enrolled in an oral hygiene program with recall visits planned every 3 to 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

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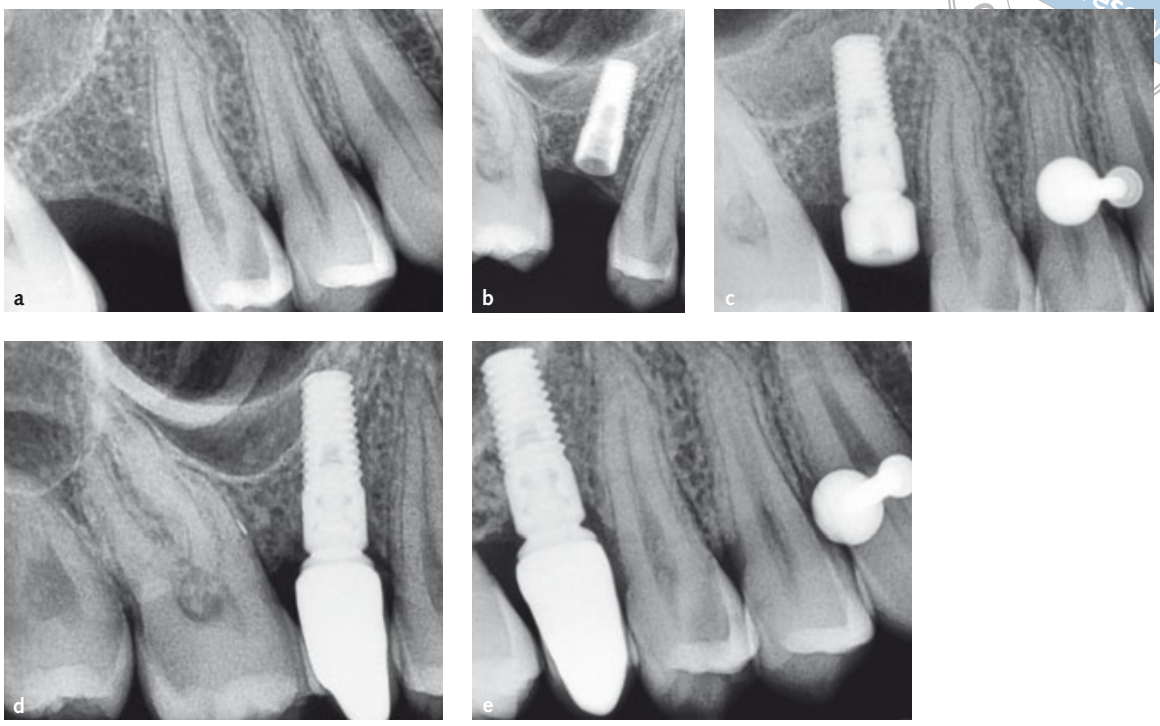

Fig 3 Periapical radiographs of one of the patients treated by Dr Pietro Felice; site randomly allocated to a Way Milan implant: (a) preoperative view; (b) just after implant placement; (c) at abutment connection; (d) at 4 months post-loading; (e) at 1 year post-loading. Please note the coronal portion of the implant neck with its inbuilt platform switching, which makes it easily distinguishable from the Kentron implant design.

two implant types against the alternative hypothesis of a difference. Outcome measures were:

- Prosthesis failure (primary outcome measure): when it was not possible to place the prosthesis due to implant failures or secondary to implant losses, and replacement of the prosthesis with a new prosthesis for any reasons.
- Implant failure (primary outcome measure): implant failure was defined as implant mobility and/or any infection dictating implant removal or any 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 or by assessing the stability of the crown using the handles of two instruments.
- Any complications and adverse events (primary outcome measure) were recorded and reported according to implant types.
- Operator preference (secondary outcome measure) for the implant system. It was expressed by clinicians in the following way: 'Way Milano', 'Kentron' and 'no preference'. Reasons for preference were recorded.
- Peri-implant marginal bone level changes (secondary outcome measure): periapical radiographs were made with the paralleling technique at implant placement, 4 months and 1 year after loading (Figs 3a to 3e and Figs 4a to 4e). Radiographs were scanned, digitised in JPG, converted to TIFF format with a 600 dpi resolution, and stored in a personal computer. Peri-implant marginal bone levels were measured using the Scion Image (Scion Corporation, Frederick, MD, USA) software. The software was calibrated for every single image using the known implant diameter. 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 or the highest level of the bone if above the implant abutment junction. The mesial and distal measurement of each implant were averaged and a mean calculated at prosthesis level and then at group level.

At each centre there was a local blind outcome assessor who recorded all clinical outcome measures. The implant type was not recognisable when assessing implant stability, but could be recognised on radiographs. Periapical radiographs were measured by a single independent, experienced assessor (CB).

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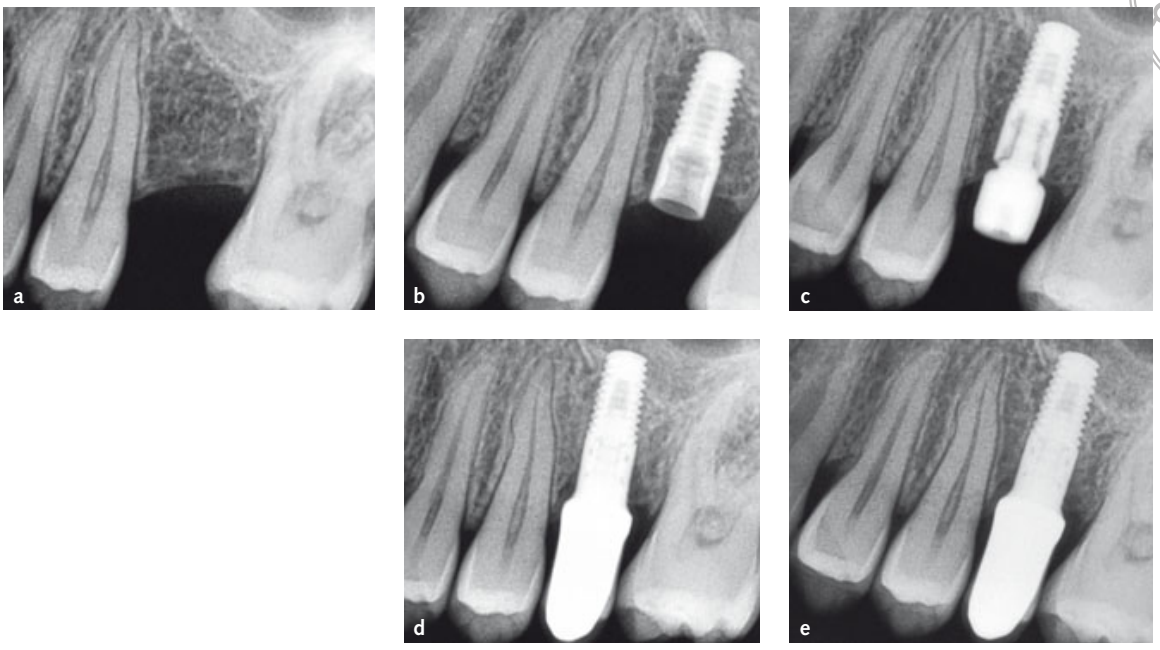

Fig 4 Periapical radiographs of the same patient as illustrated in Figs 3a to 3e; site randomly allocated to a Kentron implant: (a) preoperative view; (b) just after implant placement; (c) at abutment connection; (d) at 4 months post-loading; (e) at 1 year post-loading.

Methodological aspects

Prior to the study there was no sufficient clinical data on the implants to be evaluated to perform a reliable sample size calculation. It was therefore decided to include 84 patients, 12 at each of the seven originally planned centres, since this was the number of patients we hoped to recruit during a period of a year.

Seven computer-generated restricted random lists were created. Only one investigator (ME), who was not involved in the selection and treatment of the patients, knew the random sequence and had access to the random list stored in a password protected portable computer. The random codes were enclosed in sequentially-numbered, identical, opaque, sealed envelopes. Only after the first implant site was prepared, the envelope corresponding to the patient recruitment number was opened and the indication given to the clinician of whether to place a Way Milano or a Kentron implant. The other site received the other implant 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 pre-established analysis plan. A biostatistician with expertise in dentistry analysed the data. Differences in the proportion of patients with prosthesis/implant failures, complications (dichotomous outcomes) were compared using the exact McNemar test. Comparisons between each time points and the baseline measurements were made by paired tests, to detect any changes in marginal peri-implant bone levels. Differences in radiographic marginal bone levels (continuous outcome variable) between groups were estimated by creating 2 linear multilevel models[8] – 4 months and 1 year changes, respectively – at two levels (Centre and patient). The explicative variables used at the patient level were 'Implant' (1 = Way Milano, 0 = Kentron) and 'Baseline rx bone level' (mm). Dichotomous outcomes (implant failures and complications) are presented for the six centres but there were too few events per centre to undertake any analysis; the difference between marginal bone level changes between groups at patient level was tested by applying an analysis of variance using the centre as an explicative variable. All statistical comparisons were conducted at the 0.05 level of significance.

Results

One of the seven clinicians never supplied any data despite claiming he had recruited and treated his

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quota of patients. In total 64 patients were screened for eligibility (three patients were treated twice in one of the centres and just seven patients could be recruited at another centre), and all of them accepted to participate into the trial. All patients had their sites treated according to the allocated interventions. Six patients with 14 implants dropped-out before the 1-year follow-up: one patient with two implants died 45 days after implant placement with both implants still submerged in a motorbike accident; one patient with two implants could not be contacted after the 4-month evaluation visit; one patient with two implants moved after the 4-month evaluation visit; one patient with two implants died from head trauma after the 4-month evaluation, one patient with two implants did not come back to the 1-year follow-up because of a serious disease and the same happened to another patient with four implants. The data of all patients were included in the statistical analyses with the exception of the radiographic data of one patient (two Kentron implants) at 4 months since radiographs were not provided.

The following deviations from the protocol occurred: one centre (Dr Stacchi) treated twice three patients already included with additional implants; however, the second series of interventions was not evaluated since patients could only be included once in the study. All patients treated by Dr Marin received their restorations connecting the two different implant types (by protocol the two implant types should not be joined under the same prosthesis) and one of these patients received it 8 months after implant placement since she was unable to attend the planned appointments. One patient had both implant types loaded 2 months later than required by the protocol, since she had both sites subjected to a split-crest procedure with autogenous bone placed buccally and covered with a resorbable barrier submerged for 6 months (Dr Calvo).

Patients were recruited and implants were inserted from October 2009 to September 2011. The follow-up for all the remaining patients was 1 year post-loading. There were 35 males and 29 females with a mean age at time of implant placement of 52 years (ranging from 19 to 80 years old). Forty-seven (73.4%) patients declared to be non-smokers, 11 (17.2%) were moderate smokers (up to 10 cigarettes per day) and 6 (9.4%) were heavy smokers. The main baseline patient and intervention characteristics, divided by study group, are presented in Table 1. Seventy-one Way Milano and 73 Kentron implants were placed. There were no apparent significant baseline imbalances between the two groups apart for marginal bone levels, which were more apically located at Kentron implants (0.41 mm + 0.51 versus 0.27 mm + 0.42).

Three implants failed in three patients. They were all of the Kentron type and their prostheses could not be delivered as planned: one implant (9 × 4.5 mm), positioned in site 26 characterised by soft bone quality, was found mobile at loading in a non-smoking patient. At implant placement, the site was subjected to a crestal sinus lift procedure with granular anorganic bovine bone (Bio-Oss) and was left to heal submerged for 3 months (Dr Favaretto). One implant (10 × 3.8 mm) going to be placed in position 47, which was characterised by dense bone, had its neck fractured during insertion possibly due to an excessive insertion torque. The implant had to be removed using piezosurgery and after a month another implant was placed more distally (Dr Calvo). One implant (10 × 3.8 mm), placed in position 22 together with another implant of the same type in position 21, was found mobile during the impression taking procedures after 3 months of non-submerged healing. The implant was originally placed in a post-extractive site characterised by soft bone quality of a non-smoking patient and it did not achieve a good primary stability (Dr Calvo). There were no statistically significant differences for prosthesis/implant failures (difference in proportions = 0.05; $P = 0.25$; 95% CI -0.02 to 0.13).

Only two postoperative complications occurred, one for each implant system, and they were all successfully treated. One postoperative infection occurred 2 weeks after implant placement around a Way Milano implant in position 16 (Dr Stacchi). The area was swollen with pus discharge. The patient was treated with systemic antibiotics (amoxicillin with clavulanic acid 1 g twice a day for 6 days). At abutment connection the implant was successfully osseointegrated with no marginal bone loss. The other complication was a peri-implant soft tissue inflammation that determined bone loss around a Kentron implant in position 26, which was observed at delivery of the provisional crown (Dr Marin). The area, which was lacking in keratinised mucosa, was

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Table 1 Recipient site and implant characteristics of the 64 originally included patients.

		Way Milano implants (n = 71)	Kentron implants (n = 73*)
Bone quality	Hard bone	12 (16.9%)	13 (17.8%)
	Medium bone	35 (49.3%)	40 (54.8%)
	Soft bone	24 (33.8%)	20 (27.4%)
Jaw	Maxilla	38 (53.5%)	37 (50.7%)
	Mandible	33 (46.5%)	36 (49.3%)
Implant position	Incisor sites	8 (11.3%)	6 (8.2%)
	Canine sites	0	2 (2.7%)
	Premolar sites	22 (31%)	23 (31.5%)
	Molar sites	41 (57.8%)	42 (57.5%)
Implant diameter (mm)	3.8	38 (53.5%)	44 (60.3%)
	4.5	31 (43.6%)	27 (37%)
	5.5	2 (2.8%)	2 (2.7%)
Implant length (mm)	9	9 (12.7%)	9 (12.3%)
	10	29 (40.8%)	31 (42.5%)
	11	16 (22.5%)	15 (20.6%)
	12	12 (16.9%)	5 (6.8%)
	13	4 (5.6%)	12 (16.4%)
	15	1 (1.4%)	1 (1.4%)
Post-extractive implants	Not augmented	9	11
	Augmented with autogenous bone	0	0
	Augmented with autogenous bone + barrier	2	2
	Augmented with bone substitute	3	0
	Augmented with bone substitute + barrier	0	0
Flap characteristics	Flap elevated	62 (87.3%)	64 (87.7%)
	Flapless	9 (12.7%)	9 (12.3%)
	Submerged	55 (77.5%)	56 (76.7%)
	Non-submerged	16 (22.5%)	17 (23.3%)
Other augmentation procedures	Augmentation at exposed implant surface	5	3
	Crestal sinus lift	1	3
Type of prosthesis	Single crowns	48 (75%)	50 (78.1%)
	Fixed dental prostheses supported by 2 implants**	16 (25%)	14 (21.9%)
	Fixed dental prostheses supported by 3 implants	0	0
Time of loading	Immediate non-occlusal	0	0
	Immediate occlusal	0	0
	Early non-occlusal	0	0
	Early occlusal	1 (1.4%)	1 (1.4%)
	Conventionally at 3 months or later	70 (98.6%)	71 (98.6%)

*Including the implant that fractured at insertion.
**One operator joined the two implant types under the same bridge for all the seven treated patients.

grafted with autogenous connective tissue from the palate. There were no statistically significant differences for complications (difference in proportions = 0; $P = 1.0$; 95% CI -0.07 to 0.07).

Three operators (Drs Felice, Favaretto and Calvo) preferred the Way Milano System and three operators had no preference between the two systems. Reasons for preferring the Way Milano system were:

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Table 2 Mean radiographic peri-implant marginal bone levels between implant types and time periods

	Implant placement (Baseline)				4 months post-loading*				1 year post-loading*			
	N	Mean	(SD)	95% CI	N	Mean	(SD)	95% CI	N	Mean	(SD)	95% CI
Way Milano	64	0.27	(0.42)	0.17 to 0.37	62	0.70	(0.65)	0.54 to 0.88	58	1.01	(0.82)	0.79 to 1.22
Kentron	64	0.41	(0.51)	0.28 to 0.54	61	0.99	(0.69)	0.81 to 1.16	56	1.28	(0.73)	1.08 to 1.47
Difference (SE) (95%CI)	64	0.14	(0.04)	0.06 to 0.21	-				-			

*All changes from baseline are statistically different (P <0.001). SD = standard deviation; CI = confidence interval.

Table 3 Descriptive statistics of mean changes in peri-implant marginal bone levels at different time periods between implant types.

	Baseline – 4 months after loading				Baseline – 1 year after loading			
	N	Mean	(SE)	95% CI	N	Mean	(SE)	95% CI
Way Milano	62	-0.43	(0.05)	-0.54 to -0.32	58	-0.73	(0.07)	-0.87 to -0.58
Kentron	61	-0.57	(0.07)	-0.72 to -0.42	56	-0.84	(0.07)	-0.97 to -0.70

Table 4 Multilevel model for the radiographic peri-implant marginal bone levels changes between implant types at 4 months.

Radiographic peri-implant marginal bone levels changes at 4 months				
Term	Estimate	SE	P value	[95% CI]
Intercept	0.65	0.10		
Patient level				
Baseline rx bone level	-0.15	0.11	0.1711	[-0.36; 0.06]
Implant (1 = Way Milano; 0 = Kentron)	-0.16	0.09	0.0606	[-0.30; 0.01]
Variances				
σ_u^2	0.03	0.02		
σ_e^2	0.22	0.03		

*Statistically significant difference
Theoretic model: ^{4}m-Bas rx = β_{0ij} + β_{1ij} Implant + β_{2ij} Baseline rx bone level
σ_u^2 and σ_e^2 indicate the variances at the Centre and at the Patient level, respectively. In the theoretic model formula, the subscript j refers to the Centre level. The subscript i refers to the Patient level. β_{0ij} is the 'intercept'. SE is the standard error.

"it is easier to obtain a high insertion torque due to the more aggressive threads" (Drs Felice and Favaretto) and "it is easier to handle the vial containing the implant" (Dr Calvo).

At implant placement (baseline) difference in bone levels was statistically significant (0.14 mm, CI95% 0.06, 0.21; t test P <0.001): 0.27 mm for Way Milano implants and 0.41 mm for Kentron implants (Table 2). Both groups gradually lost statistically significant amounts of peri-implant marginal bone at 4 months and at 1 year after loading. Four months after loading, Way Milano implants lost an average of 0.43 mm peri-implant bone compared with 0.57 mm of Kentron implants. One year after loading, Way Milano implants lost an average of 0.73 mm peri-implant bone compared with 0.84 mm of Kentron implants (Table 3). Marginal bone level changes were not statistically significant different for Way Milano compared to Kentron implants at 4 months (-0.16 mm; 95% CI -0.30, 0.01; P = 0.0606) (Table 4) and 1 year (-0.09 mm; 95% CI -0.26, 0.09; P = 0.3407) after loading (Table 5).

The comparison between the six centres is presented in Table 6. There were no statistically significant differences in the number of patients experiencing failures and complications between centres (statistical tests could not be undertaken since data was too sparse). However the difference between the peri-implant marginal bone changes at 1 year between Way Milano and Kentron implants was statistically significant (P = 0.0235).

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Table 5 Multilevel model for the radiographic peri-implant marginal bone levels changes between implant types at 1 year.

Radiographic peri-implant marginal bone levels changes at 1 year				
Term	Estimate	SE	*P* value	[95% CI]
Intercept	0.81	0.12		
Patient level				
Baseline rx bone level	0.11	0.11	0.3237	[-0.11; 0.33]
Implant (1 = Way Milano; 0 = Kentron)	-0.09	0.09	0.3407	[-0.26;0.09]
Variances				
σ_u^2	0.05	0.03		
σ_e^2	0.22	0.03		

* Statistically significant difference
Theoretic model: [1] Y-Bas rx = β_{0ij} + β_{1ij} Implant + β_{2ij} Baseline rx bone level
σ_u^2 and σ_e^2 indicate the variances at the Centre and at the Patient levels, respectively. In the theoretic model formula, the subscript j refers to the Centre level. The subscript i refers to the Patient level. β_{0ij} is the 'intercept'. SE is the standard error.

Table 6 Comparison between centres up to 1 year after loading (in parentheses is the total number of implants originally placed).

	Felice 12 patients 26 implants	**Blasone 12 patients 28 implants**	**Favaretto 12 patients 29 implants**	**Stacchi 9 patients 19 implants**	**Calvo 12 patients 28 implants**	**Marin 7 patients 14 implants**	**Total (N = 144)**
Drop-out (implants)	1 (2)	0	2 (6)	1 (2)	1 (2)	1 (2)	6 (14)
4-month missing radiographic data (implants)	0	0	1 (2 Kentron)	0	0	0	1 (2 Kentron)
Implant failures							
Way Milano (N = 71)	0	0	0	0	0	0	0
Kentron (N = 73)	0	0	1	0	2	0	3
Complications							
Way Milano (N = 71)	0	0	0	1	0	0	1
Kentron (N = 73)	0	0	0	0	0	1	1
Operator preference							
	Way	**equal**	**Way**	**equal**	**Way**	**equal**	
Marginal bone level changes over 1 year (N Mean SD)							
Way Milano	11 0.67 0.31	12 0.55 0.39	9 0.48 0.27	8 1.23 0.77	10 0.53 0.41	6 1.34 0.60	56 0.73 0.54
Kentron	11 0.69 0.41	12 0.94 0.39	9 0.42 0.36	8 1.04 0.59	10 0.92 0.38	6 1.12 0.71	56 0.84 0.49
Difference[a]	11 0.02 0.41	12 0.39 0.42	9 -0.06 0.52	8 -0.19 0.52	10 0.39 0.55	6 -0.21 0.55	56 0.09 0.07

[a] Analysis of variance F ratio test *P* = 0.0235

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Discussion

This is the second follow-up report of a series aimed at evaluating whether the two implant systems had similar clinical performances or not[7]. No statistically significant differences were observed between the two implant types. The number of complications was low and identical for both implant types, though three Kentron implants failed versus none of the Way Milano implants. All three implant failures occurred early and there could be some contributory factors explaining them. The implant that fractured at placement was inserted in hard mandibular bone and had a 3.8 mm diameter. The excessive torque applied on a relatively thin implant could explain its fracture. The other two implants were either inserted in a crestally lifted sinus or in a post-extractive site without achieving a good primary stability.

Three operators preferred the Way Milano system and three had no preference. The numbers were too low to allow for a statistical analysis, however two dentists pointed out that their preference was justified by the fact that they felt the Way Milano implants having a more aggressive threads, making it easier to achieve an excellent implant stability. While from a pure geometrical point of view this observation seems a bit odd since both implant systems have identical conicity and threads, it may be that the microthreads present in the neck of the Way Milano implants gave the feeling of increased stability in the cortical portion, especially in grossly under-prepared sites.

It is also interesting to observe that despite clinicians were left the option to choose the time of implant loading, none loaded them immediately and only one patient was subjected to an early loading procedure.

There are no other published studies comparing the same implant systems, and in a systematic review of randomised controlled trials[2] no relevant statistically significant differences were found when comparing all implant material characteristics believed to be able to influence the rehabilitation outcome; with the exception of a recent RCT[3] showing that a specific implant design and connection provided 0.6 mm better maintenance of peri-implant marginal bone levels than another, 3 years after loading. The findings of this Cochrane review, though, should be interpreted with extreme caution since the sample sizes of almost all conducted studies so far were too low to detect any clinically significant difference. Consequently, despite the fact that osseointegrated dental implants have been in use for almost 50 years and that literally thousands of scientific publications have been devoted on this subjects, we are still in the situation that we do not have reliable evidence for which could be the preferable implant designs/materials/surface preparations. The discussion of the literature about other implant designs fall outside the scope of this article, however there are other two RCTs in which Way Milano implants were used and the 1-year outcome after implant loading was excellent[9-12].

The main limitations of the present trial are the small sample size and the relatively short follow-up duration. Unfortunately, the planned sample size could not be achieved due to some centres failing to recruit the assigned number of patients. It could be observed though that a much wider sample size than that originally planned would be needed to show some statistically significant differences, if any. Another limitation was the numerous protocol deviations. In particular, one centre deviated from the agreed protocol for each treated patient. In fact all of the seven included patients had both implant types joined under the same fixed dental prosthesis. Ideally, the different implant types should not be joined together, since if one implant system would fail or have certain complications (for instance implant fracture) it could have affected unfavourably the other implant type(s) holding alone the same fixed dental prosthesis.

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

Conclusions

No statistically significant differences were observed between the two implant types, although three Kentron implants failed versus none of the Way Milano type. Longer follow-up of wider patient populations are needed to better understand whether there is an effective advantage with one of the two implant designs.

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