KEY WORDS
Dental implants, Flapless, Immediate loading, Cohort study

Cohort study

FLAPLESS PLACEMENT AND IMMEDIATE LOADING OF TWO MANDIBULAR IMPLANTS RETAINING CROSS-ARCH FIXED PROSTHESES: A 13-YEAR FOLLOW-UP RETROSPECTIVE SINGLE COHORT STUDY

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PURPOSE. To evaluate the 13-year clinical outcomes of two implants placed flapless in fully edentulous mandibles and immediately restored with a metal-resin screw-retained cross-arch prosthesis.

MATERIALS AND METHODS. Eighty patients consecutively treated from June to November 2010 at a single centre with two immediately-loaded mandibular implants were recalled from June to October 2023. To be immediately loaded, implants had to be inserted with a minimum torque of 80 Ncm. Forty-six laser-welded titanium and 34 cast silver-palladium frameworks with resin teeth were initially delivered within 8 and 48 hours, respectively. Outcome measures were prosthesis and implant failures, complications, and patient satisfaction.

RESULTS. Thirteen years after loading, 12 patients (15%) were lost to follow-up and 14 prostheses (17.5%) failed or were remade. Seven implants failed in five patients (6.25%). Forty-six patients (57.5%) had at least one complication. Fifty-six (82.4%) patients were fully satisfied, 10 (14.7%) were partially satisfied, and two (2.9%) were unsatisfied.

CONCLUSIONS. Mandibular cross-arch prostheses can be immediately loaded and retained by only two implants up to 13 years if made with a robust cast framework. A multicentre trial confirming these results would be required to determine whether this conclusion could be generalized.

CONFLICT OF INTEREST STATEMENT
This study was completely self-funded, and no financial support was sought or obtained, not even in the form of free materials.

INTRODUCTION

To support a fixed mandibular cross-arch prosthesis, four implants are usually placed in the interforaminal area[1]. More implants can be placed distal to the mental foramina if there is sufficient bone height above the mandibular canal, but it may be difficult to place more than four implants between the mental foramina without risking compromise to oral hygiene procedures. Furthermore, the more implants placed, the greater the costs and difficulties involved in fabricating precise metal frameworks to be passively seated on the implants.
A common strategy for reducing treatment time, cost and complexity is to make removable overdentures supported by four or even two implants. Results from systematic reviews[2,3] and other trials[4-9] suggested that two[4,5,10-13] or even one implant[6-9] may be sufficient to successfully stabilize a mandibular overdenture. While overdentures are considered a cheaper alternative to implant-retained fixed prostheses, they may require greater maintenance to replace

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worn-out prosthetic components, potentially making them less cost-effective in the long term[14]. Moreover, patients may not like the idea of a removable implant-supported denture from a psychological point of view.

Implants can be loaded immediately after their placement without greatly increasing the risk of failure[15], especially in fully edentulous mandibles[16-19]. Good results have been reported for immediately-loaded mandibular overdentures supported by either two or four implants[16-19], whereas results for overdentures supported by single implants are still controversial[6-9].

There is less evidence on fixed cross-arch prostheses immediately loaded only on two mandibular implants, though results up to 3 years from two pilot RCTs[20-23] and from one prospective 6-month uncontrolled study[24] are encouraging. The main advantages of immediate loading are reduced patient discomfort, treatment time and costs. To further reduce patient morbidity and operating time, implants can also be placed flapless, without the aid of computer-guided surgery, if there are adequate bone volumes at the planned implant sites[19,20,25,26].

The advantages of offering edentulous patients a functional fixed prosthesis within 48 hours of implant placement, after minimal surgical intervention and at a reduced biological and financial cost, are obvious. Therefore, it would be interesting to know whether fully edentulous mandibles can be rehabilitated with a fixed cross-arch prosthesis immediately loaded onto only two implants placed flapless without excessively increasing the risk of failure.

The aim of this retrospective single cohort study was therefore to provide long-term data on the clinical outcomes of fixed metal-resin screw-retained cross-arch prostheses immediately loaded onto two implants placed flapless in totally edentulous mandibles. This article is reported in line with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines (www.strobe-statement.org). The 1-[27], 3-[28] and 5-year data[29] from the same patient cohort has been presented in previous publications. However, it should be noted that those reports stated that all[27], and later on that 74[28], prostheses had a laser-welded titanium framework; this information was later corrected, as 34 cast silver-palladium frameworks were delivered. Hence, only 46 of the prosthesis frameworks were laser-welded titanium.

MATERIALS AND METHODS

Any patient rehabilitated with a fixed mandibular prosthesis immediately loaded onto two retaining implants between June and November 2010 was eligible for inclusion in this study. Patients needed to have bone volumes allowing the placement of at least two implants of diameter at least 4 mm and length 8.5 mm between the mental foramina. Immediate post-extraction dental implants were included.

Patients were not given the above treatment if any of the following exclusion criteria applied:

- general contraindications to implant surgery (at the surgeon's discretion);
- uncontrolled diabetes;
- pregnancy or lactation;
- addiction to alcohol or drugs;
- psychiatric issues;
- unrealistic expectations;
- irradiation to the head and/or neck;
- previous or ongoing treatment with intravenous aminobisphosphonates;
- poor oral hygiene and motivation;
- untreated periodontitis;
- active infection or severe inflammation in the area intended for implant placement;
- need for bone-augmentation procedures;
- lack of opposing occluding dentition/prosthesis/denture.

According to their declaration, patients were categorized into the following three groups: non-smokers; moderate smokers (up to 10 cigarettes per day); and heavy smokers (more than 10 cigarettes per day). Patients were also classified as skeletal Class 1, 2 or 3, as well as on the basis of the clinical appearance of their masseter muscles (normal or over-developed); and according to the type of dentition in the opposite jaw (natural/fixed prosthesis or full dentures).

All patients received through explanations and signed an informed written consent form prior to treatment. The study was approved by the Milan San Raffaele Hospital Ethics Committee on 15 December 2021 (Protocol n: 190/INT/2021). Patients were recruited and treated at one private practice in Pavia, Italy. One dentist (Dr Gioacchino Cannizzaro) with extensive experience in immediate-loading and flapless procedures delivered all treatments.

When satisfactory mandibular dentures were not available, they were made prior to implantation to ensure the correct vertical dimension and occlusion. In about 30% of cases, resin replicas of the dentures were made with radiopaque teeth using two drills inserted into the planned abutment positions, to be used as radiographic guides for cone-beam computed tomography (CT) scans taken to properly locate the mental foramina. These replicas were then used as surgical templates. Preliminary screening was performed on cone-beam CT scans. All patients had a professional oral hygiene session prior to the operation, and received prophylactic antibiotics (2 g of amoxicillin orally one hour prior to the intervention, or 600 mg of clindamycin 1 hour prior to the intervention in patients allergic to penicillin). Patients rinsed with 0.2% chlorhexidine mouthwash for 1 minute immediately prior to the intervention. Local anaesthesia was administered (articaine with adrenaline 1:100,000).

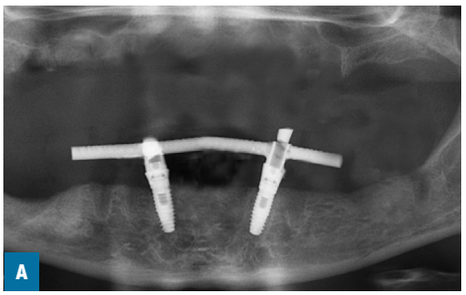
Tapered NT NanoTite implants with external connection (Biomet 3i, Palm Beach, FL, USA) were used. The operator was free to choose implant lengths (8.5, 10, 11.5, 13 or 15 mm) and diameters (4, 5 or 6 mm), according to the clinical indications and his discretion.

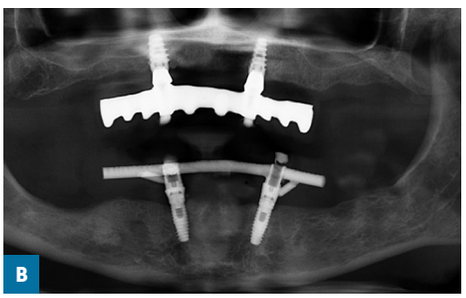
The implant sites in position of both mandibular canines/first premolars were prepared by using as final drill one size less than the implant diameter to be used directly into the mucosa without flap elevation. Bone quality was subjectively quantified by touch at drilling and classified as soft, medium and hard. In case of hard bone, the final drill had the diameter corresponding to the implant diameter to be inserted. Implants were placed either straight or distally angled with their necks flush to the bone crest.

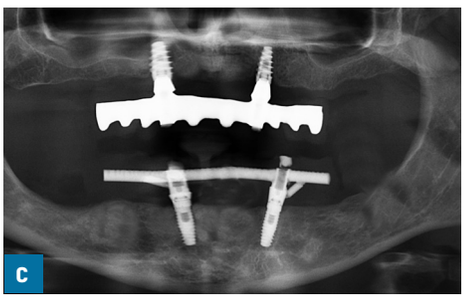
Implants were inserted with the motor (W&H Elcomed SA-310, Dentalwerk Bürmoos, Bürmoos, Salzburg, Austria) set at a torque of 80 Newton/cm, and once the motor had stopped implant stability was confirmed manually using a High Torque Indicating Ratchet Wrench (HTIRW, Biomet 3i). Implant positioning was completed with a manual ratchet until the implant was properly seated. At the protocol phase, it was decided that implants inserted with a torque of less than 80 Ncm would generally not be loaded immediately; however, it was left to the discretion of the surgeon whether to load these implants anyway, replace them with larger diameter ones, or leave the implants to heal submerged for 3 months. If needed, sutures were placed.

After surgery, patients were instructed to avoid brushing the surgical sites and to rinse twice a day with 0.12% chlorhexidine for 2 weeks. A cold, soft diet was recommended for 7 days. Analgesics (ibuprofen 400 mg) were provided, to be taken twice a day during meals as required. When placed, sutures were removed after approximately 10 days, and oral hygiene instructions were given.

The prosthetic procedures were initiated immediately after implant placement. The patient's mandibular dentures were perforated to allow their seating over the abutments, and were used as individual trays. Two different types of frameworks were made, namely laser-welded titanium (**FIGS. 1A-C, 2A, B**) or cast silver-palladium, at discretion of the operator.







FIGS. 1A-C: *Sequence of panoramic radiographs of patient #33, treated with a laser-welded titanium framework: at initial loading (A); 5 years after loading; the mandibular prosthesis was reinforced with some extra titanium reinforcement bars when the patient received a maxillary prosthesis supported by two implants (B); 13 years after loading (C).*

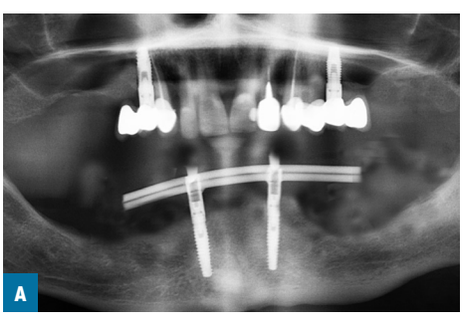
In case of titanium laser-welded frameworks, a little amount of soft relining silicone (Elite Soft Relining, Zhermack, SpA, Badia Polesine (RO), Italy) was placed around the abutments and the dentures were blocked directly to the titanium abutments with self-curing acrylic resin (Pattern Resin LS, GC America, Alsip, IL, USA). In case of cast silver-palladium frameworks, Impregum F (Espe Dental AG, Seefeld, Germany) was used as impression material, and the dentures were blocked directly to titanium abutments for cemented prostheses with Pattern Resin GC. Once the abutment/transfers with the impression tray were removed, healing screws were placed onto the implants. Screw-retained laser-welded frameworks were prepared by bending and welding with a mini-laser welder (XXS, Orotig, Cavalcaselle di Castelnuovo del Garda (VR), Italy) two overlapped titanium grade 5 bars of 2 mm diameter to the implant abutments using titanium grade 2 as filler material to compensate for the heat-induced metal retraction in order to minimise tensions and distortions of the framework. Screw-retained cast frameworks were made with a sagittal section of at least 3 mm in height and 1.5 mm in width using a low fusion silver-palladium alloy (Pal Keramit, Nobilmetal, Villafranca d'Asti, Italia). The cast frameworks were soldered on prepared titanium abutments. Resin teeth including one to three premolars in extension per side were added. Cantilever length did not exceed 1.5 cm, being each premolar about 5 mm wide in mesio-distal direction.

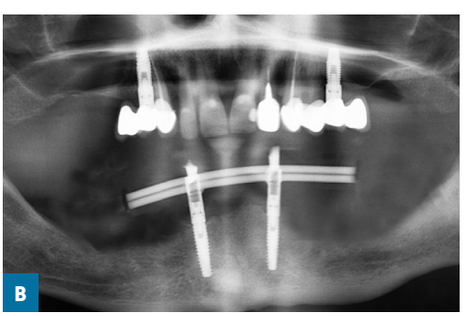
Laser-welded screw-retained metal-resin prostheses were fitted the same day as implant placement, whereas the cast prostheses within 48 hours. Prostheses were screwed onto the implants using a standard torque of 25 Ncm. Occlusion was adjusted in order to have no occlusal contacts on the cantilevers.

Patients were recalled for maintenance and occlusion check every six months. At 1, 3 and 5 years post-loading, the screw-retained prostheses were removed to check implant stability and measure the implant stability quotient (ISQ) using the Osstell device (Integration Diagnostics, Göteborg, Sweden), and periapical radiographs of the study implants were taken with the paralleling technique. After year 5, these measurement procedures were discontinued, and radiographs were only taken for diagnostic purposes in the event of suspected complications.

The outcome measures evaluated were the following.

- *Prosthesis failure*: a fixed prosthesis lost due to implant failure(s), or which had to be replaced for any reason.
- *Implant failure*: the presence of any mobility of the individual implant and/or any infection dictating implant removal, and/or any biomechanical complication (implant fracture or deformation of the connections) rendering the implant unusable. Up to the fifth year, individual implant stability was measured objectively with the prosthesis removed using the Osstell device for resonance frequency analysis (RFA). Results were expressed as ISQ (implant stability quotient) with values ranging from 1 (minimum stability) to





FIGS. 2A, B: *Sequence of panoramic radiographs of patient #32 treated with a laser-welded titanium framework: at initial loading (A); 13 years after loading (B).*

100 (maximum stability). Implants displaying values ≤40 were considered failures. After the fifth year in function, ISQ measurements were discontinued since they did not provide any useful clinical information.

- *Any biological or prosthetic complications*.
- *Patient satisfaction*: assessed 1 month, and 3, 5 and 13 years after loading by asking patients whether they were satisfied with the overall treatment. Patients had to choose one of the following answers: 1 = satisfied, 2 = partially satisfied, or 3 = unsatisfied

The final follow-up included in this publication was at 13 years after implant placement/loading. All outcomes were assessed by Dr Cannizzaro, the treating dentist.
This study was designed as a retrospective cohort study of consecutive patients treated with an immediately-loaded fixed cross-arch mandibular prosthesis on two implants. The patient was the statistical unit of the analyses. Descriptive statistics were employed.

RESULTS

Eighty patients were consecutively treated from June to November 2010. The main baseline patient, site and treatment characteristics are presented in **TABLE 1,** together with the preliminary data at 1-, 3-, and 5-year follow-up; 17 patients had various medical conditions and pathologies. The follow-up focused on the time between implant placement and 13 years after implant loading.
Flaps had to be raised in ten patients (12.5%) to check drill direction. At placement, 12 implants in seven patients did not achieve the minimal insertion torque required (at least 80 Ncm). Four implants in three patients were immediately replaced by larger diameter implants and achieved the desired torque, whereas the remaining implants, which achieved insertion torques ranging from 45 to 60 Ncm, were immediately loaded anyway.
Twelve patients dropped out over the 13-year follow-up (**TABLE 2**).

Implant failures

There were a total of seven implant failures in five patients (**TABLE 3**). Two implants failed in two patients approximately 3 weeks after placement, and their respective prostheses had to be remade. One implant was placed in a fresh extraction socket and neither implant initially achieved the required torque and were immediately replaced with wider diameter implants. When mobility was detected, both failed implants were immediately replaced by wider implants: one was loaded immediately, since a torque of 80 Ncm was achieved, whereas the other was loaded after 6 weeks of submerged healing, since the stability obtained was judged to be insufficient. After 8 years, another implant failed in a relatively young patient; two additional implants were placed, and a new fixed prosthesis was loaded onto the three implants. Finally, both implants failed in two very old and systematically compromised patients, who were rehabilitated with removable dentures.

Prosthesis failures/remakes

In addition to the five failed prosthesis described above, a further nine prostheses were remade for different reasons (**TABLE 3**): 4 were remade as cemented metal-ceramic prostheses with cast frameworks because the patients were unsatisfied with the aesthetics (they looked like dentures); three were replaced with new cast prostheses with the first molars added, because they were considered too short by the patients; and two were remade as a cast prostheses in 24 hours because the laser-welded frameworks fractured. All fixed prostheses but two were in function at the time of writing. These latter two prostheses were not

TABLE 1 PATIENT AND INTERVENTION CHARACTERISTICS (80 PATIENTS)

Patient and intervention characteristics	Numbers
Females	40 (50%)
Mean age at implant insertion (range)	53.2 years (29-85)
Skeletal Class 1	57 (71.3%)
Skeletal Class 2	17 (21.3%)
Skeletal Class 3	6 (7.5%)
Non-smokers	46 (57.5%)
Smoking up to 10 cigarettes/day	18 (22.5%)
Smoking more than 10 cigarettes/day	16 (20%)
Patients with medical conditions*	17 (21%)
Patient with hypertrophic masseters	11 (13.8%)
Patients wearing dentures in the upper jaw at implant placement	22 (27.5%)
Patients wearing dentures in the upper jaw 5 years post-loading	14 (17.5%)
Patients who had a flap raised	10 (12.5%)
Total number of inserted implants	160
Implants inserted in fresh extraction sockets (19 patients)	26 (16.3%)
Implants placed with <80 Ncm (7 patients)	12 (7.5%)
Implants placed in soft bone	9 (5.6%)
Implants placed in medium bone	72 (45%)
Implants placed in hard bone	79 (49.4%)
Implants with a diameter of 4 mm	128 (80%)
Implants with a diameter of 5 mm	26 (16.3%)
Implants with a diameter of 6 mm	6 (3.8%)
Implants of length 8.5 mm	18 (11%)
Implants of length 10 mm	63 (39.4%)
Implants of length 11.5 mm	44 (27.5%)
Implants of length 13 mm	35 (21.9%)
Number of cantilevers with one premolar at initial prosthesis delivery	9 (5.7%)
Number of cantilevers with two premolars at initial prosthesis delivery	114 (71.3%)
Number of cantilevers with three premolars at initial prosthesis delivery	37 (23.1%)
Number of laser-welded titanium prosthetic frameworks	46 (57.5%)
Number of cast silver-palladium prosthetic frameworks	34 (42.5%)
Mean marginal bone levels at implant placement (SD)	0.04 mm (0.16)
Mean marginal bone levels 1 year after loading (SD) (79 patients)	0.34 mm (0.38)
Mean marginal bone levels 3 years after loading (SD)	0.48 mm (0.44)
Mean marginal bone levels 5 years after loading (SD) (79 patients)	0.73 mm (0.68)
Mean ISQ at implant placement (SD)	75.4 (3.6)
Mean ISQ 1 year after loading (SD)	72.5 (2.3)
Mean ISQ 3 years after loading (SD) (79 patients)	75.3 (2.8)
Mean ISQ 5 years after loading (SD) (79 patients)	73.8 (3.6)

**3 patients treated with oral bisphosphonates; 2 who had a heart attack, 2 a cardiac bypass, 2 hypertension, 2 hepatitis C, 1 insulin-dependent diabetes, 1 uterus carcinoma, 1 prostate carcinoma, 1 breast carcinoma; 1 chronic bronchitis, and 1 Parkinson's disease.*

TABLE 2 LIST OF PATIENTS LOST TO FOLLOW-UP AND REASONS THEREOF IN CHRONOLOGICAL ORDER

Pat. n.	Reason	Last seen
2	Moved to another town	6 months after loading
75	Died of breast cancer	6 years after loading
50	Hospitalised for senile dementia	6 years after loading
41	Moved to another town	7 years after loading
62	Died of lung cancer	7 years and half after loading
36	Died at 90 years of age	8 years after loading
60	Died of colon cancer	8 years after loading
24	Died of heart attack	8 years and half after loading
11	Died at 95 years old (severe Alzheimer's)	9 years after loading
14	Died of heart attack	9 years after loading
71	Hospitalised for 7 years	9 years after loading
70	Unwilling to attend maintenance visits (91 years old)	11 years after loading

remade since neither patient wanted to undergo another implant placement procedure; patient #65 had neoplastic metastasis, diabetes and depression, and patient #75 had a heart attack and bypass operation.

Complications

Forty-six patients experienced at least one complication over the 13-year follow-up period. The full list of complications is presented in chronological order in **TABLE 3**, and more details can be found in a previous publication[29].

Patient satisfaction

One month after loading, 72 (90%) patients declared that they were completely satisfied with the treatment, seven (9%) partially satisfied, and one (1%) unsatisfied. The dissatisfied patient had complained about mastication, which was frontally displaced, but after 2 months was provided with a greater masticatory area by adding one premolar per side to the prosthesis. Three years after loading, most patients declared that they were completely satisfied, the exception being four patients who were only partially satisfied because they felt they could not chew as efficiently as they wished due to lack of molars. These four patients had their laser-welded prostheses either replaced with cast ones bearing first molars (three patients) or lengthened by adding first molars to the existing prosthesis (one patient). In addition, four patients complained about the aesthetic appearance of their screw-retained prostheses, suggesting they looked like dentures, and had their prostheses replaced by new cemented metal-ceramic ones. At 5 years after loading, all patients declared that they were fully satisfied with their prostheses. At 13 years, 56 (82.4%) patients were fully satisfied, 10 (14.7%) were partially satisfied and two (2.9%) were unsatisfied. Reasons for their lack of satisfaction are described in **TABLE 4**.

DISCUSSION

This retrospective study was designed to evaluate whether two implants inserted flapless and immediately loaded would be a cost- and time-efficient means of reliably retain a cross-arch

TABLE 3 SUMMARY OF ALL FAILURES AND COMPLICATIONS UP TO 13 YEARS AFTER IMPLANT PLACEMENT/LOADING IN 80 PATIENTS IN CHRONOLOGICAL ORDER

Pat. n.	Implant failures	Prosthesis
15	One implant failed at 3 weeks (one new implant placed)	Cast
43	One implant failed at 3 weeks (one new implant placed)	Laser-welded
38	One implant failed at 8 years (two additional implants placed)	Laser-welded
65	Both implants failed at 10 years (replaced with removable denture)	Cast
78	Both implants failed at 10 years (replaced with removable denture)	Laser-welded
	Prosthesis failures/remakes	
15	Prosthesis failure at 3 weeks	Cast
43	Prosthesis failure at 3 weeks	Laser-welded
80	Remade at 36 months due to functional complaint (prosthesis too short)	Laser-welded
12	Remade at 38 months due to aesthetic complaint	Laser-welded
41	Remade at 45 months due to functional complaint (prosthesis too short)	Laser-welded
45	Remade at 45 months due to aesthetic complaint	Laser-welded
62	Remade at 47 months due to aesthetic complaint	Laser-welded
72	Remade at 49 months due to functional complaint (prosthesis too short)	Laser-welded
66	Remade at 50 months due to framework fracture	Laser-welded
32	Remade at 50 months due to aesthetic complaint	Laser-welded
6	Remade at 81 months due to framework fracture; resoldered 7 months later, again due to framework fracture	Laser-welded
38	Prosthesis failure at 8 years (new fixed prosthesis on 3 implants)	Laser-welded
65	Prosthesis failure at 10 years (replaced with removable denture)	Cast
78	Prosthesis failure at 10 years (replaced with removable denture)	Laser-welded
	Complication type	
8	Implant stuck at placement	Not relevant
57	Bone perforation at implant placement; detachment of two false teeth (reattached) at 73 months	Cast
80	Haemorrhage at implant placement and functional complaint (prosthesis too short) at 36 months	Laser-welded
30	Haemorrhage at implant placement	Not relevant
19	Aesthetic complaint up to 2 months post-loading (tooth position)	Laser
50	Functional complaint up to 3 months post-loading (prosthesis too short) & chipping of an incisor at 46 months	Cast
59	Loosening of prosthesis screws at 3, 15 and 18 months	Laser-welded
40	Distal extension framework fracture after 5 months	Cast
25	Peri-implantitis at 8 months and 2 years	Cast
52	Detachment of 2 false central incisors after 14 months; peri-implantitis to the second thread of both implants at 9 years (gingivectomy and open flap debridement)	Cast
64	Soft tissue hyperplasia under the central portion of the prosthesis after 27 months	Laser-welded
33	After delivery of upper implant-supported prostheses patient complained of feeling the lower framework flexing after 37 months; bone loss to the first thread at one implant at 132 months (no treatment)	Laser-welded
12	Aesthetic complaint at 38 months; fracture of ceramic lining on a central tooth at 115 months (composite repair); peri-implantitis at both implants up to the first and third thread, respectively, at 10 years (open-flap debridement and removal of exposed threads)	Laser-welded

Pat. n.	Implant failures	Prosthesis
11	Loosening of prosthesis screws at 39 months and distal extension framework fracture after 45 months	Laser-welded
78	Framework fracture at 39 months; loosening of prosthesis screws at 49 months; peri-implantitis at both implants at 10 years (both failed)	Laser-welded
24	Functional complaint at 40 months (prosthesis too short)	Cast
39	Framework fracture at 44 months	Laser-welded
41	Functional complaint at 45 months (prosthesis too short)	Laser-welded
26	Fracture of the framework soldering at 45 months	Laser-welded
45	Aesthetic complaint at 45 months	Laser-welded
62	Aesthetic complaint at 47 months	Laser-welded
43	Fracture of the aesthetic resin veneering at 4 years; screw loosening at 96 months	Laser-welded
2	Detachment of false anterior teeth twice between years 4 and 5	Laser-welded
72	Functional complaint at 49 months (prosthesis too short)	Laser-welded
32	Aesthetic complaint at 50 months	Laser-welded
66	Framework fracture after 50 months	Laser-welded
16	Functional complaint at 55 months (prosthesis too short)	Cast
51	Unnoticed partial screw loosening at 5 years	Laser-welded
71	Loss of false incisors and one canine at 77 months (reattached when patient was hospitalised)	Cast
38	Peri-implantitis at both implants at 81 months	Laser-welded
6	Framework fracture at 81 months and 88 months (new prosthesis)	Laser-welded
14	Detachment of two false central incisors at 7 years (reattached); detached again after 1 month and posterior teeth abraded, replaced all teeth	Laser-welded
20	Mucositis at both implants and abraded teeth at 7 years (all teeth replaced); peri-implantitis to the second thread of both implants at 11 years	Cast
69	Peri-implantitis at both implants at 91 months	Cast
67	Loosening of left screw at 95 months (re-tightened)	Laser-welded
23	Mucositis at both implants at 8 years; peri-implantitis at both implants at 10 years (open-flap debridement and exposed threads removal)	Laser-welded
36	Peri-implantitis at both implants at 8 years (antibiotic treatment)	Laser-welded
77	Screw loosening at 8 years (screws replaced)	Cast
1	Angular cheilitis (loss of height due to wear) at 98 months (all false teeth replaced)	Laser-welded
24	False canine detachment at 103 months (reattached)	Cast
3	Buccal bone loss to the second thread at 103 months	Laser-welded
27	Peri-implantitis up to the second thread of both implants at 110 months (open-flap debridement, osteoplasty and removal of the exposed threads); peri-implantitis at both implants at 134 months	Cast
9	Fracture of the false front teeth (repaired chairside) at 10 years; fractured again after 1 week (lining remade at the lab)	Cast
53	Fracture of both connecting screws at 124 months	Cast
48	Peri-implantitis to the first thread of both implant at 11 years	Laser-welded
70	Peri-implantitis at the right implant at 11 years (close debridement and antibiotics)	Laser-welded
TOTAL	46 patients experienced at least one complication	

TABLE 4 REASONS FOR PARTIAL SATISFACTION AND DISSATISFACTION WITH THE TREATMENT AFTER 13 YEARS IN FUNCTION

Pat. n.	Satisfaction	Reason
6	Partial	The prosthesis fractured twice and had to be remade (at no cost)
8	Partial	Patient became depressed: generally dissatisfied
12	Partial	Had to be treated for peri-implantitis at both implants
15	Unsatisfied	Abraded posterior teeth but treating physician doctor insisted that the prosthesis not be unscrewed due to risk of uncontrolled bleeding (patient on anticoagulants)
23	Partial	Became edentulous in the upper jaw and denture (made at another centre) was unstable
31	Partial	Affected by senile dementia: generally dissatisfied
38	Partial	Lost one implant due to peri-implantitis and prosthesis remade on three implants
43	Unsatisfied	Connecting screws loosened on holiday and impaired eating
49	Partial	Complained of tartar formation on front teeth (but failed to regularly attend hygiene recalls)
58	Partial	Unhappy with the colour of false teeth (but prostheses of different colours in the upper jaw and devitalized teeth)
67	Partial	One screw loosened
80	Partial	Problems chewing since becoming edentulous in the upper jaw

prosthesis for rehabilitation of edentulous mandibles with low morbidity. The findings are encouraging, since up to 13 years after loading, only five out of 80 patients experienced implant failure (6.25%) and only two (2.5%) returned to a removable denture. Our findings are in substantial agreement with two other pilot RCTs[20-23] and one prospective study[24] which also suggested a good short-term outcome of this option, as well as other RCTs evaluating immediate loading of overdentures onto two mandibular implants[16-19].

Nevertheless, in this study 14 prostheses (17.5%) had to be remade or were lost. This figure is rather high, but it should be noted that only seven prostheses failed due to biological or biomechanical complications (five prostheses because of implant failures and two due to fractures in the laser-welded framework); the other seven were remade because four patients were not satisfied with the aesthetics, and three complained of limited masticatory function since the first molars were lacking. A further three patients requested to have the first molars added onto the original prostheses, despite all patients having previously been informed in most cases that their prosthesis would only have 10 teeth (from second premolars to second premolar) and in a few eight teeth only. Thus, a total of 12.5% of patients were dissatisfied with their initial prosthesis, indicating that this treatment may not suit all patients.

This study was not designed to evaluate two different types of framework (laser-welded *versus* cast), and the operator mainly chose the type of framework for financial reasons. However, at the 5-year follow-up[29], it was observed that laser-welded titanium frameworks seemed to have higher complications rates than cast silver-palladium ones, so it was decided to compare the two types via post-hoc analysis (chi-squared testing). This revealed that laser-welded prosthesis frameworks were affected by a significantly higher complication rate (19 patients out of 46 *versus* six patients out of 34, respectively; difference in proportion = 0.23, 95% CI: 0.03 to 0.43; Pearson's chi-squared test, P = 0.032). Therefore, we decided to no longer use laser-welded frameworks for definitive prostheses. Exactly the same problem was noticed in another cohort study[30], and we therefore recommend that laser-welded frameworks should be only considered for temporary prostheses.

Implant placement was intended to be flapless, but in ten patients flaps had to be raised to

check the direction of the implants. Implant insertion without flap elevation was conducted free-hand based on information derived from cone-beam CT scans, without the aid of any planning software for implant placement[31], although stents were used to facilitate implant positioning and orientation in a few cases. A great deal of expertise in patient selection and surgical technique is required for such procedures to be performed successfully. If one has less clinical experience, it might be wiser to use computer-guided surgery or raise a flap so that anatomical landmarks can be identified, and implant direction controlled[32].

The main operator of this study decided immediately to load only those implants that achieved an insertion torque of at least 80 Ncm. To achieve such a high insertion torque, implant sites were under-prepared to various degrees, depending on bone quality[33]. However, while favouring high insertion torques, extreme under-preparation may cause implants to get stuck in the bone, and their removal may not be as straightforward as it might be imagined. Therefore, it may be that good results could also be achieved with lower insertion torque, as suggested by the successful outcomes of those eight immediately loaded implants inserted with torques ranging from 45 to 60 Ncm in the present study, and of immediately loaded implants inserted with a minimum torque of even 20[34] or 32 Ncm[35].

The major limitation of the present study was that patients were treated by a single experienced operator, who also recorded all outcome measures after the fifth year of follow-up (self-assessment). This may limit the external validity of the present findings to other settings, since the operator was highly experienced in flapless placement and immediate loading procedures. Additional long-term multicentre randomized controlled trials are therefore needed to evaluate the general prognosis of this treatment modality. In addition, peri-implant bone levels were not assessed after the fifth year in function. Nonetheless, treatments were delivered under normal clinical conditions with the application of broad patient inclusion criteria.

CONCLUSIONS

Immediately loaded mandibular cross-arch prostheses can be retained up to 13 years by only two implants, if made with a robust cast framework.

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