

Maxillary implant overdenture retained by four unsplinted attachments and opposed by a natural or fixed dentition: Five-year clinical outcomes. A prospective case series

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Abstract

Objectives: The objective of this study was to assess, over a period of 5 years, implant prosthesis and patient-reported outcomes of complete dentures retained by four implant-supported attachments in the edentulous maxilla facing either natural teeth or fixed rehabilitation in the lower jaw.

Materials and Methods: Implant, prosthodontic and patient-related outcomes were assessed in 30 patients at 1, 3 and 5 years. Prosthodontic survival, complications or maintenance events as well as implant survival were recorded. Patient-reported outcome measures (PROMs) were evaluated with the Oral Health Impact Profile (OHIP-20) questionnaire and a visual analogue scale (VAS) before implant placement (baseline) and during the follow-up period.

Results: After 5 years, three patients dropped out, 21 implants failed, and four overdentures were replaced leading to a prosthesis survival rate of 85.2% (95% CI: 71.8%–98.6%) and an implant survival rate of 80.6% (95% CI: 73.1%–88.0%). Prosthodontic success rate decreased from 86.2% to 74% between the 1st and the 3rd year and reached 63% after 5 years. OHIP results improved significantly from baseline to 1 year ($p < .0001$) and to 3 years ($p = .036$), but, at 5 years, the improvement was no longer significant when compared to baseline ($p = .12$). The overall VAS score remained significantly higher up to 5 years ($p < .001$).

Conclusion: A substantial number of prosthetic complications and replacements occurred over the 5-year follow-up. After 5 years, the OHIP-20 deteriorated and reached again the baseline level. Nonetheless, the VAS results suggest significantly increased patient satisfaction after implant-supported retention was provided for the removable prostheses.

KEYWORDS

dental implants, dental prosthesis, edentulous maxilla, implant overdenture, removable, Locator®

1 | INTRODUCTION

Maxillary implant overdentures (IOD) aim to improve the retention and the stability of complete dentures in patients with persistent

complaints or insufficient residual tissue support (Emami et al., 2014; Laurito et al., 2012; Sadowsky, 2007; Slot et al., 2010).

Implant overdentures are widely described as dentures on bars supported by four to five implants, and the literature reports implant

survival rates higher than 95% when implants are splinted (Boven et al., 2020; Doornwaard et al., 2021; Slot et al., 2014).

However, IOD supported by individual attachments are increasingly proposed to restore the maxilla of elderly patients because of limited anatomical contra-indications, cost-effectiveness and ease to clean (Heydecke et al., 2003; Offord et al., 2017; Sadowsky, 2007; Zou et al., 2013).

In the literature, different protocols with various types of attachments and implant number are described to restore the edentulous maxilla. In a recent systematic review, implant survival rates varied from 95% to 100% when maxillary IOD are supported by at least four unsplinted implants attachments and implant survivals decreased from 73.5% to 100% with less than four implants (di Francesco, de Marco, Gironi Carnevale, et al., 2019). However, these data mainly considered short-term data and prospective long- or medium-term studies are rather limited. Ma and co-workers reported in a 10-year prospective study on three unsplinted implant attachments an implant survival rate that yielded 86.3% (Ma, Tawse-Smith, et al., 2016). Moreover, two retrospective studies evaluating the clinical outcomes of IOD supported by four unsplinted implants, reported respectively implant survival rates 98.7% and 95.2% at 5 years (Frisch et al., 2015; Wang et al., 2016). Prospective studies with a longer follow-up are therefore needed to evaluate the implant survival rate of such removable implant rehabilitations. Additionally, the literature on maxillary overdentures mainly focuses on implant results while the prosthodontic outcomes and complications remain poorly investigated (di Francesco et al., 2021; Ghiasi et al., 2021; Ma, Waddell, et al., 2016; Osman et al., 2012; Payne et al., 2001).

In the above cited studies, the antagonist is often an overdenture supported by two implants while some authors suggested that the nature of the opposing jaw could have an impact on the implant and prosthetic survival rates as well as on the prosthodontic complications (Ohkubo & Baek, 2010; Parel & Phillips, 2011; Slot et al., 2014). To the best of our knowledge, there are no prospective data about long-term outcome of maxillary IOD retained by four unsplinted attachments and opposed by a natural or fixed dentition.

The aim of the present study was to report the clinical outcomes of removable prostheses retained by four implant-supported Locators® in the edentulous maxilla and with natural dentition or fixed rehabilitation in the lower jaw, over a period of 5 years. The primary objective was to evaluate the prosthodontic survival rate as well as complications and the secondary objectives were to report implant survival and peri-implant soft tissue health as well as patient-related outcome measures.

2 | MATERIALS AND METHODS

2.1 | Study design

This study was designed as a prospective descriptive case series. The study protocol was approved by the Ethics Committee of the University Hospital of Liège, Belgium, and was registered at www.clinicaltrials.gov (ethical file number: B7072014199817 and clinical

trial registration number: NCT02380404). The study was conducted according to the STROBE guidelines. The present study conforms to the Declaration of Helsinki and to the European Medicines Agency Guidelines for Good Clinical Practice.

A total of 30 consecutive patients consulting at the University Hospital of Liège with an existing complete maxillary removable prosthesis and natural or fixed dentition in the lower jaw were considered for possible inclusion. The following inclusion criteria were considered:

- Complete definitive maxillary dentures (CD) were made of heat-cured poly-methyl-methacrylate without a metal framework and with palatal coverage.
- The dentures fulfilled functional and aesthetic criteria; in case of minor deviations, the necessary adjustments were made (e.g. relining).
- The patient was encountering problems with the existing dentures and in need of implant treatment.
- Natural teeth and fixed rehabilitation at the antagonistic jaw (at least from 36 to 46) were present.
- Healthy dental condition at the lower jaw (e.g. controlled periodontitis and the absence of caries).
- Physical status was 1.2 according to the American Society of Anaesthesiologists (ASA).
- Tobacco use was <10 cigarettes/day.
- It was possible to place four implants of at least 3.3 mm in diameter and 8 mm in length without the need for any further bone augmentation

Patients with signs of bruxism, such as wear facets, abfractions, chipping, cracks or fractures on the antagonist jaw, were not excluded from this study. Patients were followed for a period of 5 years. Clinical data as well as Patient-reported outcome measures (PROMs) were collected at 1, 3 and 5 years.

2.2 | Pre-treatment examination

The patients were informed about the study details (surgical phase, healing period and prosthetic phase) and given adequate time to decide before signing an informed consent form. The upper removable denture and the lower dentition were clinically evaluated. Oral hygiene instructions were given. At baseline, the patients received an Oral Health Impact Profile 20 (OHIP-20) and patient satisfaction questionnaire. The patients were subjected to dental cone beam computed tomography (CBCT; (NewTom 5G CBCT imaging system)) wearing their CD, in which several landmarks had been made in the positions of the central incisors, canines and first molars.

2.3 | Surgical and prosthodontics procedures

All participants received four tissue-level implants of 3.3, 4.1 or 4.8 mm in diameter and ranging from 6 to 12 mm in length (Standard® implants, Roxolid®, Institut Straumann AG) according to the surgical

protocol recommended by the manufacturer. The implant positions were determined based on bone availability (CBCT) and according to the prosthodontic parameters.

After 3 months, Locator® attachments with a torque of 35 N/cm (Zest Anchors LLC) were connected to the implants and during the same day, the titanium female parts were polymerized into the prostheses by the dental technician. No metal reinforcements were incorporated. The retentive female nylon inserts (blue, 680) were initially placed in all patients. The bilateral balance of the occlusion was controlled, and instructions for IOD handling and hygiene were given to the patients.

2.4 | Data collection and follow-up visits

Demographic and clinical data were collected in a remote and secured database. Patients were seen at 1, 3 and 5 years after abutment connection for data collection. At each follow-up visit, clinical evaluation of the implants and the prosthesis were carried out. Complaints or adverse events, patient satisfaction and quality of life were also recorded. Additionally, there were enrolled in an annual routine recall programme and invited to contact the clinic in case of adverse event. In case of complications, the data were recorded (Figure 1).

2.5 | Prosthodontic outcomes

The resulting prosthodontic outcomes were collected and reported as follows, based on Payne and co-workers:

1. Patrix unscrewing, fracture, loss or replacement due to significant wear
2. Matrix fracture or replacement
3. Dislocation, loss and wear of the matrix component (female nylon inserts)
4. Overdentures maintenance such as fracture, puncture, reline or prosthesis modification necessary to reposition a new matrix after replacement of a failing implant
5. Overdenture replacement in case excessive wearing of the teeth or repetitive fracture of the prosthesis requiring metal reinforcement

Prosthodontic success, complications or failures were defined as follows:

1. A *successful* prosthesis corresponds to patients without evidence of retreatment beyond accepted prosthodontic *maintenance events*, which were defined as no more than two replacements of the patrices, matrices or the matrix component (1, 2, 3) during the first year and no more than five replacements in 5 years. The replacement of worn or teeth/fractured overdentures or

relining (4) no more than once in 5 years was also considered as a *success*.

2. If the maintenance events exceeded the above-mentioned criteria, it was considered as prosthodontic *complications*. The need for prosthesis modification related to an implant loss (4) more than once in 5 years was also considered as an adverse event and therefore as a complication.
3. If the overdenture was no longer serviceable and its replacement was indicated (5), it was considered as a prosthodontic *failure*. Prosthesis presenting more than two repeated fractures of the IOD for which the installation of a metallic reinforcement was then necessary (5), were also considered as a failure.

2.6 | Implant outcomes

Implant survival was defined as the percentage of implants initially placed that was still present and not mobile at the follow-up visits. In case of implant loss, it was considered as an implant failure directly affecting the implant survival rates. Lost implants were replaced 3 months after their removal and the new implants were not considered for further statistics.

The peri-implant soft tissue health was assessed based on bleeding on probing and the plaque index. The Sulcular Modified Bleeding Index as described by Mombelli was used to monitor the peri-implant inflammation (Mombelli et al., 1987), while the Dichotomous Plaque Index described by Loe and Silness was used to check the presence or absence of dental plaque (Løe & Silness, 1963). Additionally, probing depth in the mesial, distal, lingual and buccal aspects of each implant was measured at 5 years. The 1-year radiographic outcomes (peri-implant bone remodelling) previously reported (Bouhy et al., 2020) were based on CBCTs and additional follow-up CBCTs were not considered for ethical reasons. After 1-year, routine 2D radiographies were taken in a non-standardized methods and could not be used for research purposes.

2.7 | Patient-reported outcome measures

The OHIP-20 questionnaire was used to assess oral health-related quality of life. This 20-item questionnaire measures self-reported impairment in edentulous populations within seven domains: functional limitations, physical discomfort, psychological discomfort, physical disability, psychological disability, social disability and handicap (F. Allen & Locker, 2002). The items were rated on six-point Likert scales (“never” = 1, “rarely” = 2, “occasionally” = 3, “often” = 4, “very often” = 5, or “all of the time” = 6). The OHIP-20 total range was therefore 20–120 points, and lower scores indicated better Oral health-related quality of life (OHRQoL).

An adaptation of the McGill Denture Satisfaction Instrument proposed by some authors was used to evaluate patient satisfaction (Awad et al., 2003; Awad & Feine, 1998; de Grandmont et al., 1994; Michaud et al., 2012). The subjects answered a 100mm VAS

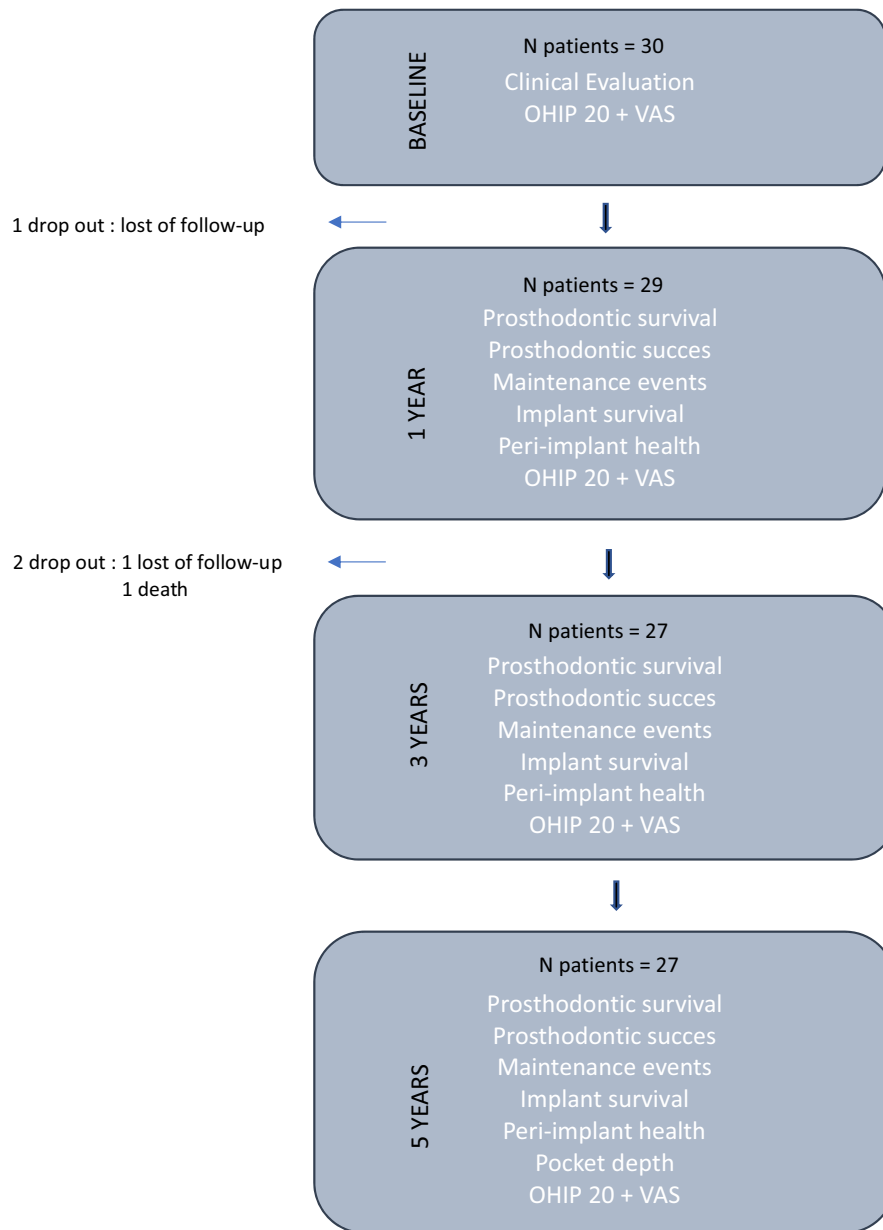


FIGURE 1 Clinical situation after 5 years of follow-up (a) Frontal view. (b) Orthopantomogram radiography. (c) Occlusal view of Locator® attachment; note the inflammation around most of the attachments. (d) Frontal view with prosthesis. (e) Prosthesis with the female parts of the Locators®.

illustrated by “not at all satisfied” on the left side and “extremely satisfied” on the right side. Six aspects were assessed: general comfort, stability, ability to chew, speech, cleaning ability and pain.

2.8 | Statistical analyses

The results were summarized as mean and standard deviation (SD) and range for quantitative variables and as frequency tables and 95% confidence intervals for categorical findings at each time point. Comparisons of the variables between the groups were conducted using Student's *t*-test (or the Kruskal–Wallis test) for the quantitative variables and by a chi-squared test (or Fisher's exact test) for the categorical variables. The evolution of the OHRQoL and PS results from baseline (with a CD before implant placement) to 5 years was analysed globally using a general linear mixed model (GLMM). Adjusted Scheffe post hoc test was used for the pairwise comparisons. The

results were considered significant at the 5% level ($p < .05$). The statistical analyses were carried out using SAS version 9.4 (SAS Institute) and the figures were realized with R version 4.1.

3 | RESULTS

3.1 | Demographics

Thirty subjects were included in the study. Seventeen were males and 13 were females, with a mean age of 66.4 ± 7.7 years (range: 48 to 82 years). Four patients were smokers (<10 cigarettes/day) and 16 patients showed signs of bruxism. A single patient dropped out at 12 weeks and did not show up to recalls for unknown reasons; therefore, the statistical analyses were based on 29 patients. After 1 year, one patient died, and another was unable to attend the check-up visit (Figure 2).

3.2 | Prosthodontics outcomes and maintenance events

Prosthodontic outcomes and overdentures maintenance events after 1, 3 and 5 years are presented in Table 1. According to the selected criteria, the prosthodontic success rate decreased from 86.2%

(1 year) to 74% (3 years) and 63% (5 years). Four prostheses failed in 4 patients and were replaced during the study follow-up leading to a prosthodontic survival rate of 85.2% after 5 years (Table 2). The reason for prosthesis failures was excessive worn ($n = 2$) and repeated fracture leading to the need of a metal framework ($n = 2$). No prosthesis failure occurred because of an implant loss.

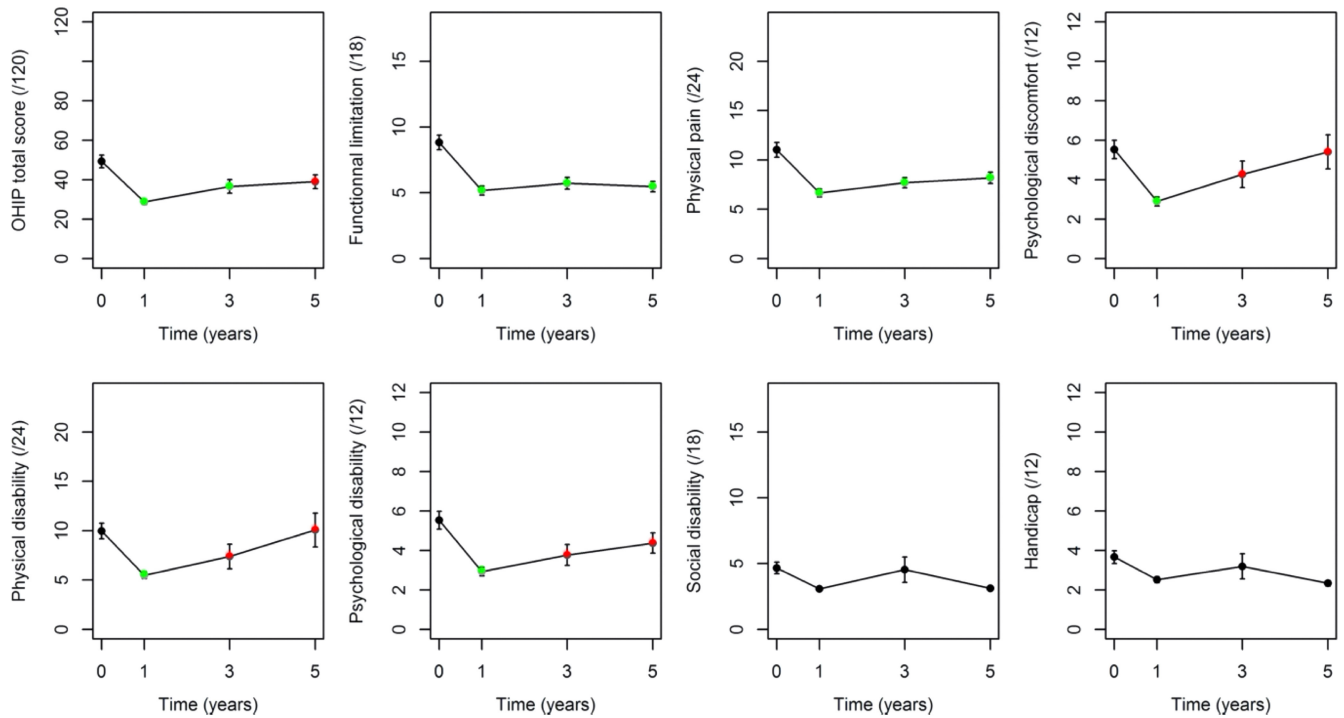


FIGURE 2 Study design.

TABLE 1 Prosthodontic outcomes and maintenance events up to 5 years.

	0–1 year		1–3 years		3–5 years		0–5 years	
	Implant level	Patient level	Implant level	Patient level	Implant level	Patient level	Implant level	Patient level
	(N = 116)	(N = 29)	(N = 108)	(N = 27)	(N = 108)	(N = 27)	(N = 108)	(N = 27)
Patric: screw fracture	0	0	0	0	0	0	0	0
Patric: fracture	0	0	0	0	0	0	0	0
Patric: loose	0	0	0	0	0	0	0	0
Patric: replaced	0	0	0	0	0	0	0	0
Matrix: replace	0	0	0	0	0	0	0	0
Matrix: fracture	0	0	0	0	0	0	0	0
matrix component: dislodged/worn/loose	6 (5.2%)	3 (10.3%)	25 (23.2%)	10 (37.0%)	11 (10.2%)	4 (14.8%)	35 (32.4%)	12 (44.4%)
Overdenture: fractured, puncture fracture of acrylic over patric or fractured teeth		5 (17.2%)		7 (25.9%)		3 (11.1%)		12 (44.4%)
Overdenture: reline		0 (0.0%)		3 (11.1%)		3 (11.1%)		6 (22.2%)
Overdenture: new		1 (3.5%)		0 (0.0%)		3 (11.1%)		4 (14.8%)
Overdenture: modification		9 (31.0%)		2 (7.41%)		0 (0.0%)		9 (33.3%)

	0–1 year		0–3 years		0–5 years	
	Frequency	Per cent	Frequency	Per cent	Frequency	Per cent
Success	25	86.2	20	74	17	63
Complications	3	10.3	6	22.2	6	22.2
Failure	1	3.4	1	3.7	4	14.8

Note: $N = 29$ after 1 year, $N = 27$ after 3 and 5 years.

Loss, wear, fracture or replacement of the patrix or matrix were not observed over the 5-year follow-up. However, at 5 years, 44.4% of the patients were subjected to overdenture fracture, puncture fracture of acrylic over patrix or fractured teeth (incidence: 0.088/patient/year). Overdenture adaptations were necessary in 31% of the patients and mainly occurred during the first year due to implant replacement and resulting modification of the matrix housing. During the overall follow-up, 32.4% of the female nylon inserts had to be replaced in 12 patients to improve the prosthesis retention (incidence: 0.25/patient/year). However, these maintenance events never happened more than once a year. Finally, six prostheses had to be relined (incidence: 0.044 relining/patient/year) but not more than once during the 5-year follow-up period and they were therefore considered as maintenance events. Overall, the maintenance events occurred with an incidence of 0.48 /patient/year. These prosthodontic maintenance events occurred to 60% (9/15) of patients presenting signs of bruxism (bruxers) and to 25% of other patients (3/12).

According to the definition criteria for prosthodontic complications (repeated maintenance events), 22.2% of the patients were subjected to complications over the 5-year follow-up.

3.3 | Implant outcomes

Over the follow-up period, 16 failed in 10 patients during the first year, four implants failed in 2 patients between the 1st and 3rd year and one implant failed after 4 years leading to implant survival rates of 86.2% (CI: 79.9%–92.5%), 81.5% (CI: 74.2%–88.8%) and 80.6% (CI: 73.1%–88.0%) at 1, 3 and 5 years follow-up, respectively. Up to 5 years, 40.7% (11/27) of the patients were subjected to at least one implant failure. No statistical difference was observed in the implant survival rates according to implant length or diameter, age, gender or the presence of bruxism or smoking. At 5 years, 78.2% of the remaining implants displayed an absence of plaque and healthy peri-implant mucosa. Only two implants revealed pocket depths deeper than 6 mm at 5 years. The detailed data related to peri-implant tissue health are reported in Table 3.

3.4 | Patient-reported outcome measures

3.4.1 | Oral health-related quality of life

There was a significant improvement in Oral health-related quality of life (OHRQoL) ($p < .0001$) from baseline to 1 year observed

in most of the domains: functional limitation, physical pain, psychological discomfort, physical disability and psychological disability ($p < .0001$). Thereafter, OHRQoL improvement remained stable up to 3 years while a reduction was observed at 5 years. Only, the domains “functional limitation” and “physical pain” remained improved. At 5 years, the total OHIP score reached 39.0 ± 18.3 (49.2 ± 17.3) but was not statistically significant from baseline (Figure 3 and Appendix S1). Additionally, after 5 years, the occurrence of complications or failures did not significantly influence the OHIP scores.

3.4.2 | Patient satisfaction (PS)

The results of PS are shown in detail in Figure 4 and Appendix S2. At baseline, the patients were less satisfied with stability, general comfort and ability to chew with their CDs. The overall PS score rose from 41.1 to 53.2 (max 60) with the implant rehabilitation ($p < .0001$). General comfort, stability, ability to chew and speech significantly improved, whereas cleaning ability and pain remained unchanged. After 3 and 5 years, the overall PS score remains significantly improved. The same observations were made for ability to chew and speech.

Additionally, after 5 years, the occurrence of complications or failures did not significantly influence the VAS scores.

4 | DISCUSSION

The results observed in this 5-year prospective study displayed an implant survival rates of 80.6% and prosthetic survival rates of 85.2%. According to the selected criteria, the prosthetic success rate reached 63%. Patients' satisfaction after treatment remained high after 5 years for all patients while the improvement of the OHIP score was no longer significant after 5 years.

4.1 | Prosthodontics outcomes

In the present study, the prosthetic failure rate at 5 years reached 14.8%. According to a recent systematic review, the failure rate for maxillary implant-supported overdentures yields 3.7% after a mean period of 21.4 months (range: 6–240) and the cumulative failure rate was 20.2% after 19 years. This review included results from both splinted and unsplinted implants overdentures as well as a variable number of implants (Ghiasi et al., 2021). Another systematic

TABLE 2 Prosthodontic outcomes after 1, 3 and 5 years after abutment connection.

TABLE 3 Implant-related data.

	1 year		3 years		5 years	
	Patient-level data	Implant-level data	Patient-level data	Implant-level data	Patient-level data	Implant-level data
Implant-related-data	N = 29	N = 116	N = 27	N = 108	N = 27	N = 108
Implant failure ^a	10	16	2	4	1	1
Drop-out ^b	1	4	2	8	0	0
Implant survival rate (%)	NA	86.2 (100 / 116) (79.9–92.5)	NA	81.5 (88 / 108) (74.2–88.8)	NA	80.6 (87 / 108) (73.1–88.0)
Implant follow-up	N = 28	N = 100	N = 24	N = 88	N = 24	N = 87
Plaque index scores (%)						
No	75.0 (21) (56.6–87.3)	84.0 (84) (75.6–89.9)	83.3 (20) (64.2–93.3)	89.8 (79) (81.7–94.5)	50.0 (12) (31.4–68.6)	78.2 (68) (68.4–85.5)
Yes	25.0 (7) (12.7–43.4)	16.0 (16) (10.1–24.4)	16.7 (4) (6.7–35.9)	10.2 (9) (5.5–18.3)	50.0 (12) (31.4–68.6)	21.8 (19) (14.5–31.6)
Modified bleeding index scores (%)						
No bleeding	71.4 (20) (52.9–84.8)	81.0 (81) (72.2–87.5)	75.0 (18) (55.1–88.0)	86.4 (76) (77.7–92.0)	50.0 (12) (31.4–68.6)	78.2 (68) (68.4–85.6)
Bleeding on probing	28.6 (8) (15.3–47.1)	19.0 (19) (12.5–27.8)	25.0 (6) (12.0–44.9)	13.6 (12) (8.0–22.4)	41.7 (10) (24.5–61.2)	19.5 (17) (12.6–29.1)
Spontaneous bleeding	0.0 (0) (0.0–12.3)	0.0 (0) (0.0–3.6)	0.0 (0) (0.0–14.3)	0.0 (0) (0.0–4.1)	8.3 (2) (2.3–25.9)	2.3 (2) (0.6–8.0)
Pocket depth ≥6 mm					8.33 (2/24) (2.32–25.9)	2.30 (2/87) (0.14–8.49)

^aDuring the follow-up period of 5 years, 21 implant failures occurred in 11 patients.

^bThree patients dropped out from the study. Two patients were lost of follow-up and one patient died after 1 year.

review assessing the prosthodontic outcome of splinted versus unsplinted IOD on 4 implants, reported a prosthodontic survival rate of 95%–100% and no difference was found between the bar versus the unsplinted attachment configuration (di Francesco, de Marco, Sommella, & Lanza, 2019). However, most of the studies included in the above-mentioned reviews had a follow-up of <5 years and the majority of the IOD were designed with a metal frame, while in the present study, the existing prostheses were readjusted without reinforcement (Ghiasi et al., 2021). The natural or fixed opposing dentition may have also led to higher functional masticatory forces and may have therefore influenced the prosthodontic failures and complications as already described for maxillary conventional complete denture opposed to a natural dentition (Bhandari, 2016). Moreover, in the present study, a higher rate of maintenance events occurred for the bruxers patients suggesting that bruxism might be a contributing factor for prosthodontic complications, as already suggested by some authors (Zhou et al., 2015; Zou et al., 2013).

According to the established criteria, prosthodontic complications or failure occurred in 10 patients, leading to a prosthodontic success rate of 63% at 5 years. These results are comparable to those obtained in the study of Ma and co-workers using a similar classification. Even though the IOD were supported by only three

implants and that the criteria were slightly different, a success rate of 57% was found after 5 years (Ma, Waddell, et al., 2016; Payne et al., 2001).

One of the most frequent maintenance events was female nylon inserts replacement; however, it did not occur more than once a year per implant and therefore it had no influence on the prosthodontics success rate. Indeed, the loss of retention in Locator-supported IOD is frequently described in the literature as a common maintenance event; nevertheless, it is easy to replace the nylon coating at reduced cost without any further laboratory process (Engelhardt et al., 2016; Matthys et al., 2019; Mo et al., 2016; Wang et al., 2016).

Zou and co-workers evaluated three different anchorage system (telescopic crowns, bar or Locator) to retain a maxillary IOD on four implants. During the 3 years follow-up, the mean number of complications yielded 0.13 per patient in the locator group, which is significantly lower than those observed in the present study as the mean annual repairs including maintenance events reached 0.48 per patient (Zou et al., 2013). This difference seems to be essentially attributed to the nylon insert replacements which often occurred in our study while it was interestingly not reported in the Zou and co-workers study. Additionally, in the present study, the need for

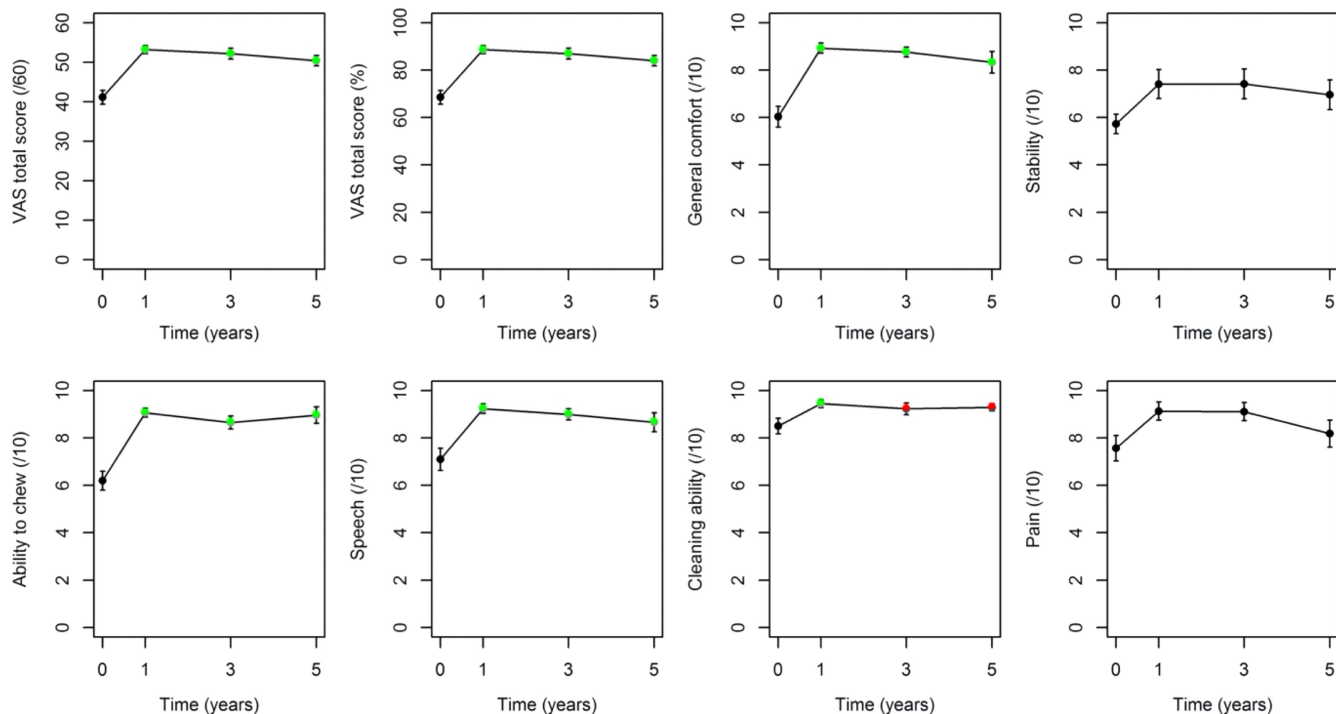


FIGURE 3 Distribution of the Oral Health Impact profile, total score and sub-scores before implant placement (baseline) and at 1 year, 3 years and 5 years after abutment connections. Means and standard errors (SE) are reported at each time point. A green point indicates a significant change since baseline, a red one indicates that the change is no more significant, and if all points are black, there is no significant evolution of the parameter.

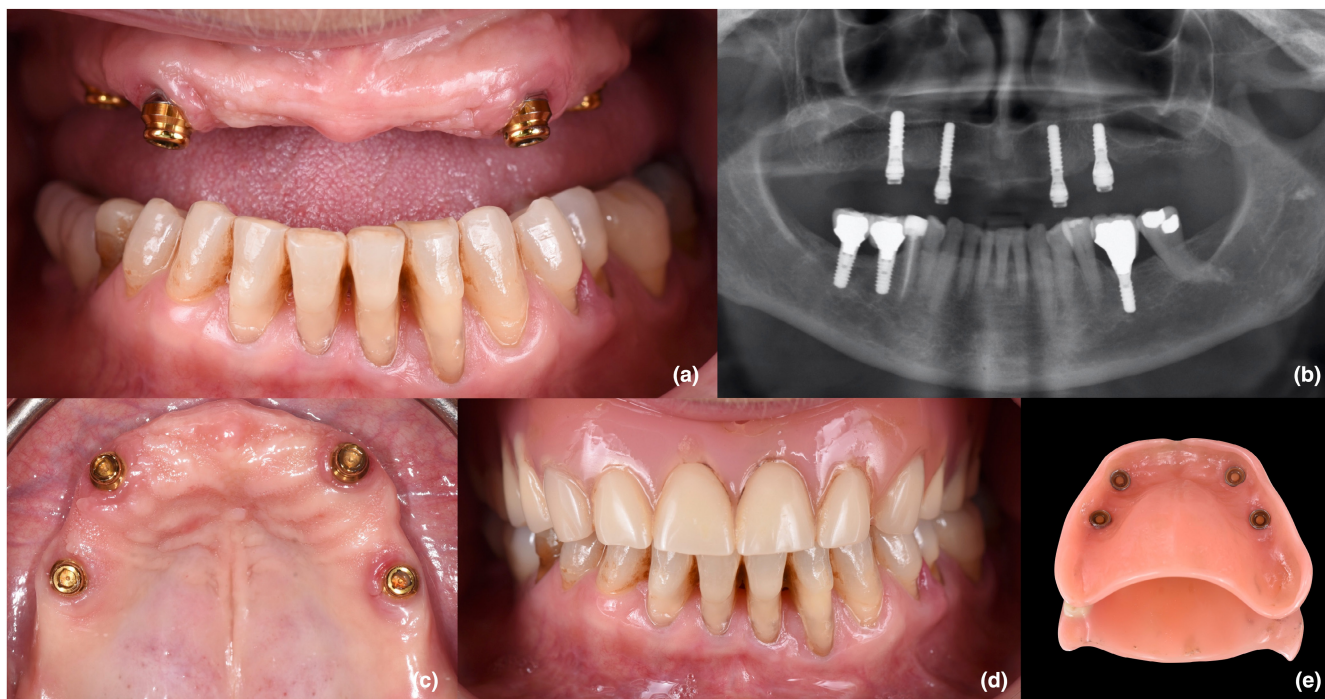


FIGURE 4 Distribution of patient satisfaction, total score and sub-scores before implant placement (baseline) and at 1 year, 3 years and 5 years after abutment connections. Means and standard errors (SE) are reported at each time point. A green point indicates a significant change since baseline, a red one indicates that the change is no more significant, and if all points are black, there is no significant evolution of the parameter.

prosthesis modification related to an implant loss occurring more than once in 5 years was also considered as an adverse event and negatively influenced the mean annual repairs.

Compared with other attachment systems, the current scientific evidence is limited in establishing the superiority of one attachment system in terms of prosthodontic success or maintenance (Ghiasi et al., 2021; Stafford, 2019).

4.2 | Implant outcomes

Most of the implant failures occurred during the first year (16 implants –13.8%), and five implants additional implants were lost from 1 to 5 years leading to an implant failure rate of 19.4% (implant level) in 40% of the patients. In a recent systematic review on maxillary overdenture supported by implants, the overall implant failure rate yielded 6% in 14.8% of the patients after a mean period of 21.4 ± 26.0 (range: 0.5–247) months (Ghiasi et al., 2021). When considering the studies with a minimum follow-up of 5 years to assess the implant outcomes of IOD supported by four unsplinted implants, only few retrospective studies were found and report implant survival rates varying from 81.4%–98.7% (Frisch et al., 2015; Lian et al., 2019; Wang et al., 2016). The results observed in the present prospective study are less conclusive with an implant survival rate of 80.6% at 5 years. However, it should be taken into consideration that the surgical/loading approach and the antagonist configuration were different from the previously reported study. Indeed, a submerged implant healing (Lian et al., 2019) or a restriction to wear the denture post-operatively (Wang et al., 2016) may have influenced the results. Moreover, the relatively low implant survival rate found at 5 years in the present study may be attributed to the natural teeth or fixed rehabilitation opposing dentition in all included patients, which may impact the biomechanical stress over the implants. In fact, a greater masticatory force, harmful lateral forces to implants or occlusal contact between the implant and antagonist teeth while the denture is removed (Ohkubo & Baek, 2010) might explain this relatively low implant survival rate at 5 years of follow-up.

Additionally, several systematic reviews have proposed that implants supporting maxillary overdentures should be splinted to ensure a biomechanical advantage, enable better force balance, provide cross-arch stabilization, and avoid potential overloading of single implants (di Francesco, de Marco, Gironi Carnevale, et al., 2019; di Francesco, de Marco, Sommella, & Lanza, 2019; Raghoebar et al., 2014; Slot et al., 2010). Therefore, splinting four implants with a bar may improve implant survival (Doornewaard et al., 2021) and this configuration may be relevant with a natural antagonist, as suggested by several authors (di Francesco, de Marco, Sommella, & Lanza, 2019; Slot et al., 2014). However, the use of a bar involves a certain cost compared with solitary attachment and, in some cases, the available vertical dimension of occlusion (VDO) does not allow enough space for a bar. Moreover, with bars, the implant replacement in cases of failure is more complex than with solitary

attachment, because it basically compromises the overall rehabilitation. Indeed, in the present study, the failing implants were replaced 3 months after their removal, and the reconnection to the removable prosthesis was made easily (Bouhy et al., 2020).

As previously suggested by Chrcanovic and co-workers, although it is very likely that the alveolar bone demonstrates a different degree of tolerance depending on the individual, the location and other anatomic and physiological parameters, it is challenging for clinical studies to demonstrate a possible correlation between occlusal overload and implant failures (Chrcanovic et al., 2017).

Moreover, in a recent systematic review on four implant supporting a maxillary overdenture, no statistical difference was detected in the survival rate of implants between the splinted implant group and the unsplinted implant group ($p = .1$). The issue of splinting or not splinting four implants supporting a maxillary overdenture still requires further investigation. (di Francesco, de Marco, Sommella, & Lanza, 2019). This finding has also been corroborated by the results of other systematic studies (Leão et al., 2018; Raghoebar et al., 2014; Sadowsky, 2007; Sadowsky & Zitzmann, 2016; Stoumpis & Kohal, 2011).

4.3 | Patient-reported outcome measures

The OHIP results improved significantly from baseline (49.2 ± 17.3) to 1 year (28.7 ± 7.21), but at 5 years the improvement in quality of life was no longer significant (39.0 ± 18.3). The decrease in OHRQoL from baseline to 5 years may be attributed to the biological and prosthetic complications or maintenance events encountered during the follow-up. For example, locator attachments regularly require matrix activation and although these maintenance costs are minimal, they may affect OHRQoL as already suggested by some authors (Matthys et al., 2019; Zembic et al., 2019). The same idea goes for implant failures or late biological problems, which may only be noticeable after long-term observation (Sharka et al., 2019). There are only few studies looking at the OHIP-20 questionnaire values for a period longer than 1 year. Even though there were no significant differences from baseline, Zembic and co-workers reported OHIP-20 improvement with maxillary IODs supported by two implants at 1 and 4 years, especially in the physical, psychological and social disability and handicap domains. Despite the difference in terms of implant number, these results are roughly in line with the present study (Zembic et al., 2019).

On the contrary, when looking at the patient satisfaction, the results improved from baseline to 1 year and remained stable. María Martínez-González et al. (2013) also reported that patient satisfaction after completion of treatment could be maintained in the long term, regardless of the mode of rehabilitation whether it is an implant-supported fixed denture or an IOD (María Martínez-González et al., 2013).

As already suggested by some authors (Yao et al., 2018), these controversial PROMS results may relate to the fact that these two measurements (OHIP-20 and VAS patient satisfaction) highlight

different outcomes. Satisfaction is perceived as a simple and comprehensible instrument that tend to be more understandable for both patients and clinicians. By contrast, OHRQoL is usually measured with multidimensional variables and the concept behind it might not always be clear for patients and clinicians. According to systematic reviews, the improvement of OHRQoL (measuring by OHIP) is usually inferior to patient satisfaction measures and the correlation coefficients between these two parameters were moderate (Allen et al., 2001; Yao et al., 2018).

4.4 | Limitations

Despite the relevance of the five-year prospective data, the present study suffers from several limitations that need to be highlighted.

The criteria to define the prosthodontic complications directly affecting the prosthodontic success rates versus routine maintenance events are very heterogenic in the literature and therefore the comparison of the present results with the existing literature should be interpreted cautiously. This also indicates the great need for further standardization to evaluate prosthodontics outcomes and maintenance events in this field of research, as already suggested by some authors (Ghiasi et al., 2021). Additionally, regarding the study design, criteria to change the nylon insert were not predefined and was left to the appreciation of the prosthodontist or based on patient demands, and this may have influenced the results.

Finally, PROMs must be interpreted carefully because the patients were obviously not blinded. Although the patients filled out the baseline questionnaires before being informed about the study details, a possible bias on patient-reported outcomes cannot be fully excluded. On the contrary, the within-patient study design may attenuate this limitation (Abu Hantash et al., 2006; Siadat et al., 2008).

5 | CONCLUSIONS

Within the limit of the present study, a substantial number of prosthetic complications and replacements occurred in the maxillary implant-retained removable dentures investigated in this study over a 5-year follow-up period. These may be attributed to the nature of the antagonist or to the clinical methodology. After 5 years the OHIP-20 deteriorated and reached again the baseline level. Nonetheless, the VAS results suggest significantly increased patient satisfaction after implant-supported retention was provided for the removable prostheses.

AUTHOR CONTRIBUTIONS

Alice BOUHY: Data curation (equal); investigation (equal); methodology (equal); writing – original draft (equal). **Marc Lamy:** Supervision (equal). **Yaman Altaep:** Investigation (supporting). **France Emmanuelle Lambert:** Conceptualization (equal); funding acquisition (equal); investigation (equal); methodology (equal); project

administration (equal); supervision (equal); validation (equal); writing – review and editing (equal).

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

Research data are not shared due to privacy or ethical restrictions.

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