Int. J. Oral Maxillofac. Surg. 2019; xxx: xxx–xxx
https://doi.org/10.1016/j.ijom.2021.05.015, available online at https://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Clinical Paper
Pre-Implant Surgery

Patient- and clinician-reported outcomes for the additively manufactured sub-periosteal jaw implant (AMSJI) in the maxilla: a prospective multicentre one-year follow-up study

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C. Van den Borre, M. Rinaldi, B. De Neef, N. A. J. Loomans, E. Nout, L. Van Doorne, I. Naert, C. Politis, H. Schouten, G. Klomp, L. Beckers, M. M. Freilich, M. Y. Mommaerts: Patient- and clinician-reported outcomes for the additively manufactured sub-periosteal jaw implant (AMSJI) in the maxilla: a prospective multicentre one-year follow-up study. Int. J. Oral Maxillofac. Surg. 2019; xxx: xxx–xxx. © 2021 Published by Elsevier Inc. on behalf of International Association of Oral and Maxillofacial Surgeons.

Abstract. The clinical outcomes of maxillary rehabilitation with the additively manufactured sub-periosteal jaw implant (AMSJI; CADskills BV) were evaluated in edentulous patients with a Cawood–Howell atrophy classification ≥5 in all regions of the maxilla. Fifteen consecutive patients were included in the study and followed up for 1 year. They were interviewed using a survey protocol and were examined clinically and radiographically preoperatively (T0) and at 1 (T1), 6 (T2), and 12 (T3) months after permanent upper prosthesis placement. The patients reported an increased oral health-related quality of life. The overall mean Oral Health Impact Profile-14 score at T0 was 17.20 (standard deviation (SD) 6.42). When results at T0 were compared to those at T1 (mean 8.93, SD 5.30), a statistically significant difference was seen ($P = 0.001$). At T3, the mean value was 5.80 (SD 4.18). Compared to T0, there was also a statistically significant difference at T3 ($P = 0.001$). General satisfaction based on the numerical rating scale was a

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mean 49.93 at T1, which was less than patient expectation prior to treatment at T0 (52.13). A higher overall value was seen at T3 (53.20) when compared to T0. Within the constraints of the short follow-up, the AMSJI appears to be a promising tool for patients with extreme jaw atrophy. The high patient expectations were met without complications.

Key words: maxilla; edentulous jaw; sub-periosteal implantation; alveolar bone loss; patient satisfaction.

Accepted for publication 19 May 2021

An implant-retained prosthesis is a commonly used treatment option in the rehabilitation of edentulous patients[1]. Advanced resorption of the jawbone may occur, particularly in the maxilla, resulting in insufficient bone width and/or height to allow the placement of endosseous implants.

These patients have traditionally very few rehabilitation options, each associated with risks[2,3]. The additively manufactured sub-periosteal jaw implant (AMSJI; CADskills BV, Ghent, Belgium) is a contemporary new alternative[4] (Fig. 1). The AMSJI revisits the almost 80-year-old concept of sub-periosteal implants and uses the midfacial pillars for fixation with osteosynthesis screws. These pillars do not undergo marked atrophy, and their sufficient thickness ensures primary stability to support the endoprosthesis and exoprosthesis. With the earlier proof-of-concept of the AMSJI[5], this made-to-measure option provides immediate functional restoration within one intervention.

The efficacy of the AMSJI needs to be proven in long-term prospective registries or observational studies. The aim of this study was to evaluate the clinical efficacy of the maxillary AMSJI treatment protocol after 1 year.

Patients and methods

A multicentre study was conducted by the International Workgroup on AMSJI. Fifteen Belgian, Dutch, and Italian patients participated and were followed up for 1 year after instalment of the permanent restoration. The inclusion criteria were as follows: all consecutive patients who underwent bilateral AMSJI placement in the maxilla and who themselves and their surgeon agreed to collaborate in the study before their inclusion.

Placement of the AMSJI was performed under local or general anaesthesia based on the technique described by Mommaerts in 2017[4]. After the surgery, a temporary additively manufactured NextDent prosthesis was positioned in proper occlusion with the lower dental arch. The definitive restoration was constructed 2 months later[4].

Data collection

Evaluations were performed preoperatively (T0), and at 1 (T1), 6 (T2), and 12 (T3) months after prosthesis installation. A prospective data collection form comprising three sections was used (Supplementary Material). All of the surveys were anonymized using a patient code.

The first section collected general information including the Cawood–Howell grade of atrophy, details of comorbidities, the time of implantation, and general information concerning the surgery.

The second section collected objective data (clinical and radiological) and was completed by the surgeon at fixed intervals. At T0, a check was performed for sinusitis according to the Lanza–Kennedy staging[6] and radiological sinusitis according to the Lund–Mackay computed tomography (CT) staging[7]. The degree of comfort experienced by the patient with their prosthesis (discomfort, speech, and hindrance in maintaining good oral hygiene) was recorded as well. The stability of the endoprosthesis after unmounting the exoprosthesis (overdenture with connecting bar or hybrid fixed full prosthesis) from both the left and right AMSJIs was also evaluated (T1, T2, and T3). The health of the keratinized mucosa around the different posts of the endoprosthesis was also studied over time. Fig. 1 gives

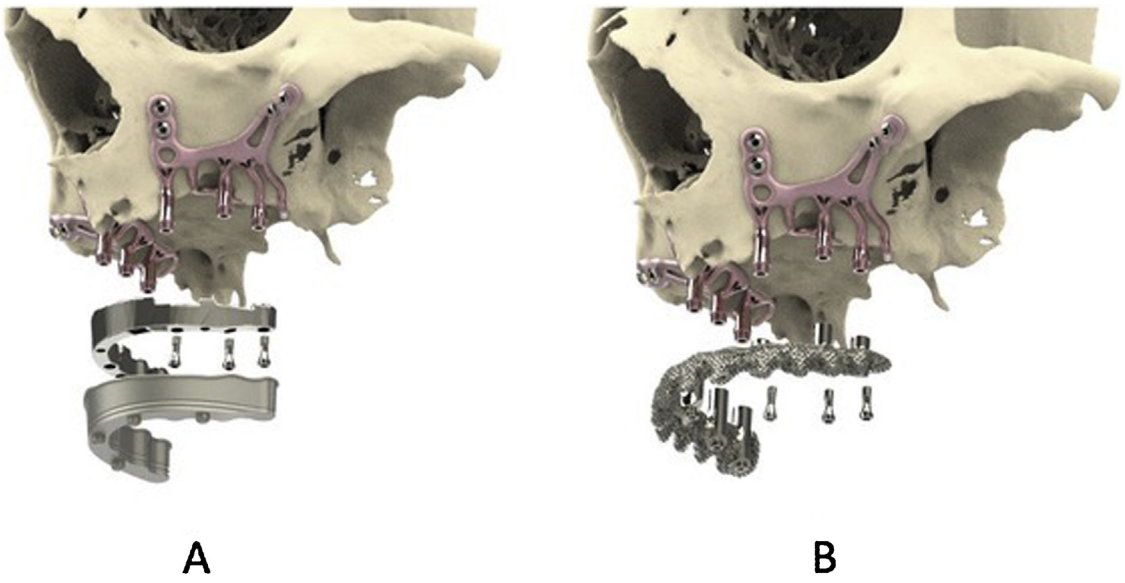

Fig. 1. The AMSJI with double structure (A) and hybrid bridge (B) suprastructure options.

more information concerning the locations of the posts. Complications such as infection, pain, fracture of a post, or the need for urgent removal of any AMSJI or post were recorded as well.

The third section collected subjective data in the form of patient-reported outcome measures (PROMs). These were also collected at T0, T1, T2, and T3. Patients were interviewed using the short form of the Oral Health Impact Profile-14 (OHIP-14)[8], which comprises 14 questions covering functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicaps. Patient satisfaction was also assessed using numerical rating scales (NRS)[9]; six questions were asked, covering aesthetic benefit, chewing, comfort, phonetics, cleaning, and general satisfaction. At T0, the patient's expectation of the treatment outcome was tested. The result was than compared to those obtained after AMSJI installation at T1, T2, and T3.

Interpretation of the objective data

Most of the objective data (Supplementary Material, second section) were collected using a dichotomous table with assigned values of 0 or 1, with 1 being the total score and representing the presence of any sinusitis (radiological and/or clinical) or mobility. The mobility of each AMSJI was tested manually by the clinician after unscrewing the final restoration. The condition of the tissue around the posts (peri-post tissue condition) was the only exception. This was graded using a four-point scale ranging from 0 to 3: 0, no inflammation; 1, slight colour change and oedema; 2, redness/glazing; 3, marked redness/inflammation/ulceration.

Interpretation of the subjective data

Each question of the OHIP-14 was scored using a five-point scale: 0, never; 1, hardly ever; 2, occasionally; 3, fairly often; 4, very often or every day. The domain scores of the OHIP-14 were obtained by summing the responses to the two corresponding questions, and overall scores were derived by summing the seven domain scores. In total, the score could range from 0 to 56, with domain scores ranging from 0 to 8. The higher the OHIP-14 score, the poorer the oral health-related quality of life (OHRQoL).

The NRS is based on the visual analogue scale (VAS) and aims to quantify characteristics that cannot easily be measured directly. The present study included six questions answered with a NRS on an 11-point scale ranging from '0' representing 'not satisfied at all' to '10' representing 'very satisfied'. A total score was calculated by summing the responses. The total score value could range between 0 and 60, with 60 being the highest possible satisfaction and 0 the very worst.

Statistical analysis

The data were analysed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA) for macOS Mojave. The mean and standard deviation (SD) values were calculated for the OHIP-14 scores. The OHIP-14 scores (overall and domain level) of adjacent stages were compared using the Wilcoxon signed-rank test: T0 compared with T1, T1 compared with T2, T2 compared with T3, and T3 compared with T0 to determine critical time intervals. The NRS scores (overall and for each question) were also compared between the time points using the Wilcoxon signed-rank test.

Results

Eight male patients (mean age 57.38 years, SD 8.70 years) and seven female patients (mean age 62.17 years, SD 3.43 years) were followed up for 1 year after receiving their final (exo)prosthesis. In total, 60 surveys were completed and analysed.

Stability of the endoprosthesis

No mobility of the left or right AMSJI was observed at any time point. The results are presented in Table 1.

Rhinosinusitis

Four patients reported clinical rhinosinusitis according to the Lanza and Kennedy staging[6] at T0 and at T1. However, no aggravation of the clinical symptoms was reported at T2 or T3. Five patients were found to have radiological rhinosinusitis according to the Lund–Mackay CT staging[7] at T0. Four of them were also diagnosed with clinical rhinosinusitis. Both clinical and radiological rhinosinusitis appeared to disappear over time, with one patient reporting sinusitis at T2 and no patients reporting problems at T3. The results are presented in Table 2.

Reported complication(s)

No complications were reported at any time point, and no post had to be removed because of inflammation, infection, or fracture.

Peri-post tissue condition

The peri-post tissue condition was measured and analysed based on the four-point scale described above. Mean values were calculated for each post at each time point and these are presented in Table 3. Generally, colour changes and oedema were observed at T1, with reported mean values ranging between 0.00 and 0.53. Posts 3 and 4 were more prone to inflammation at T1, T2, and T3 (Fig. 2).

Oral Health Impact Profile-14 results

The overall OHIP-14 score was calculated to provide a general representation at the set time points. A mean value of 17.20 (SD

Table 1. Stability of the endoprosthesis.

Time point	No mobility, *n*	Mobility (>0 mm), *n*
T1	30	0
T2	30	0
T3	30	0

Mobility reported per unilateral AMSJI ($n = 30$). T1, 1 month after prosthesis installation; T2, 6 months after prosthesis installation; T3, 12 months after prosthesis installation.

Table 2. Clinical and radiological rhinosinusitis.

Time point	Clinical rhinosinusitis		Radiological rhinosinusitis	
	Present	Not present	Present	Not present
T0	4	11	5	10
T1	4	11	4	11
T2	1	14	1	14
T3	0	15	0	15

The presence and/or absence of rhinosinusitis (clinical and radiological) at the different time points. T0, preoperatively; T1, 1 month after prosthesis installation; T2, 6 months after prosthesis installation; T3, 12 months after prosthesis installation.

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Table 3. Peri-post tissue condition at each time point: mean scores on a four-point scale.

Post of the endoprosthesis[a]	T1	T2	T3
1	-	-	-
2	0.40	0.40	0.13
3	0.53	0.53	0.40
4	0.67	0.47	0.27
5	0.33	0.27	0.13
6	0.27	0.27	0.13
7	0.33	0.13	0.07
8	-	-	-

The mean values of the peri-post tissue condition were calculated for each post at each time point. T1, 1 month after prosthesis installation; T2, 6 months after prosthesis installation; T3, 12 months after prosthesis installation. At T1, posts 2 to 7 all showed minor inflammation. This improved, but some redness was still seen at T3 around posts 3 and 4.

[a] All patients had an AMSJI designed with six posts (posts 2–7). For this reason, no values could be calculated for posts 1 and 8.

Numerical rating scale results

The NRS questions were presented to all patients at T0, T1, T2, and T3. The patients initially reported a high expectancy of the AMSJI, with a mean score of 52.13 (SD 6.24). At T1, the mean score was 49.93 (SD 4.54). The NRS score increased to 51.20 (SD 3.80) at T2 and 53.20 (SD 3.41) at T3 (Table 6). The *P*-values for the comparisons of NRS values between the different time points are reported in Table 7. The mean overall NRS score for all patients at each time point is visually represented in Fig. 4.

Discussion

Adequate dental articulation is crucial for good quality of life and well-being[10]. Despite many advances in preventive dentistry, edentulism remains a major public health issue worldwide. One of the main problems with losing teeth is the effect on the alveolar process. The alveolar ridge of

6.42) was calculated at T0, 8.93 (SD 5.30) at T1 (P = 0.001 compared to T0), 7.80 (SD 4.96) at T2, and 5.80 (SD 4.18) at T3 (P = 0.001 compared to T0) (Tables 4 and 5). The *P*-values for the comparisons of OHIP-14 values between the different time points are reported in Table 5. At each successive postoperative time point, the mean score rating decreased, indicating a higher OHRQoL. Each domain was also evaluated separately (Tables 4 and 5). The mean overall OHIP-14 score for all patients at each time point is visually represented in Fig. 3.

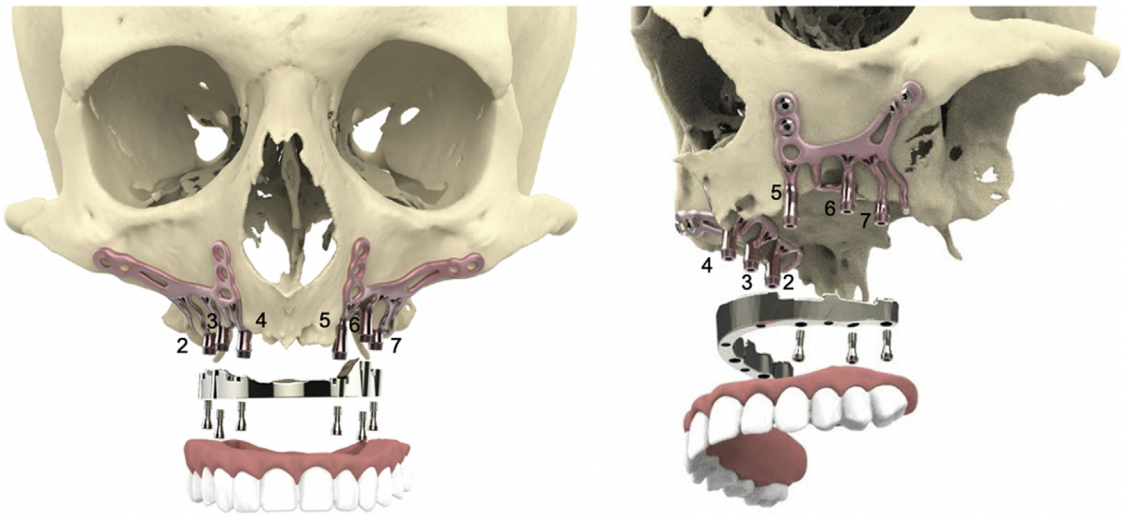

Fig. 2. Left and right AMSJI (endoprosthesis) in frontal and side views, with the numbered posts, the connecting bar structure, and the overdenture (exoprosthesis).

Table 4. Results of the Oral Health Impact Profile-14 (OHIP-14) at the different time points.

	T0		T1		T2		T3	
Domain	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Overall OHIP-14	17.20	6.42	8.93	5.30	7.80	4.96	5.80	4.18
1. Functional limitation	2.80	1.52	2.00	1.36	1.53	1.19	1.20	1.08
2. Physical pain	3.27	1.52	2.07	1.44	1.53	1.19	1.20	1.01
3. Psychological discomfort	1.73	2.19	0.93	1.22	1.13	1.25	0.73	1.10
4. Physical discomfort	3.33	2.16	1.80	1.66	1.47	1.51	1.07	0.96
5. Psychological disability	2.53	1.96	1.00	1.07	1.00	0.85	0.73	0.80
6. Social disability	2.20	1.90	0.47	0.92	0.47	0.83	0.53	0.92
7. Handicap	1.33	1.63	0.67	0.98	0.67	0.98	0.33	0.72

SD, standard deviation; T0, preoperatively; T1, 1 month after prosthesis installation; T2, 6 months after prosthesis installation; T3, 12 months after prosthesis installation. The table reports the overall general values of the OHIP-14 and the values for each domain. At T0, OHIP-14 values were high, with a mean value of 17.20. This value decreased over time, with a mean value of 5.80 at T3, meaning a very high level of satisfaction.

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Table 5. Significance of differences in Oral Health Impact Profile-14 (OHIP-14) values between the different time points.

Domain	T0 to T1 *P*-value	T1 to T2 *P*-value	T2 to T3 *P*-value	T0 to T3 *P*-value
Overall OHIP-14	0.001*	0.117	0.005*	0.001*
1. Functional limitation	0.290	0.121	0.260	0.018*
2. Physical pain	0.044*	0.023*	0.096	0.002*
3. Psychological discomfort	0.084	0.257	0.034*	0.071
4. Physical discomfort	0.004*	0.160	0.161	0.002*
5. Psychological disability	0.017*	1.000	0.157	0.004*
6. Social disability	0.005*	1.000	0.705	0.007*
7. Handicap	0.015*	1.000	0.059	0.028*

T0, preoperatively; T1, 1 month after prosthesis installation; T2, 6 months after prosthesis installation; T3, 12 months after prosthesis installation. Statistical analysis: Wilcoxon signed-rank test; IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA) for macOS Mojave.

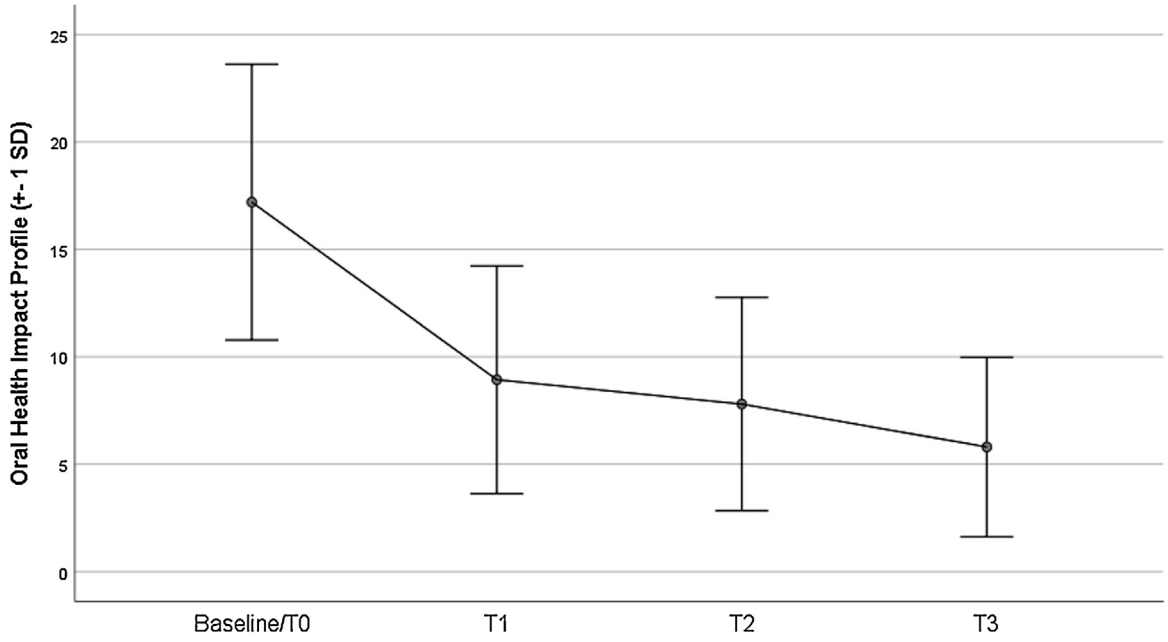

Fig. 3. Visual representation of the mean overall OHIP-14 score for all patients at each time point.

patients who remain edentulous for a long time will become vestigial as a result of bone resorption[1]. Continuous resorption may result in ill-fitting dentures requiring several relining sessions and denture adhesives in an attempt to improve stability during masticatory function and speech.

Patients with extreme jaw atrophy have limited options concerning oral rehabilitation. Autogenous bone transplantation for the augmentation of the alveolar ridge remains a frequently used method. Mostly, calvarial or iliac bone is used in patients with severe to extreme

Table 6. Results of the numerical rating scale (NRS) for patient satisfaction at the different time points.

	T0		T1		T2		T3	
Question	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Overall NRS	52.13	6.24	49.93	4.54	51.20	3.80	53.20	3.41
1 (aesthetic benefit)	8.67	1.11	8.27	0.96	8.53	0.74	9.00	0.65
2 (chewing)	8.60	1.18	8.00	1.36	8.53	0.64	8.93	0.88
3 (comfort)	8.60	1.18	8.60	0.91	8.87	0.64	8.67	1.45
4 (phonetics)	8.60	1.18	8.13	0.99	8.33	0.90	8.67	0.82
5 (cleaning)	8.67	1.23	8.27	1.10	8.27	1.03	8.73	0.88
6 (general satisfaction)	9.00	0.93	8.67	0.90	8.67	0.72	9.20	0.41

SD, standard deviation; T0, preoperatively; T1, 1 month after prosthesis installation; T2, 6 months after prosthesis installation; T3, 12 months after prosthesis installation. The mean values for each time point are given. The mean overall NRS value decreased from T0 to T1. However, at T2 the mean value was almost the same as that at T0. T3 showed an even higher mean patient satisfaction value. Mean values are also given for each question separately.

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Table 7. Significance of differences in the mean numerical rating scale (NRS) values for patient satisfaction between the different time points.

Question	T0 to T1 *P*-value	T1 to T2 *P*-value	T2 to T3 *P*-value	T0 to T3 *P*-value
Overall NRS	0.172	0.208	0.050*	0.569
1 (aesthetic benefit)	0.163	0.206	0.008*	0.190
2 (chewing)	0.117	0.167	0.109	0.403
3 (comfort)	0.666	0.340	1.000	0.564
4 (phonetics)	0.208	0.366	0.132	0.856
5 (cleaning)	0.271	0.862	0.083	0.917
6 (general satisfaction)	0.132	1.000	0.0050*	0.439

T0, preoperatively; T1, 1 month after prosthesis installation; T2, 6 months after prosthesis installation; T3, 12 months after prosthesis installation. Statistical analysis: Wilcoxon signed-rank test; IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA) for macOS Mojave.

atrophy[10]. Wortmann et al. evaluated patient satisfaction for both calvarial and iliac bone grafts in 20 patients with a bone height of <3 mm in the maxillary sinus area and a bone width of <2 mm in the anterior maxillary area[11]. A mean VAS score of 93 (out of 100) was achieved for all participants at 12 months after the instalment of their implant-retained maxillary overdenture. The mean OHIP-49NL was 78.80 preoperatively and decreased to 16.00 after treatment. Patient satisfaction with the AMSJI rivals the mean satisfaction value of autologous bone augmentation procedures and has the additional benefit of providing comprehensive reconstructive therapy in only one surgical intervention. Harvesting extraoral bone grafts requires an additional surgery under general anaesthesia, carrying the risk of complications and adverse effects. Although Wortmann et al. reported high satisfaction, several patients reported postoperative infection at the donor site, scar formation, and loss of sensitivity, and three patients reported problems with walking after 1 year[11]. All 15 AMSJI patients in the present study remained complication free at 12 months. Furthermore, the patients did not have to undergo extra implant placement, and immediate mastication was provided.

As another alternative, the flapless placement of mini dental implants with overdenture treatment could be suggested. However, in cases with a high degree of resorption of the maxilla, not even this type of implant can be placed due to a lack of bone. Moreover, several publications have reported high failure rates, especially in the maxilla. This treatment is therefore aimed particularly at medically and financially compromised patients[12,13].

Zygomatic implants may be used as an alternative to bone grafts. Studies have shown that they are more predictable than alveolar crest augmentation techniques using autologous bone[14]. With a clinical survival rate as high as 96.7% (after 36 months of follow-up), zygomatic implants have proven their value in the past[14]; however, the success rate has been far less described. If mentioned, success was frequently based on scientific evidence found by researchers and not on the patient's perspective. The few studies that have analysed quality of life have not mentioned any grade of atrophy of the maxilla[14,15]. Only subjective classification using 'severe' and 'major' atrophy have been reported to justify the placement of zygoma implants, and thus the conclusions must be interpreted with significant caution. While the use of zygoma implants may be considered for the treatment of the severely resorbed maxilla, the known risks and complications associated with this approach cannot be ignored. Severe rhinosinusitis, infection, and fistula formation may arise, gravely affecting the oral health condition[16]. Zygoma implants should only be placed by well-trained clinicians with extensive experience. When complications arise, zygoma implants can be very difficult to remove and such removals are often accompanied by the loss of a significant amount of bone[15]. The latter effect could further compromise

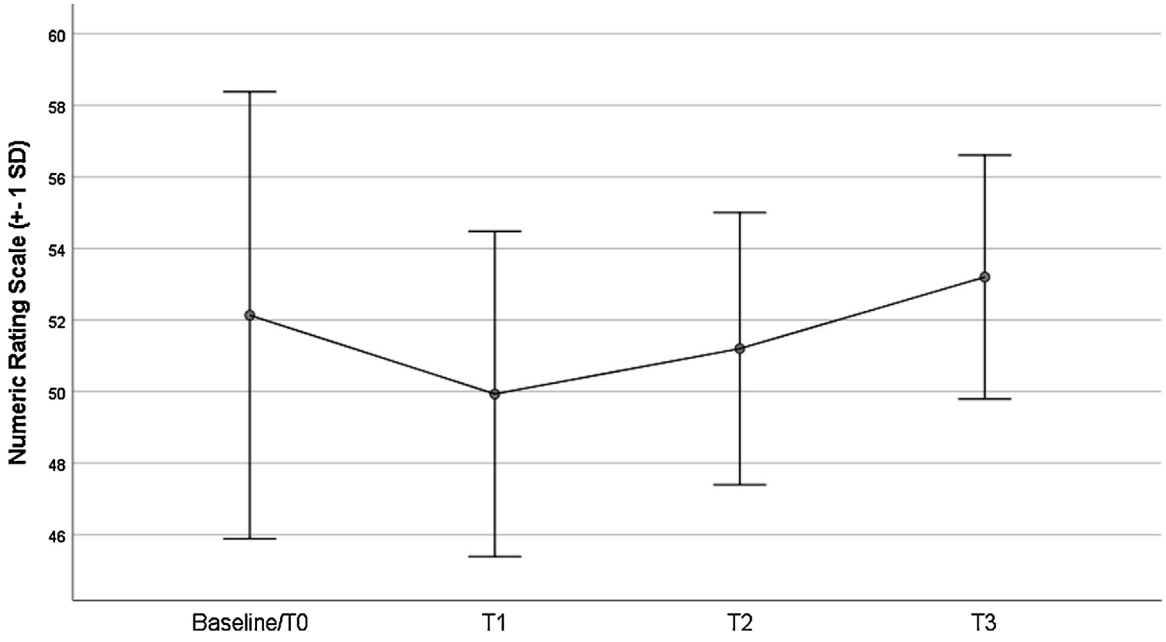

Fig. 4. Visual representation of the mean overall numerical rating scale score for all patients at each time point.

the patient's health because of the already low volume of bone in the maxilla. Zygomatic implant placement should always be regarded as a major surgical procedure. Furthermore, if removed, the installation can never be reused.

Regarding the AMSJI, a few fail-safes are built into the design[4]. Certain areas are specifically designed to be weak, facilitating cutting if any of the four arms should show any complication for which removal is necessary. If complete removal of the AMSJI is indicated, a replica can be three-dimensionally printed because the STL files are permanently stored in the database.

Patient satisfaction with the AMSJI rivals the mean satisfaction value of autologous bone augmentation procedures. Compared with AMSJI surgery, however, bony reconstruction of the atrophic maxillary crest entails a number of drawbacks, often not fully commented upon in the literature[17]. The anterior iliac crest and the calvaria are preferred regions for harvesting[18]. Usually, the anterior and premolar zone of the maxilla are broadened with the harvested bone, whilst in the molar zone, sinus floor augmentation is performed[19]. Often, two to three surgical procedures are required, the first being bone harvesting and transplantation and the second being implant placement, with the variable need for a third minor surgery for exposure of the submerged staged implants. Circular bone augmentation necessitates general anaesthesia entailing two operative sites including their potential complications[11,18,20]. Early resorption may result in an unaesthetic and difficult to clean 'stilt house' in the anterior and premolar zone[21,22]. Torres et al. reported bone grafting success of 76% following iliac and calvarial bone augmentation in the anterior zone, from 5 to 15 years[23]. Bone loss or resorption are more frequently observed in horizontal augmentations than in vertical augmentations of localized defects[24]. Marginal bone loss increases over a period of 10 years before reaching a stable value[23]. Results are superior in the molar zone with sinus augmentation[25] and with calvarial bone as compared to iliac crest bone (11% vs 33% vertical resorption after 19 months on average in mixed mandible and maxillary crestal augmentations). Complications of crestal augmentation (partial and total dehiscence, graft loss) in the anterior zone are to be feared[26–28]. Schneiderian membrane perforation, as well as acute, chronic, and late-onset sinusitis are feared complications with sinus floor augmentation[29,30].

The provision of conventional endosseous implant therapy, which requires the scope of graft procedures and surgical staging as discussed, usually necessitates that the patient not wear a denture for a considerable period of time, resulting in compromised masticatory function. In some cases, a cemented provisional prosthesis may be placed on provisional implants during the bone healing phase, but this may be limited by the availability of bone[12]. In contrast, the AMSJI can readily be placed in the private clinic, and in medically comprised and/or elderly patients, without having to resort to a hospital, decreasing the burden for society (depending on national healthcare systems). In the case of total loss of an AMSJI, none of the anatomical structures have been damaged. The frame can be printed and if the soft tissues are well healed, the AMSJI can be installed again, whilst reusing the existing suprastructure and denture. This would be impossible in treatments that incorporate zygomatic implants or the All-on-Four concept; with these treatments, the anatomy is unfavourably affected, and suprastructures and dentures would have to be manufactured de novo.

Excellent OHIP-14 scores were obtained for the patients who underwent AMSJI placement in this study. Both the mean overall OHIP-14 score and the mean individual domain scores decreased over time, resulting in an overall mean OHIP score of 5.80 (SD 4.18) at 12 months (T3). Dahl et al. reported an OHIP-14 score of 4.1 in the Norwegian adult population (2441 patients)[31]. That the AMSJI score is only slightly worse in the current study patients could easily be explained by all 15 patients being orally compromised and aware of having very few options for obtaining fixed teeth. Many of them had experienced oral problems in the past, and some had already undergone several surgeries for oral rehabilitation. Their satisfaction with obtaining fixed dentures at the completion of their treatment directly impacted their perceived oral health condition and this explains why they reported a good OHRQoL.

Some patients might have had inaccurate pre-treatment perceptions concerning the AMSJI. At T0, several patients expected an (almost) perfect score based on the NRS. Some found it difficult to see their expectations met at T1.

With severe oral compromise, prospective patients must understand that their situation is extremely complex and difficult to manage. Efficient communication is vital to address their desires and perhaps relay some unrealistic expectations. Fortunately, many patients appreciated the AMSJI, as demonstrated by the increased NRS scores at T2 and T3 compared with that at T1, in most cases even surpassing the preoperative score.

In conclusion, the AMSJI is a valuable new alternative to treat extreme bone atrophy of the upper jaw.

Funding

None.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Competing interests

Prof. Mommaerts declares that he is innovation consultant at CADskills BV. All other authors report no conflict of interest.

Ethical approval

All procedures in studies involving human participants were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Ethics committee approval was granted on May 5, 2019 (code B.U.N. 143201939806).

Patient consent

Informed consent was obtained from all individual participants included in the study.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijom.2021.05.015.

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Please cite this article in press as: Van C, et al. Patient- and clinician-reported outcomes a prospective multicentre one-year follow-up study, *Int J Oral Maxillofac Surg* (2021), https://doi.org/10.1016/j.ijom.2021.05.015