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Retrospective analyses of additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible

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Abstract:	This multicentre retrospective study aims to evaluate the success rate, adverse events, and patient satisfaction related to additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible. The study includes data from 40 AMSJI® implants placed between 2017 and beginning of 2024 in 19 patients with severe mandibular atrophy (Cawood-Howell classes IV-VII). The results indicate a high level of patient satisfaction, with a survival rate of 92.5% after an average follow-up of 804 days (SD ± 540 days). The primary issue post-operative encountered was immediate post-post operative oedema and temporary infection, which was generally managed with chlorhexidine mouth rinses, antibiotics, and paracetamol. One implant showed increased mobility (movement in any direction greater than 1 mm) at the time of the interview. Two other implants had to be removed due to persistent infection and suppuration, with an additional implant scheduled for removal. Patient satisfaction in general was high at the time of the interview, with an average OHIP-14 score of 6.68 (SD ± 7.99) and a NRS score of 51.26 (SD ± 7.63). Mucosal recession (both buccal and lingual) was observed around 13 implants (32.25%); however, patients did not perceive this as a functional or aesthetic issue. Within the limitations of a short-term follow-up period, AMSJI in the mandible shows promise as an effective option for rehabilitating patients with severe mandibular atrophy. Despite the positive results, longer-term follow-up is necessary to confirm the implant system's durability and performance over time.

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Prof. Dr. Jörg Wiltfang
Editor-in-Chief
Journal of Cranio-Maxillo-Facial
Surgery (JCMS)

November 01, 2024

Dear Prof. Jörg Wiltfang

I am pleased to submit an original research article entitled*:"**Retrospective analyses of additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible**"* for consideration for publication in "*Journal of Cranio-Maxillo-Facial Surgery (JCMS)*". Complete list of authors and their affiliation can be found in appendix 1. More than six authors contributed and made a substantial contribution to the article.

Patients suffering from advanced jawbone resorption may have limited options for oral rehabilitations. This manuscript expands on the prior research conducted by Mommaerts (2017 and 2019) and published by "International Journal of Oral and Maxillofacial surgery". These papers first described the additively manufactured subperiosteal jaw implant (AMSJI) as a contemporary "high tech" alternative for patients suffering with extreme atrophy.

This multicentre retrospective study aims to evaluate the success rate, adverse events, and patient satisfaction related to additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible. We believe this manuscript is appropriate for publication by JCMFS because despite many innovations and advances in preventive dentistry, edentulism remains a major worldwide public health issue. With its efficacy proven in the past (Mommaerts 2019), AMSJI can help patients who need oral rehabilitation.

This manuscript has not been published and is not under consideration for publication elsewhere.

The authors received no financial support for the research, authorship, and/or publication of this article. We do declare that Prof. Mommaerts is innovation consultant at CADskills BV. All other authors report no conflict of interest. All authors have approved of and have agreed to submit the manuscript to JCMS.

We would also like to state that all raw data can be made public of you so desire.

Thank you for your consideration!

Sincerely,

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Appendix 2: references

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Retrospective analyses of additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible

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Abstract

This multicentre retrospective study aims to evaluate the success rate, adverse events, and patient satisfaction related to additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible. The study includes data from 40 AMSJI® implants placed between 2017 and beginning of 2024 in 19 patients with severe mandibular atrophy (Cawood-Howell classes IV-VII). The results indicate a high level of patient satisfaction, with a survival rate of 92.5 % after an average follow-up of 804 days (SD ± 540 days). The primary issue post-operative encountered was immediate post-post operative oedema and temporary infection, which was generally managed with chlorhexidine mouth rinses, antibiotics, and paracetamol. One implant showed increased mobility (movement in any direction greater than 1 mm) at the time of the interview. Two other implants had to be removed due to persistent infection and suppuration, with an additional implant scheduled for removal. Patient satisfaction in general was high at the time of the interview, with an average OHIP-14 score of 6.68 (SD ± 7.99) and a NRS score of 51.26 (SD ± 7.63). Mucosal recession (both buccal and lingual) was observed around 13 implants (32.25%); however, patients did not perceive this as a functional or aesthetic issue.

Within the limitations of a short-term follow-up period, AMSJI in the mandible shows promise as an effective option for rehabilitating patients with severe mandibular atrophy. Despite the positive results, longer-term follow-up is necessary to confirm the implant system's durability and performance over time.

Keywords: Alveolar bone loss; Subperiosteal dental implantation; Patient satisfaction

Introduction

Restoring masticatory function in patients with a severely atrophied mandible (Cawood IV-VIII) has consistently presented a significant challenge (Cawood and Howell, 1988). To improve the retention of removable lower dentures, various preprosthetic surgical techniques (soft tissue management and bone augmentation) have been utilized (Obwegeser, 1977; Stoelinga et al., 1986, Bell et al., 2002; Cawood and Stoelinga, 2005) . However, these methods have inherent limitations and may lead to considerable patient morbidity (Nkenke and Neukam, 2014). Non-titanium, double staged subperiosteal implants have provided an alternative treatment modality (Dahl, 1957). Although reliable results were published by Bodine in 1974, several factors have contributed to the declining use of lost-wax casted chrome-cobalt-molybdenum (CrCoMo) subperiosteal implants. These implants demonstrate minor osseointegration and soft tissue integration capabilities due to the alloy's limited bioactivity. While CrCoMo is biocompatible and not toxic to surrounding tissues, it lacks the bioactivity needed to actively interact with bone and soft tissue in a way that stimulates or encourages growth. In contrast, materials like titanium oxide on titanium implants promote superior integration due to their favorable bioactive properties. Additionally, the CrCoMo frame utilized in subperiosteal implants is prone to hypersensitivity reactions (type IV) and stress shielding (Linkow and Ghalili, 1998). These factors could lead to early and late implant exposure, bone resorption, discomfort, infection, fistula formation and ultimately implant and prosthetic failures.

Today, single-stage, additively manufactured titanium subperiosteal implants—specifically AMSJI®, the first of this kind—are regaining popularity due to advancements in technology, materials, digital medicine and dentistry, clinical expertise and increased public awareness of oral hygiene (Fig 1,2 and 3). AMSJI® has shown excellent clinical outcomes in the upper jaw

(Van den Borre et al., 2022, 2023). The aim of this study was to analyze the short to medium-term survival and success rate, adverse effects, and patient satisfaction when the AMSJI® solution is used to provide a fixed lower dental prosthesis.

Patients and Methods

This retrospective multicentre study included patients who underwent AMSJI® placement in the mandible from 2017 till beginning 2024, specifically for severe mandibular atrophy (Cawood-Howell IV or higher) (Mommaerts, 2020). A total of 23 patients treated by 11 surgeons from ten different surgical centers were eligible for inclusion. Four patients were excluded because of the unwillingness of the surgeon or the patient to comply with the study. No other exclusion criteria were applied. Ultimately, 19 patients with a total of 40 AMSJI's were included in the analysis.

Data collection included patient demographics such as age, ASA score, gender, and co-morbidity assessments (e.g., history of radiotherapy, bisphosphonate use) as well as risk factors like smoking (Van den Borre et.al, 2024). Bone atrophy was evaluated using the Cawood-Howell classification. Implant-specific details, including the use of horizontal and vertical ostectomy guides (HOG/VOG) were also documented. Additionally, information about the opposing jaw was recorded noting conditions such as dentate status, AMSJI or other implant retained prostheses, partial removable prosthesis, and other relevant factors.

Post-operative adverse events were systematically classified into three distinct classifications to enable a thorough evaluation of their impact on patient recovery. *Problems* were defined as adverse effects that did not require surgical intervention for resolution, including conditions such as infection, suppuration, pain, and swelling. In contrast, *obstacles* referred to issues that necessitated surgical intervention, such as debridement or removal of posts. Lastly, any unresolved conditions were classified as *complications*, which included severe outcomes like implant fractures or the need for implant removal.

The clinical evaluation included assessments of implant stability and mucosal phenotype. Implant stability was evaluated by checking for mobility after the suprastructure was

removed, with no mobility indicating stability and mobility exceeding 1 mm indicating instability. The mucosal phenotype was determined using a periodontal probe. If the circumference of the probe was visible, it was categorized as thin (score: 0); if not, it was categorized as thick (score: 1). Additionally, mucosal recession and/or exposure of the arms of the frame as well as the height of keratinized mucosa (measured from the junctional epithelium to the mucogingival junction), were documented.

Patient reported outcomes were measured using the OHIP-14 and NRS scales. The OHIP-14 consists of seven domains addressing functional limitations, physical pain, psychological discomfort, and physical, psychological, and social disabilities. Each domain includes two questions scored on a five-point scale: 0, never; 1, almost never; 2, occasionally; 3, often; and 4, very often or every day. Domain scores are calculated by summing the responses to the two questions, with total scores derived from all 14 questions. Scores range from 0 to 56, with domain scores ranging from 0 to 8; a higher OHIP-14 score indicates a poorer oral health-related quality of life (OHRQoL). The NRS, based on the visual analogue scale (VAS), provides insights into aesthetic benefits, chewing, comfort, phonetics, cleaning, and overall satisfaction. This scale consists of six questions rated on an eleven-point scale from 0 for (not at all satisfied) to 10 for (very satisfied). The total score is obtained by summing the responses to all six questions.

Statistical Analysis

The data were analysed using SPSS version 26.0. (IBM, New York, NY, USA) for macOS Big Sur.

Results

This study included 5 males (mean age: 61,40 years, SD ± 13.51 years) and 14 females (mean age: 68.12 years, SD ± 9.68 years), with a mean follow-up period of 804 days post-AMSJI installation (SD ± 540). All patients were ASA I (n = 11) and ASA 2 (n = 8) and had a Cawood-Howell degree of mandibular atrophy of IV (n = 5), V (n = 8), VI (n = 4) and VII (n = 2). Six patients had a dentate opposite jaw. Four had AMSJI-supported fixed dental prostheses. Three had an endosseous implant retained denture and six had removable prostheses. In two patients horizontal/vertical ostectomy guides were used. None of the patients smoked. All patients were edentulous before in the region were planned AMSJI implantation was going to take place (severe mandibular atrophy (Cawood-Howell classes IV-VII). Twelve patients presented with a thick gingival phenotype, and seven with a thin. The mean height of keratinized mucosa was 2.66 and 2.73 mm, respectively. Five patients reported with post-operative problems, all initially treated with antibiotics and mouth rinse. One obstacle (debridement, removal of post(s)) and two true complications were documented (Table 1).

At the time of examination, all but one AMSJI implant was firmly fixed, with mobility exceeding 1 mm after removal of the final restoration. Partial exposure of the arms was observed in 13 AMSJI subunits; however, patients did not perceive this as a functional or aesthetic issue. Only a thin biotype could be indicated as a significant risk factor (p-value <0.001). The final restoration was successful for all patients, with all but one patient using their fixed or removable prostheses in use at the time of consultation.

Total OHIP-14 and NRS were calculated to assess treatment benefits and patient satisfaction yielding a mean OHIP-14 score of 6.68 (SD ± 7.99) and a mean NRS scale value of 51.26 (SD ± 7.63). See table 2 and 3.

Discussion

Edentulous patients, whether partially or fully in the upper or lower jaw, typically have two options for oral rehabilitation. One option is a removable denture, which replaces missing teeth and alveolar bone by depending on the underlying soft tissues and remaining bone for support, retention, and stability. However, prolonged edentulism often leads to significant residual alveolar ridge resorption, resulting in a vestigial alveolar crest. These patients often face issues with ill-fitting dentures, leading to difficulties with chewing, speech, and functional and sensory impairments in the oral mucosa, salivary glands, and musculature. For those seeking a fixed solution (the second option), implant-supported dentures are recommended, relying on endosseous implants placed in the alveolar process or basal bone for support. However, severe residual ridge and even jawbone resorption can result in insufficient bone, making endosseous implant placement impossible. While short, narrow, or tilted implants may help, a minimum bone volume is still needed, excluding patients with extremely atrophied jaws.

Custom-made titanium subperiosteal implants, like AMSJI®, are placed beneath the periosteum and rest on the basal bone (Mommaerts, 2017, 2019). They connect to the prosthesis via per-mucosal extensions (posts). These implants are ideal for patients with insufficient bone, as they eliminate the need for bone grafting. This simplifies surgery, reduces treatment time, and allows for immediate but progressive loading, offering quicker functional and aesthetic improvements compared to delayed protocols. Several authors have confirmed the efficacy of new generation of custom-made, 3D printed subperiosteal implants, reporting positive outcomes in clinical trials and case studies (Van den Borre et. al,

2022,2023; Vaira et. al, 2024; Onică et. al, 2024; Dimitroulis et. al, 2023, Mangano et. al, 2020).

Contemporary additively manufactured subperiosteal implants are gaining prominence, demonstrating promising short- to medium-term outcomes. In a recent systematic review by Anitua et. al, (2024), 13 studies (5 cohort studies and 8 case series) were analyzed, encompassing 227 patients (121 females, 106 males; mean age of 62.42 years) and 227 implants. With a mean follow-up of 21.42 months, the survival rate of these implants was reported at 97.81 %, closely aligning with our findings, where 92.50 % of AMSJI implants remained functional after an average follow-up of 26.41 months (804 days). Anitua et al. also documented 5 true complications (2.20 %) and 12 instances of soft tissue challenges (5.28 %), a comparison that parallels the results observed in our study. Furthermore, Anitua et al. reported that 25.61% of subperiosteal implants exhibited partial exposure. In comparison, we observed soft tissue recession in 13 implants (32.25%). Despite the relatively higher occurrence of tissue recession in our study, this did not appear to adversely impact implant survival in the short to medium term. These findings suggest that while soft tissue complications may arise, they do not necessarily compromise the overall success of the implants within this timeframe. An attached keratinized mucosal zone around the implant shoulder is crucial for endosseous implants, forming a biological seal that protects against pathogenic microorganisms (Thoma et. al, 2022; Ravida et. al, 2022). Without this barrier, the risk of peri-implantitis and failure increases. While only one implant failure occurred in this study, long-term success depends on soft tissue health. Exposure heightens the risk of infection, bone resorption, and failure, making timely interventions like soft tissue grafting or the use of collagen matrices, allografts, or xenografts critical. Future studies should explore these techniques to reduce complications. However, a comparison with endosseous implant-

based prosthetics is not possible, as AMSJI is specifically indicated for cases where endosseous implants are not suitable.

Vaira et al. conducted a retrospectively analyses of patients with posterior mandibular atrophy rehabilitated using custom-made subperiosteal implants. The study included data from 30 implants placed in 17 patients, with an average follow-up of 22.5 months. No infections or implant losses were reported. In 10 cases, the patients reported chewing discomfort immediately after delivery of the provisional prosthesis linked to the conditioning of the gingiva or to the transmission of masticatory forces to the periosteum.

However, 10 patients experienced chewing discomfort immediately after the provisional prosthesis delivery, attributed to gingival conditioning or the transmission of masticatory forces to the periosteum. Notably, none of the implants showed any structural exposure, with 100% of cases scoring 0 for exposure.

A significant distinction between the subperiosteal implants described by Vaira et. al (2023) and the AMSJI system lies in the design and placement of the abutments. Vaira et. al (2023) observed that the abutments of their subperiosteal implants were strategically placed within specially designed recesses in the residual crest to minimize the risk of progressive bone resorption. During the installation process, a small amount of basal bone was removed to facilitate abutment placement, a technique aimed at improving implant stability and preventing mechanical complications, such as screw loosening and soft tissue recession, which could occur due to ongoing resorption. In contrast, Van den Borre et. al, (2021) specifically investigated the effect of AMSJI implants on supporting bone resorption. They reported an average bone remodeling of -0.26 mm (SD 0.65 mm) across six reference points on the residual crest, indicating a minimal negative impact on the surrounding bone.

To combat progressive residual ridge resorption, cutting jigs for vertical and horizontal ostectomies can be employed to proactively remove bone that is susceptible to future resorption (Rinaldi et. al, 2021). This strategy enhances long-term stability and minimizes the risk of implant failure, offering a customized solution for addressing severe atrophy and ensuring lasting clinical success.

This study found tissue biotype to be a highly significant ($P < 0.001$) and independent risk factor for peri-implant recession with no other risk factors identified. This finding aligns with multiple prior studies suggesting that a thin periodontal phenotype can predispose individuals to soft tissue recessions (Claffey and Shanley, 1986; Lin et.al, 2020, Van den Borre. et. al, 2024). Thus, ascertaining the biotype represents a pivotal aspect of the preoperative assessment in patients. In cases where patients exhibit a thin biotype, surgical intervention utilizing soft tissue flaps—either free or pedicled—can facilitate biotype conversion. Lin et al. (2020) validated the efficacy of soft tissue grafting (subepithelial connective tissue graft), demonstrating that approximately a 1 mm increase in tissue thickness can be anticipated postoperatively. Furthermore, alloplastic materials, such as collagen matrices, have been used to increase soft tissue thickness without requiring additional surgical interventions. These materials are strategically placed between the underlying structure and the gingival flap during implant placement, functioning as a comprehensive solution to enhance clinical outcomes (Kim et al., 2018).

The results of this study, alongside those of Vaira et al., indicate that additively manufactured subperiosteal implants may represent a safe and effective solution for rehabilitating severe mandibular atrophy, especially in the posterior regions. However, further validation through larger, prospective studies involving diverse patient populations is necessary. Until such data are obtained, the selection of implant designs should align with the principles of osteosynthesis, osseointegration, and soft tissue integration to optimize clinical outcomes.

Additionally, long-term follow-up studies are crucial to evaluate the durability and effectiveness of this approach.

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Institutional Review Board Statement

All patient data has been carefully anonymized to protect individual identities, ensuring that no personal or identifiable information is disclosed at any stage of the research process. Additionally, written informed consent has been obtained from each patient, affirming their understanding and agreement that their anonymized data may be used for research purposes in compliance with ethical standards and privacy regulations. The work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

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None

Data Availability Statement

The data presented in this study are available on request from the corresponding author.

Conflicts of Interest

Prof. Maurice Mommaerts and Dr. Casper Van den Borre declare to be medical consultants to CADskills BV. The other authors report no conflicts of interest.

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Tables

Post operative events			Treated with antibiotics +
n= 19 patients	Problems	3 (15.78 %)	Chlorhexidine mouthwash
	Obstacles	1 (5.26 %	Infection with debridement
	Complications	2 (10.54%)	Removal due to permanent infection

Table 1. Post-operative adverse events were classified into three categories: problems (non-surgical issues like infection and pain), obstacles (requiring surgical intervention), and complications (severe unresolved conditions). Five patients experienced problems, one had an obstacle, and two true complications were documented.

Domain	Mean	SD
Overall OHIP-14	6.68	7.99
1. Functional limitation	0.63	1.01
2. Physical pain	1.68	2.03
3. Psychological discomfort	1.37	2.09
4. Physical discomfort	1.11	1.82
5. Psychological disability	0.84	1.34
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SD = standard deviation. The overall OHIP-14 score is presented along with the values for each domain separately. The calculated mean OHIP score of 6.68 (SD ± 7.99) reflects a high oral health-related quality of life.

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Table 3. Results of the Numerical Rating Scale (NRS)

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Captions to the Figures

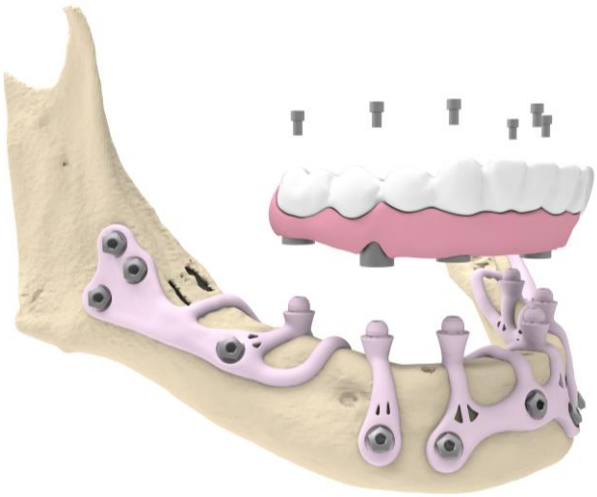

Figure 1. Representation of the patient-specific AMSJI® for the mandible.

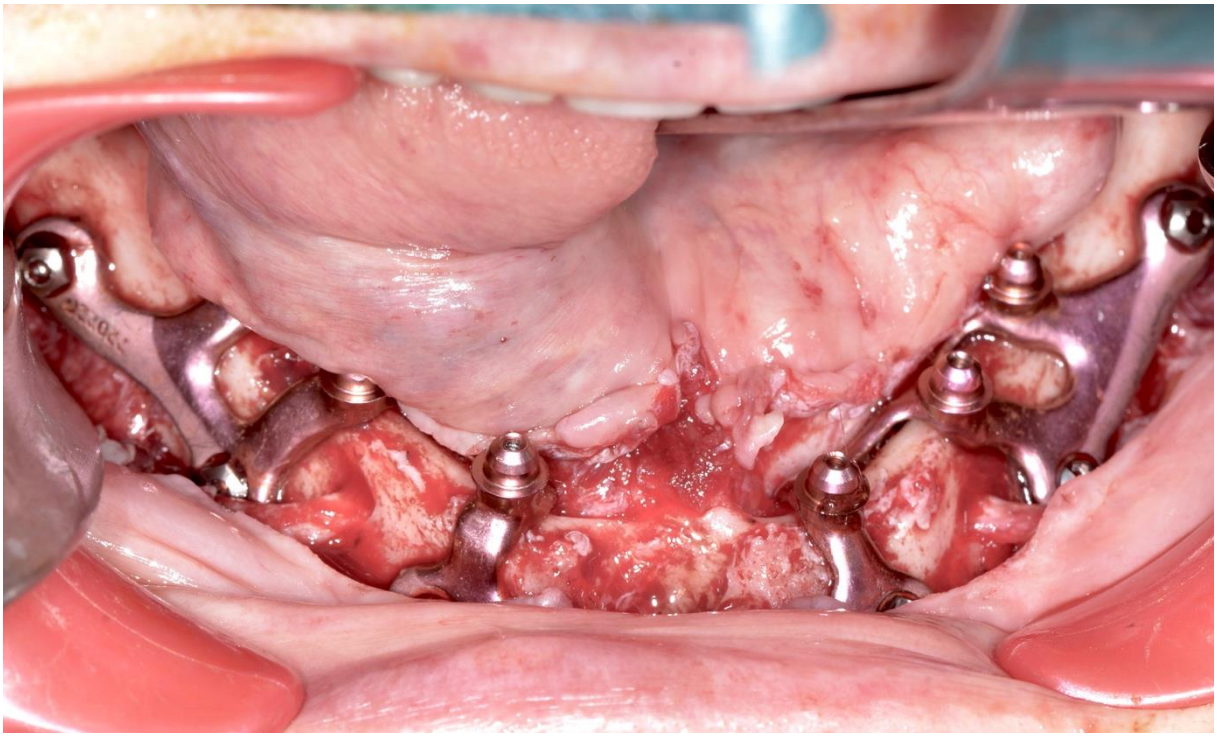

Figure 2. Clinical picture after mucoperiosteal flap raising and fixation with osteosynthesis screws

Figure 3. A stable 2-year postoperative result without recessions in a patient with AMSJI in the mandible

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Retrospective analyses of additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible

Abstract

This multicentre retrospective study aims to evaluate the success rate, adverse events, and patient satisfaction related to additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible. The study includes data from 40 AMSJI® implants placed between 2017 and beginning of 2024 in 19 patients with severe mandibular atrophy (Cawood-Howell classes IV-VII). The results indicate a high level of patient satisfaction, with a survival rate of 92.5 % after an average follow-up of 804 days (SD ± 540 days). The primary issue post-operative encountered was immediate post-post operative oedema and temporary infection, which was generally managed with chlorhexidine mouth rinses, antibiotics, and paracetamol. One implant showed increased mobility (movement in any direction greater than 1 mm) at the time of the interview. Two other implants had to be removed due to persistent infection and suppuration, with an additional implant scheduled for removal. Patient satisfaction in general was high at the time of the interview, with an average OHIP-14 score of 6.68 (SD ± 7.99) and a NRS score of 51.26 (SD ± 7.63). Mucosal recession (both buccal and lingual) was observed around 13 implants (32.25%); however, patients did not perceive this as a functional or aesthetic issue.

Within the limitations of a short-term follow-up period, AMSJI in the mandible shows promise as an effective option for rehabilitating patients with severe mandibular atrophy. Despite the positive results, longer-term follow-up is necessary to confirm the implant system's durability and performance over time.

Keywords: Alveolar bone loss; Subperiosteal dental implantation; Patient satisfaction

Introduction

Restoring masticatory function in patients with a severely atrophied mandible (Cawood IV-VIII) has consistently presented a significant challenge (Cawood and Howell, 1988). To improve the retention of removable lower dentures, various preprosthetic surgical techniques (soft tissue management and bone augmentation) have been utilized (Obwegeser, 1977; Stoelinga et al., 1986, Bell et al., 2002; Cawood and Stoelinga, 2005) . However, these methods have inherent limitations and may lead to considerable patient morbidity (Nkenke and Neukam, 2014). Non-titanium, double staged subperiosteal implants have provided an alternative treatment modality (Dahl, 1957). Although reliable results were published by Bodine in 1974, several factors have contributed to the declining use of lost-wax casted chrome-cobalt-molybdenum (CrCoMo) subperiosteal implants. These implants demonstrate minor osseointegration and soft tissue integration capabilities due to the alloy's limited bioactivity. While CrCoMo is biocompatible and not toxic to surrounding tissues, it lacks the bioactivity needed to actively interact with bone and soft tissue in a way that stimulates or encourages growth. In contrast, materials like titanium oxide on titanium implants promote superior integration due to their favorable bioactive properties. Additionally, the CrCoMo frame utilized in subperiosteal implants is prone to hypersensitivity reactions (type IV) and stress shielding (Linkow and Ghalili, 1998). These factors could lead to early and late implant exposure, bone resorption, discomfort, infection, fistula formation and ultimately implant and prosthetic failures.

Today, single-stage, additively manufactured titanium subperiosteal implants—specifically AMSJI®, the first of this kind—are regaining popularity due to advancements in technology, materials, digital medicine and dentistry, clinical expertise and increased public awareness of oral hygiene (Fig 1,2 and 3). AMSJI® has shown excellent clinical outcomes in the upper jaw

(Van den Borre et al., 2022, 2023). The aim of this study was to analyze the short to medium-term survival and success rate, adverse effects, and patient satisfaction when the AMSJI® solution is used to provide a fixed lower dental prosthesis.

Patients and Methods

This retrospective multicentre study included patients who underwent AMSJI® placement in the mandible from 2017 till beginning 2024, specifically for severe mandibular atrophy (Cawood-Howell IV or higher) (Mommaerts, 2020). A total of 23 patients treated by 11 surgeons from ten different surgical centers were eligible for inclusion. Four patients were excluded because of the unwillingness of the surgeon or the patient to comply with the study. No other exclusion criteria were applied. Ultimately, 19 patients with a total of 40 AMSJI's were included in the analysis.

Data collection included patient demographics such as age, ASA score, gender, and co-morbidity assessments (e.g., history of radiotherapy, bisphosphonate use) as well as risk factors like smoking (Van den Borre et.al, 2024). Bone atrophy was evaluated using the Cawood-Howell classification. Implant-specific details, including the use of horizontal and vertical ostectomy guides (HOG/VOG) were also documented. Additionally, information about the opposing jaw was recorded noting conditions such as dentate status, AMSJI or other implant retained prostheses, partial removable prosthesis, and other relevant factors.

Post-operative adverse events were systematically classified into three distinct classifications to enable a thorough evaluation of their impact on patient recovery. *Problems* were defined as adverse effects that did not require surgical intervention for resolution, including conditions such as infection, suppuration, pain, and swelling. In contrast, *obstacles* referred to issues that necessitated surgical intervention, such as debridement or removal of posts. Lastly, any unresolved conditions were classified as *complications*, which included severe outcomes like implant fractures or the need for implant removal.

The clinical evaluation included assessments of implant stability and mucosal phenotype. Implant stability was evaluated by checking for mobility after the suprastructure was

removed, with no mobility indicating stability and mobility exceeding 1 mm indicating instability. The mucosal phenotype was determined using a periodontal probe. If the circumference of the probe was visible, it was categorized as thin (score: 0); if not, it was categorized as thick (score: 1). Additionally, mucosal recession and/or exposure of the arms of the frame as well as the height of keratinized mucosa (measured from the junctional epithelium to the mucogingival junction), were documented.

Patient reported outcomes were measured using the OHIP-14 and NRS scales. The OHIP-14 consists of seven domains addressing functional limitations, physical pain, psychological discomfort, and physical, psychological, and social disabilities. Each domain includes two questions scored on a five-point scale: 0, never; 1, almost never; 2, occasionally; 3, often; and 4, very often or every day. Domain scores are calculated by summing the responses to the two questions, with total scores derived from all 14 questions. Scores range from 0 to 56, with domain scores ranging from 0 to 8; a higher OHIP-14 score indicates a poorer oral health-related quality of life (OHRQoL). The NRS, based on the visual analogue scale (VAS), provides insights into aesthetic benefits, chewing, comfort, phonetics, cleaning, and overall satisfaction. This scale consists of six questions rated on an eleven-point scale from 0 for (not at all satisfied) to 10 for (very satisfied). The total score is obtained by summing the responses to all six questions.

Statistical Analysis

The data were analysed using SPSS version 26.0. (IBM, New York, NY, USA) for macOS Big Sur.

Results

This study included 5 males (mean age: 61,40 years, SD ± 13.51 years) and 14 females (mean age: 68.12 years, SD ± 9.68 years), with a mean follow-up period of 804 days post-AMSJI installation (SD ± 540). All patients were ASA I (n = 11) and ASA 2 (n = 8) and had a Cawood-Howell degree of mandibular atrophy of IV (n = 5), V (n = 8), VI (n = 4) and VII (n = 2). Six patients had a dentate opposite jaw. Four had AMSJI-supported fixed dental prostheses. Three had an endosseous implant retained denture and six had removable prostheses. In two patients horizontal/vertical ostectomy guides were used. None of the patients smoked. All patients were edentulous before in the region were planned AMSJI implantation was going to take place (severe mandibular atrophy (Cawood-Howell classes IV-VII). Twelve patients presented with a thick gingival phenotype, and seven with a thin. The mean height of keratinized mucosa was 2.66 and 2.73 mm, respectively. Five patients reported with post-operative problems, all initially treated with antibiotics and mouth rinse. One obstacle (debridement, removal of post(s)) and two true complications were documented (Table 1).

At the time of examination, all but one AMSJI implant was firmly fixed, with mobility exceeding 1 mm after removal of the final restoration. Partial exposure of the arms was observed in 13 AMSJI subunits; however, patients did not perceive this as a functional or aesthetic issue. Only a thin biotype could be indicated as a significant risk factor (p-value <0.001). The final restoration was successful for all patients, with all but one patient using their fixed or removable prostheses in use at the time of consultation.

Total OHIP-14 and NRS were calculated to assess treatment benefits and patient satisfaction yielding a mean OHIP-14 score of 6.68 (SD ± 7.99) and a mean NRS scale value of 51.26 (SD ± 7.63). See table 2 and 3.

Discussion

Edentulous patients, whether partially or fully in the upper or lower jaw, typically have two options for oral rehabilitation. One option is a removable denture, which replaces missing teeth and alveolar bone by depending on the underlying soft tissues and remaining bone for support, retention, and stability. However, prolonged edentulism often leads to significant residual alveolar ridge resorption, resulting in a vestigial alveolar crest. These patients often face issues with ill-fitting dentures, leading to difficulties with chewing, speech, and functional and sensory impairments in the oral mucosa, salivary glands, and musculature. For those seeking a fixed solution (the second option), implant-supported dentures are recommended, relying on endosseous implants placed in the alveolar process or basal bone for support. However, severe residual ridge and even jawbone resorption can result in insufficient bone, making endosseous implant placement impossible. While short, narrow, or tilted implants may help, a minimum bone volume is still needed, excluding patients with extremely atrophied jaws.

Custom-made titanium subperiosteal implants, like AMSJI®, are placed beneath the periosteum and rest on the basal bone (Mommaerts, 2017, 2019). They connect to the prosthesis via per-mucosal extensions (posts). These implants are ideal for patients with insufficient bone, as they eliminate the need for bone grafting. This simplifies surgery, reduces treatment time, and allows for immediate but progressive loading, offering quicker functional and aesthetic improvements compared to delayed protocols. Several authors have confirmed the efficacy of new generation of custom-made, 3D printed subperiosteal implants, reporting positive outcomes in clinical trials and case studies (Van den Borre et. al,

2022,2023; Vaira et. al, 2024; Onică et. al, 2024; Dimitroulis et. al, 2023, Mangano et. al, 2020).

Contemporary additively manufactured subperiosteal implants are gaining prominence, demonstrating promising short- to medium-term outcomes. In a recent systematic review by Anitua et. al, (2024), 13 studies (5 cohort studies and 8 case series) were analyzed, encompassing 227 patients (121 females, 106 males; mean age of 62.42 years) and 227 implants. With a mean follow-up of 21.42 months, the survival rate of these implants was reported at 97.81 %, closely aligning with our findings, where 92.50 % of AMSJI implants remained functional after an average follow-up of 26.41 months (804 days). Anitua et al. also documented 5 true complications (2.20 %) and 12 instances of soft tissue challenges (5.28 %), a comparison that parallels the results observed in our study. Furthermore, Anitua et al. reported that 25.61% of subperiosteal implants exhibited partial exposure. In comparison, we observed soft tissue recession in 13 implants (32.25%). Despite the relatively higher occurrence of tissue recession in our study, this did not appear to adversely impact implant survival in the short to medium term. These findings suggest that while soft tissue complications may arise, they do not necessarily compromise the overall success of the implants within this timeframe. An attached keratinized mucosal zone around the implant shoulder is crucial for endosseous implants, forming a biological seal that protects against pathogenic microorganisms (Thoma et. al, 2022; Ravida et. al, 2022). Without this barrier, the risk of peri-implantitis and failure increases. While only one implant failure occurred in this study, long-term success depends on soft tissue health. Exposure heightens the risk of infection, bone resorption, and failure, making timely interventions like soft tissue grafting or the use of collagen matrices, allografts, or xenografts critical. Future studies should explore these techniques to reduce complications. However, a comparison with endosseous implant-

based prosthetics is not possible, as AMSJI is specifically indicated for cases where endosseous implants are not suitable.

Vaira et al. conducted a retrospectively analyses of patients with posterior mandibular atrophy rehabilitated using custom-made subperiosteal implants. The study included data from 30 implants placed in 17 patients, with an average follow-up of 22.5 months. No infections or implant losses were reported. In 10 cases, the patients reported chewing discomfort immediately after delivery of the provisional prosthesis linked to the conditioning of the gingiva or to the transmission of masticatory forces to the periosteum.

However, 10 patients experienced chewing discomfort immediately after the provisional prosthesis delivery, attributed to gingival conditioning or the transmission of masticatory forces to the periosteum. Notably, none of the implants showed any structural exposure, with 100% of cases scoring 0 for exposure.

A significant distinction between the subperiosteal implants described by Vaira et. al (2023) and the AMSJI system lies in the design and placement of the abutments. Vaira et. al (2023) observed that the abutments of their subperiosteal implants were strategically placed within specially designed recesses in the residual crest to minimize the risk of progressive bone resorption. During the installation process, a small amount of basal bone was removed to facilitate abutment placement, a technique aimed at improving implant stability and preventing mechanical complications, such as screw loosening and soft tissue recession, which could occur due to ongoing resorption. In contrast, Van den Borre et. al, (2021) specifically investigated the effect of AMSJI implants on supporting bone resorption. They reported an average bone remodeling of -0.26 mm (SD 0.65 mm) across six reference points on the residual crest, indicating a minimal negative impact on the surrounding bone.

To combat progressive residual ridge resorption, cutting jigs for vertical and horizontal ostectomies can be employed to proactively remove bone that is susceptible to future resorption (Rinaldi et. al, 2021). This strategy enhances long-term stability and minimizes the risk of implant failure, offering a customized solution for addressing severe atrophy and ensuring lasting clinical success.

This study found tissue biotype to be a highly significant ($P < 0.001$) and independent risk factor for peri-implant recession with no other risk factors identified. This finding aligns with multiple prior studies suggesting that a thin periodontal phenotype can predispose individuals to soft tissue recessions (Claffey and Shanley, 1986; Lin et.al, 2020, Van den Borre. et. al, 2024). Thus, ascertaining the biotype represents a pivotal aspect of the preoperative assessment in patients. In cases where patients exhibit a thin biotype, surgical intervention utilizing soft tissue flaps—either free or pedicled—can facilitate biotype conversion. Lin et al. (2020) validated the efficacy of soft tissue grafting (subepithelial connective tissue graft), demonstrating that approximately a 1 mm increase in tissue thickness can be anticipated postoperatively. Furthermore, alloplastic materials, such as collagen matrices, have been used to increase soft tissue thickness without requiring additional surgical interventions. These materials are strategically placed between the underlying structure and the gingival flap during implant placement, functioning as a comprehensive solution to enhance clinical outcomes (Kim et al., 2018).

The results of this study, alongside those of Vaira et al., indicate that additively manufactured subperiosteal implants may represent a safe and effective solution for rehabilitating severe mandibular atrophy, especially in the posterior regions. However, further validation through larger, prospective studies involving diverse patient populations is necessary. Until such data are obtained, the selection of implant designs should align with the principles of osteosynthesis, osseointegration, and soft tissue integration to optimize clinical outcomes.

Additionally, long-term follow-up studies are crucial to evaluate the durability and effectiveness of this approach.

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Institutional Review Board Statement

All patient data has been carefully anonymized to protect individual identities, ensuring that no personal or identifiable information is disclosed at any stage of the research process. Additionally, written informed consent has been obtained from each patient, affirming their understanding and agreement that their anonymized data may be used for research purposes in compliance with ethical standards and privacy regulations. The work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

Acknowledgments

None

Data Availability Statement

The data presented in this study are available on request from the corresponding author.

Conflicts of Interest

Prof. Maurice Mommaerts and Dr. Casper Van den Borre declare to be medical consultants to CADskills BV. The other authors report no conflicts of interest.

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Tables

Post operative events			Treated with antibiotics +
n= 19 patients	Problems	3 (15.78 %)	Chlorhexidine mouthwash
	Obstacles	1 (5.26 %	Infection with debridement
	Complications	2 (10.54%)	Removal due to permanent infection

Table 1. Post-operative adverse events were classified into three categories: problems (non-surgical issues like infection and pain), obstacles (requiring surgical intervention), and complications (severe unresolved conditions). Five patients experienced problems, one had an obstacle, and two true complications were documented.

Domain	Mean	SD
Overall OHIP-14	6.68	7.99
1. Functional limitation	0.63	1.01
2. Physical pain	1.68	2.03
3. Psychological discomfort	1.37	2.09
4. Physical discomfort	1.11	1.82
5. Psychological disability	0.84	1.34
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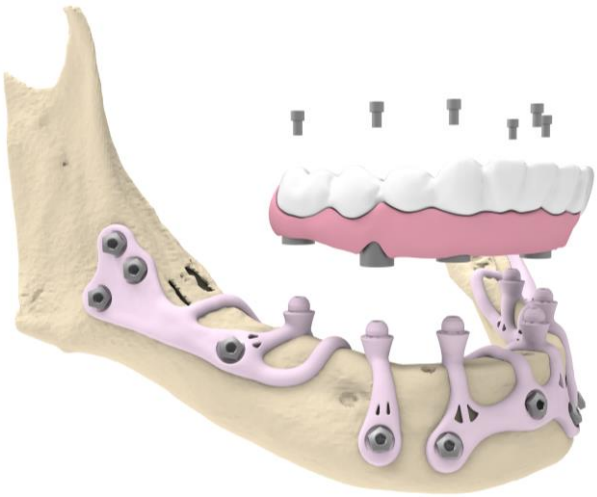

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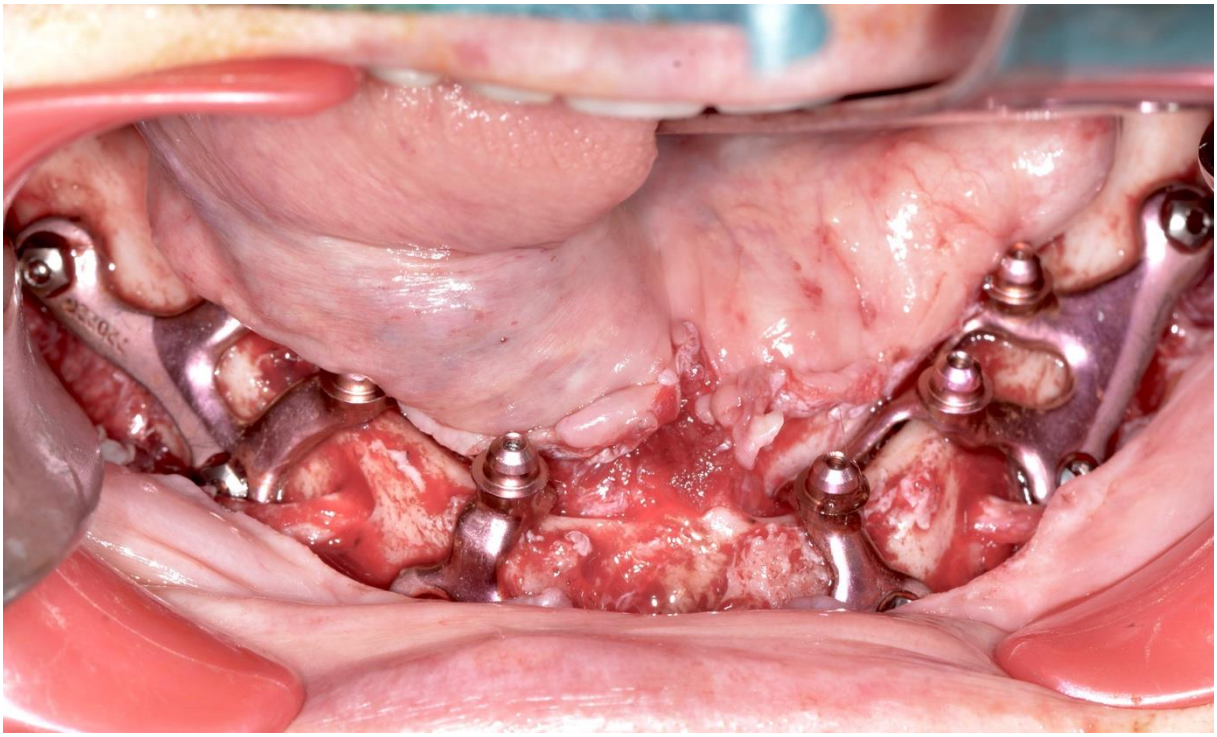

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CONFIRMATION OF AUTHORSHIP FORM

Title of Submission: **Retrospective analyses of additively manufactured subperiosteal jaw implants (AMSJI®) in the mandible**

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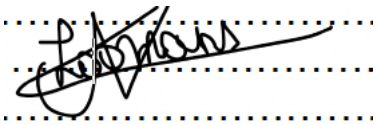

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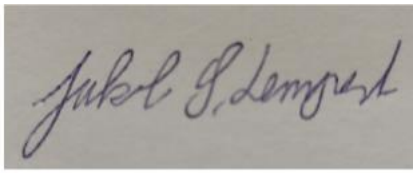

Marc Baltensperger

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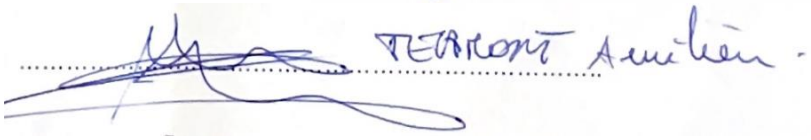
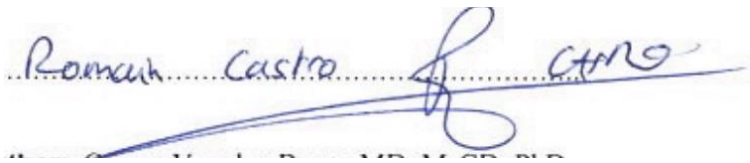


Romain Castro



Maurice Y. Mommaerts

“I warrant that all the authors listed above have made a significant contribution to this manuscript and have agreed to its submission to the JCMFS”.

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