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Willingness to accept or refuse mandibular implant overdenture treatment: a prospective study on edentulous enrolled in a clinical trial

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Author contributions

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Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Abstract

Objective: The aim was to evaluate edentulous patient's willingness to accept or refuse the offer and provision of implant-retained treatment. Methods: As part of a clinical trial, edentulous subjects were offered a mandibular overdenture retained by four mini-implants opposing a conventional maxillary denture. Treatment was offered without any financial costs for the patients. Patients' level of interest in receiving treatment was assessed using a 5-point Likert scale and they were asked to respond to a list of reasons that led to their decision to accept or refuse implants. Those who refused implants received conventional prosthodontic interventions as required, and those who accepted implant treatment underwent surgical planning and implant placement. Results: Of 175 eligible subjects, 147 accepted the offer of treatment and were invited to take part in the study (69.4% women, mean age 67.4±10.0 years). Overall, 111 patients (75.5%) expressed a positive intention to undergo implant treatment at the initial contact. Implant treatment was performed for 56.3% (9/16) of those who answered "probably yes" about their level of interest in implant treatment on the Likert scale, and 69.6% (64/92) of "certainly yes" ($p<0.001$). Older subjects were less likely to receive implants (OR=0.93; p=0.036), whilst those with a positive intention toward implants (OR=3.15; p=0.001), those previously treated by the dental team (OR=7.89; $p<0.001$), and who actively demanded implants (OR=18.1; $p<0.001$) were more likely to accept treatment. Improved chewing was the most common reason for accepting implants, whilst fear of surgery was the most reported reason for refusal. Conclusion: Refusal of implants was high amongst edentate patients even when financial costs were removed. Patients' initial attitude towards acceptance is a key factor in the demand for and uptake of implant therapy.

Introduction

Although the conventional complete denture is the most common treatment for edentulous patients in clinical settings worldwide, a significant proportion of complete denture wearers have major complaints regarding their performance. Therefore, it is likely that these dissatisfied users will seek treatment with implants to improve the retention and stability of their dentures, especially for the mandibular denture [1]. Implant-retained mandibular overdentures have been considered a suitable alternative for patients who fail to accommodate to their dentures [2], with significant improvement in function, oral comfort, overall satisfaction, and better quality of life demonstrated [3,4].

Although virtually all edentulous patients can be potential candidates for implants, there are several barriers which shape the demand for and utilization of implant therapy [5]. Previous studies showed that improving public awareness may increase the willingness to seek treatment in a population who is interested in dental implants [1,6-10]. Treatment cost and availability are relevant factors that limit access to dental implants. However, other factors related to patients' negative attitudes towards dental

implants are also key factors which compromise their willingness to accept and undergo treatment [1]. These factors include fear and anxiety, perception of surgical and post-insertion complications, low perceived need and satisfaction with their existing conventional prosthesis. It is also reported that older adults are more likely to refuse implants treatment [11].

Although age alone should not be a limiting factor for implant treatment [12] and is not necessarily associated with a negative attitude towards implants [8], many older patients weigh the perceived potential for complications against the potential benefits and often conclude that the procedure would be more complex than the professional might lead them to believe [11]. Therefore, it is not surprising that many older patients prefer to maintain their conventional dentures instead of undergoing implant interventions [13,14]. It had been suggested that only a small proportion of edentulous patients proceed with the placement of implants to retain a mandibular overdenture [10]. The restricted demand for implants suggests that many older patients are able to accept the limitations of their conventional dentures and feel psychologically satisfied with their oral condition, which helps to explain the lack of interest in receiving dental implants [15].

The financial costs of implant therapy are recognized as a major barrier to accessing treatment. However, previous studies have suggested that even when financial costs factor are removed, the refusal rate remains high. In a study with edentulous subjects enrolled in a clinical trial [16], when overdenture treatment was offered with no costs for the patient, 36% of patients refused implant therapy, mainly due to concerns about surgical risks. Therefore, removing costs as an influencing factor should provide valuable information on the clinical and psychosocial factors which influence the acceptance or refusal of implant therapy by edentulous patients. In addition, it should provide important information to identify those most likely to benefit from implants in the treatment decision-making process. Therefore, this study aimed to investigate the willingness to accept or refuse the offer and provision of mandibular overdentures retained by narrow-diameter implants offered free of charge within the context of a clinical trial, whilst also capturing the factors influencing patients' decisions.

Material and Methods

Study design and sample

This study was conducted alongside a randomized clinical trial previously registered at ClinicalTrial.gov before initiating patient recruitment (NCT04760457), comparing different surgical and loading protocols using four narrow-diameter implants to retain a mandibular overdenture opposing a conventional maxillary complete denture [17]. The study design comprised data collection throughout four consecutive phases of the study: (1) invitation and treatment offer (2) clinical assessment and baseline prosthodontic procedures, (3) implant treatment planning, and (4) implant surgery.

All phases of the study were conducted at the clinical settings of the School of Dentistry of the Federal University of Goias, Brazil, between September 2020 and November 2021. This report covers the preliminary stage of the clinical trial, which was approved by the local research ethics committee (CAAE 24833219.4.0000.5083 – Protocol 3.702.392). Informed consent was obtained by all participants who agreed to take part in the study. Since this investigation comprises cross-sectional data and a prospective assessment, this report followed the STROBE checklist for observational studies.

At the recruitment phase of the study, eligible fully edentulous subjects were contacted by telephone call and invited to enroll in the clinical trial. The list of eligible patients was made up of an existing waiting list of patients referred from the local public health service for complete denture and/or implant treatment in the university clinics.

The inclusion criteria for the study were edentate patients with no gender or age restrictions. The patients had a wide range of treatment needs varying from patients with newly fabricated dentures and referred for implant treatment, patients who required adjustments or repairs to their current dentures, or patients needing new complete dentures. The criteria for considering the quality of patients' current dentures at the time of assessment was based on conditions such as poor retention or stability, and occlusal problems (lack or excess of vertical dimension) [18]. In these cases, a new set of dentures was planned.

Those subjects who could not be contacted, were unwilling to complete the study questionnaires, or who had previous implant treatment were excluded from the study. The target sample size for the randomized clinical trial was 74 patients (n=74).

Participant flow and questionnaires

Initial assessment for eligibility was performed by via a telephone screening call with a follow-up clinical appointment. When the treatment was offered, the patients were informed about the type of implant-supported intervention included in the study. At the assessment appointment patients completed a questionnaire focused on current use of maxillary and mandibular dentures and their perceived prosthodontic needs and complaints. Patients were questioned about their interest in being enrolled in a clinical study to receive dental implants for stabilization of their mandibular denture. All patients were clearly informed that treatments would be provided in the university setting by specialist clinicians and, as part of a study supported by external funding, they would not be charged for any costs related to the prosthodontic and implant interventions.

Following these initial explanations, a single question was asked: "Would you be interested in receiving implants for stabilization of your mandibular denture?". Responses were graded on a 5-point Likert scale: 1 – certainly no; 2 – probably no; 3 – neutral; 4 – probably yes; and 5 – certainly yes. Those who provided scores of 1 and 2 were asked to complete a further questionnaire about the reasons for refusing implant treatment, containing eight yes/no items, an open question about other

reasons not included, and a final question to choose the most important reason (among those previously mentioned) for the decision to refuse treatment.

Similarly, those who responded positively to the offer of implant treatment (scores 4 and 5) were invited to answer a questionnaire listing possible reasons for accepting implant treatment, containing eight items, an open question to detail reasons, and to indicate of the most important reason which influenced their decision to accept implant treatment. Finally, those who were uncertain about refusal or acceptance (score 3) were assessed again after two weeks and asked to make a final decision, and to respond to the questionnaire about refusal or acceptance.

All respondents who accepted or refused the offer of implants were invited for conventional prosthodontic treatment, according to the participant's needs, independent of proceeding with the implant phase of the study. Prosthodontic treatment included fabrication of new conventional complete dentures or adjustments to existing clinically satisfactory dentures. After adaptation to the new dentures or resolution of clinical problems related to the current dentures, patients proceeded to implant treatment planning. Patients who had satisfactory dentures and no complaints, and expressed a strong intention to receive implants were immediately referred for implant treatment planning.

In addition, a questionnaire to assess knowledge about dental implants was administered to all the participants. This questionnaire included questions related to educational level, how they are informed about implants, sources of information and specific dichotomous questions addressed to laypeople about clinical and technical features related to dental implants.

In the final stage of the study, implant surgery was scheduled and performed for the participants who accepted implant treatment. In cases where the patient's initial response of acceptance of dental implants changed to refusal, they were asked to respond to the questionnaire about reasons for refusal. In cases of implant treatment withdrawal or changed decision due to medical or personal reasons, the main reason for refusal was recorded. Therefore, the final treatment behaviour was coded as positive (conclusive acceptance) or negative (refusal) and was considered the study's main outcome.

In summary, implant treatment consisted of insertion of four one-piece narrow-diameter implants with a miniaturized carbon-coated prosthetic connection and an Optiloc® female PEEK matrix insert (Straumann® Mini Implant System). In the experimental phase of the clinical trial, different surgical (flapped or flapless) and loading (immediate or delayed) protocols were randomly assigned to participants in a factorial design. The previously constructed conventional dentures were converted into implant retained overdentures through chairside pick up of the implant components.

Data analysis

Descriptive analysis, chi-square tests, and independent t-tests were used to summarize data and compare participant subgroups according to the study outcomes related to intention and behaviour towards implant treatment. In addition, Spearman's correlation was used to test the association between age and the participants' responses regarding acceptance or refusal of implants, followed by a multiple logistic regression analysis that tested the effect of independent variables on the provision of implant therapy. The IBM-SPSS 24.0 software was used for data analysis, and the 5% level of significance was adopted for statistical inferences.

Results

A total of 175 potentially eligible participants were listed for telephone contact. Twenty-eight were excluded due to an inability to make contact (n=23), previous implant treatment (n=2), medical conditions (development of dementia) (n=2), or death (n=1). Prosthodontic and subsequent implant treatments were offered to the remaining 147 subjects, and 74 (50.3%) received implant treatment.

Of the 147 respondents, 102 (69.4%) were female, and their ages ranged from 34 to 92 years old (mean ± SD = 67.4 ± 10.0). The proportion of participants who received implant treatment did not differ significantly between females (47.1%) and males (57.8%) ($p=0.231$). However, the mean age was higher for those who refused (70.7±10.7) compared to those who accepted (64.1±8.0) implants ($p<0.001$). Figure 1 shows a negative correlation between the score of refusal/acceptance and the respondents' age (Spearman's $r = -0.36$; $p<0.001$). Overall, 111 respondents (75.5%) had a positive intention (scores 4 and 5), 24 during telephone contact, and 87 during the clinical visit.

The crosstabulation between the initial response to the acceptance/refusal questionnaire and the final behavior (implant treatment performed) showed that no participants who initially refused (certainly no, and probably no) underwent implant treatment. Positive behavior was observed for 14.3% (1/7), 56.3% (9/16), and 69.6% (64/92) from those who responded as being neutral, probably yes, and certainly yes, respectively ($p<0.001$).

The complete flowchart of the study is presented in Figure 2, focused on the patients who actually underwent implant surgery. A preliminary assessment restricted to a telephone call was conducted for 49 subjects and gave rise to refusal due to various reasons that resulted in prompt declination of the implant offer (n=25) or further refusal in subsequent telephone contacts (n=24), as detailed in Figure 2.

Ninety-eight participants were scheduled for a clinical appointment when they were informed about the study objectives and procedures, implant treatment protocols, and subsequent follow-up program. After the clinical visit, participants were assigned to prosthodontic treatments as required, such as fabrication of new dentures (n=28) or denture adjustment (n=15). Subsequently, one participant who was initially neutral

about accepting implants underwent surgery. Amongst all participants who intended to accept implants, 76 completed diagnostic imaging, implant treatment planning, and baseline data collection (for the purposes of the clinical trial). Nevertheless, three withdrew when the surgery was scheduled, with the remaining 73 participants undergoing implant surgery (Figure 2).

Of all included participants, 69.4% were initially referred for complete denture treatment, with 30.6% referred specifically for implant treatment. Positive willingness to accept implants was higher for those initially referred for implant treatment ($p<0.001$), and the proportion of participants who underwent implant surgery was also higher for participants this group (89.5%) compared to the group of participants who were referred only for complete denture provision (37.3%) ($p<0.001$).

Table 1 shows the results of the multiple logistic regression analysis. Overall, it was observed that age patient attitudes and previous treatment experience had a significantly positive impact on acceptance of implant treatment. Older subjects were less likely to receive implants (OR = 0.93; $p = 0.036$), whilst participants who reported positive intention at the initial contact (OR = 3.15; $p = 0.001$), who were previously treated by the dental team (OR = 7.89; $p <0.001$), and who actively demanded implants (OR = 18.1; $p < 0.001$) were significantly more likely to receive implant treatment. The independent variables in the current model explained a high proportion of the total variation of the acceptance of implants (R-square = 0.645).

Concerning the reasons for acceptance or refusal of implant treatment, Table 2 summarizes the overall frequencies of the selected items and the most important reason to accept or refuse implants. Items related to oral function and psychological comfort were the most prevalent, reaching frequencies higher than 90%. All patients who accepted implants listed better chewing, improved denture stability, and improved confidence as reasons to accept. It should be noted that the lack of cost of the dental implant treatment in this study was listed as the most important factor in accepting care by 20.2%.

Only 29 subjects who refused implants provided information about their reasons. The most reported reasons listed were that the provision of the implant was not convenient at that time for the participant (89.7%) and fear of surgery (75.9%). Fear of surgery was the most important item for 37.9% of respondents who refused implants.

Discussion

This study investigated patients' acceptance and refusal of implant-retained mandibular overdenture treatment. The results illustrate that even when there is no cost involved, the refusal rate for implant-retained mandibular overdentures in this patient group was high. In addition, the results demonstrate that patients initial intentions towards implant treatment can be a strong predictor of their desire to actually

undergo therapy or not. In fact, expressed desire for implant treatment is a strong prediction of effective acceptance [5].

In this study, acceptance of implants was high among those who attended the initial clinical appointment (74 out of 98 – 75.5%) but decreased at the end of the study (50.3%). Similar findings were observed by Walton et al. [16], who found a 79% acceptance rate at the initial offer of implants for mandibular overdenture retention, and 64% at the end of the study. Both studies were similar regarding the design for a clinical trial and the offer of free implant treatment. However, there were contrasts regarding the strategy for patient recruitment, prosthodontic needs as a condition for enrollment, and previous referral for implant therapy. Nevertheless, differences in acceptance rates before and after complete denture construction were also a common finding in the two studies, as many patients felt satisfied after improvement of their conventional dentures.

Another study with a prospective design [14] provided new conventional dentures and then offered patients the opportunity of two implants to modify their prosthesis into an implant overdenture at a reduced fee. Only 16.8% initially showed interest in implants, and only 12% actually had the implants placed [14]. In this study, the provision of treatment with no costs for the patients was the second most important reason to accept implant treatment (20.2%). Previous studies showed that people with higher income, living in urban areas, and with higher education levels are more likely to undergo implant treatment [19]. Nevertheless, income seems to be a more relevant factor since people with high educational levels but low income are more likely to have limited access to dental implants [20].

Although removing the cost factor has the advantage of exploring the patient's intrinsic willingness and desire to undergo implant treatment, reducing the role of external factors such as financial issues and treatment availability may overestimate acceptance rates when compared to a real world clinical setting. Moreover, when the cost was removed as a barrier for treatment acceptance, concerns about the implant surgery remained as the most common obstacle for accepting the treatment including factors such as pain, fear, and anxiety [6].

In this study the concept adopted for intention was: "...an indication of an individual's readiness to perform a certain behavior", while the concept adopted for behavior was "...the observable response of an individual in a given situation in relation to a given target" [21]. Therefore, it is also interesting to note that in the period between the offer and the actual provision of implant treatment, some patients changed their minds and refuse implants even after an initial acceptance, as observed in this study and in others [14,16]. Among the participants who had a strong intention towards acceptance of implants at the initial offer stage, 21.4% did not maintain the positive behavior, i.e., did not ultimately undergo implant placement surgery. This difference in actual acceptance may be associated with a lack of clear understanding about the treatment at the time of acceptance, confirming the need for patients to be better informed about the treatment beforehand [22].

Moreover, there are a variety of factors which influence individual patterns of demand and effective utilization of health services, and it is a challenging task to identify and explain how expectations, judgments, beliefs, and intentions lead to various behaviors concerning the utilization of oral health care services [23]. In the case of prosthodontic rehabilitation, the intention-behavior process is particularly modulated by the individual's perceived ease or difficulty in performing the particular behavior (implant intervention) [24], taking into account aspects such as time availability, management of financial costs, and access to health care services [25]. Moreover, the history and attitude of edentulous patients towards the decision to have implants placed are probably more relevant influences on treatment choice than objective assessments of diagnostic complexity [14].

Therefore, a more comprehensive approach should consider other aspects of patient's attitudes towards implant intervention, considering the invasiveness of surgical procedures that are associated with varying levels of dental anxiety, perception of potential benefits and risks within the context of long-term use of conventional dentures, and advanced age. As well as the social normative pressures of the market and relevant others towards the use of dental implants.

Another relevant aspect of this study was that the timeline did include the COVID-19 pandemic, which had a strong negative impact on the utilization of dental services worldwide [26]. Although only three subjects refused to take part in the study due to compliance with social distancing during the pandemic, the role of the pandemic on the acceptance and refusal rates was minimized by adjusting the timings for dental visits and procedures according to government restrictions. Recent studies have also shown a statistically significant association between the pandemic and the postponement of routine clinical care and elective treatments [27,28].

The findings of this study have clinical implications. Firstly, clinicians and policymakers should understand that not all patients who are candidates for implants are likely to undergo treatment. The initial desire for implants is a strong predictor for acceptance and delivery, especially when financial barriers are removed or appropriately managed. Secondly, conventional complete dentures constructed to a high standard may satisfy the needs of a large proportion of edentulous subjects [29]. Hence, when patients are properly informed about the actual benefits and risks of implant interventions, the patients themselves should be able to decide about further treatments based on their own expectations concerning oral function, comfort, and well-being. This is part of the principle of informed consent which is central to all clinical decision making, including decisions related to clinical research.

Finally, it should be acknowledged that there are some limitations of this study. It was beyond the scope of this study to collect detailed information on patients' psychological characteristics which may have played an important role in their decision to accept or refuse treatment. Furthermore, this could have provided an insight into patients' capacity for adaptation to new prostheses or previous experiences with new complete dentures. This information could have been used to build a more complex picture of

each of the patients but would have required significant additional expertise within the research team.

Conclusion

This study illustrates that for patients who refuse implant treatment, fear of surgery is the most important barrier, when financial considerations are removed. For those who accepted implant treatment improved chewing ability was the most important perceived benefit. These results suggest that patients' initial perspectives on implant provision is very relevant in understanding the demand for and utilization of implant-retained prostheses, and should be taken into account when estimating the likelihood of acceptance of implant interventions. These findings have relevance for both clinical practice and in recruitment strategies for clinical trials in prosthodontics and implant dentistry.

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Conflict of interest statement

The authors declare no conflicts of interest with respect to the authorship and/or publication of this article.

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FIGURE LEGENDS

Figure 1. Percent frequencies of the response to implant treatment offer (black line and markers), and age distribution among groups of respondents (n=147).

Figure 2. Flowchart of the participants throughout the study. The gray boxes represent the path followed by participants until receiving implant treatment (black boxes).

Table 1. Logistic regression analysis of factors predicting the acceptance of implant treatment (n=147)

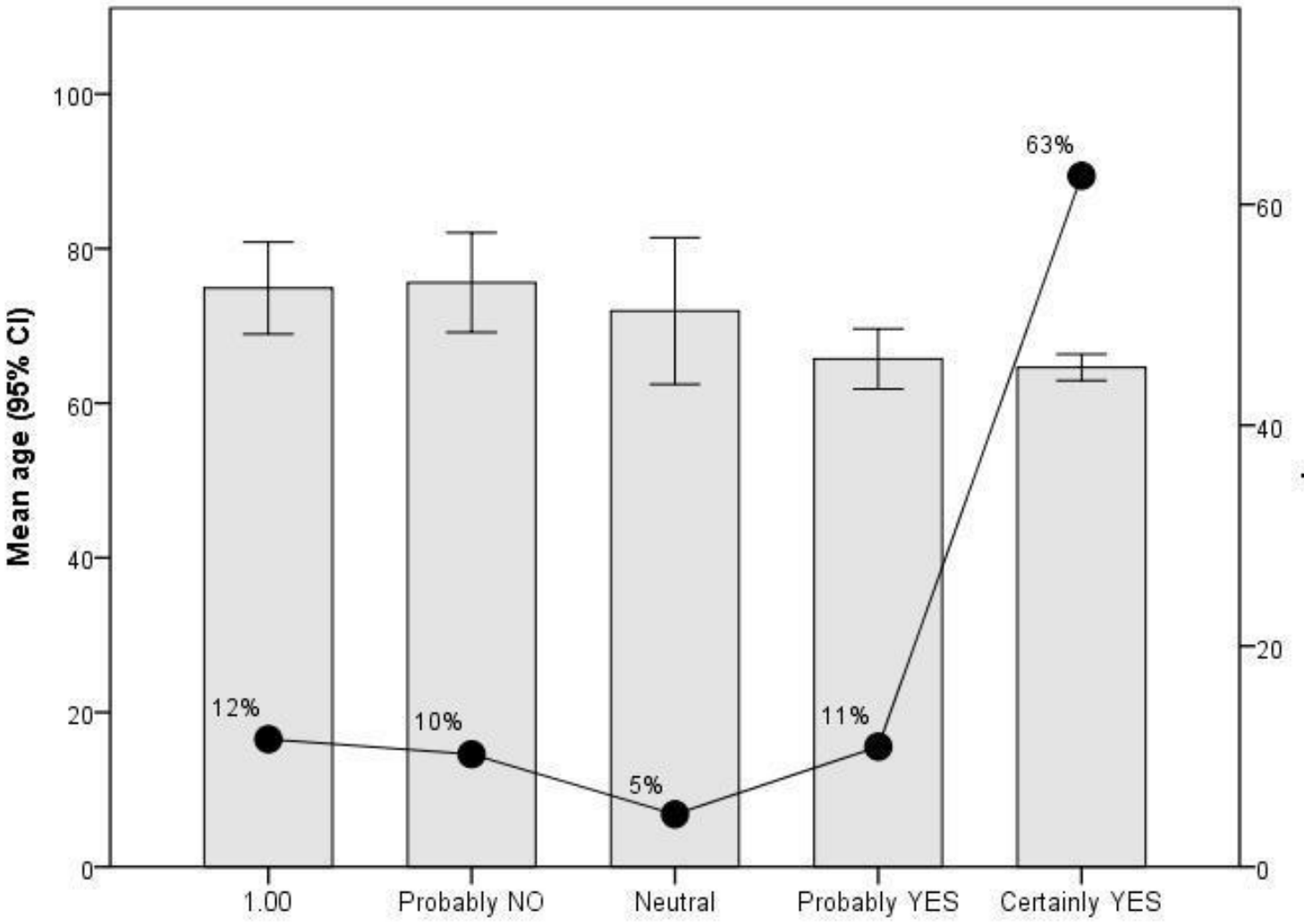
		Crude		Adjusted	
Predictors	n (%)	OR (95% CI)	p-value	OR (95% CI)	p-value
Sex (Female)	102 (69.4)	0.65 (0.32 – 1.32)	0.232		
Age (years)	–	0.93 (0.89 – 0.96)	<0.001	0.93 (0.86 – 0.99)	0.036
Initial intention to receive implants (1–5 ordinal scale)	–	3.86 (2.24 – 6.64)	<0.001	3.15 (1.57 – 6.30)	0.001
Previous treatment (Yes)	104 (70.7)	5.07 (2.26 – 11.4)	<0.001	7.89 (2.51 – 24.7)	<0.001
Referred for implant treatment (Yes)	38 (25.9)	14.3 (4.71 – 43.5)	<0.001	18.1 (4.73 – 69.4)	<0.001

Nagelkerke R Square = 0.645

Table 2. Frequency of the reported reasons for acceptance or refusal of implant treatment.

Reasons to		Overall frequency*		Most relevant reason	
		n	%	n	%
Accept (n=84)	Better chewing	84	100.0	35	41.7
	Treatment free of charge	82	97.6	17	20.2
	Improve denture stability	84	100.0	9	10.7
	Improve speaking	82	97.6	8	9.5
	Feel better with others	77	91.7	7	8.3
	Feel more confident	84	100.0	4	4.8
	Stop avoiding foods	72	85.7	3	3.6
	Feel younger	64	76.2	1	1.2
Refuse (n=29)	Fear of surgery	22	75.9	11	37.9
	The timing is not right	26	89.7	7	24.1
	Poor general health	14	48.3	5	17.2
	Advanced age	14	48.3	3	10.3
	No time available	3	10.3	2	6.9
	Satisfied with the dentures	14	48.3	1	3.4
	Unable to go to the dental school	6	20.7	0	0.0

* More than one item is allowed.



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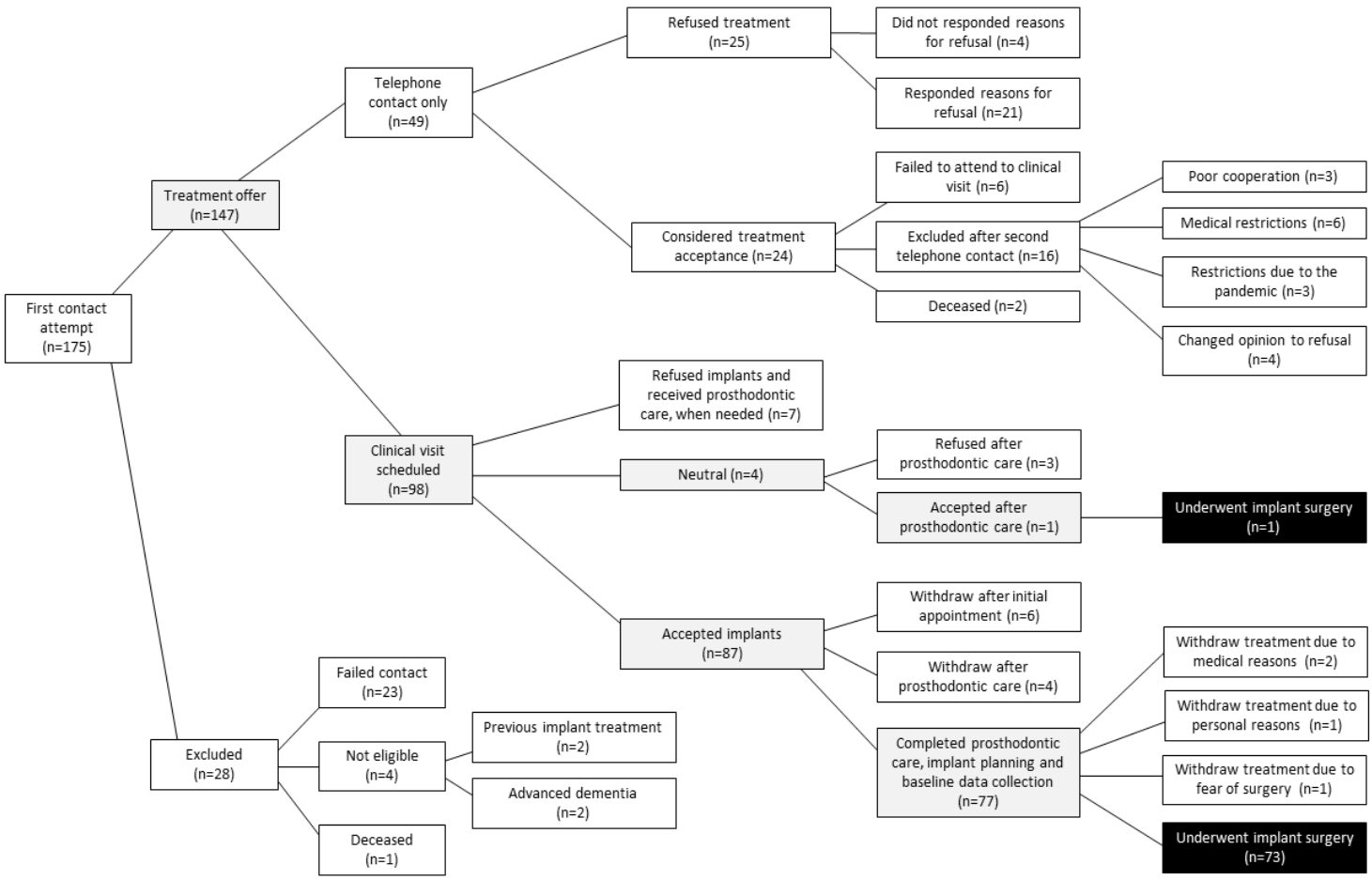

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