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ORIGINAL ARTICLE

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Evaluation and characteristics of "dropouts" in a longitudinal clinical study

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Abstract This paper attempts to identify characteristics of a longitudinal clinical study's "dropout" population (1974–1996) of patients using overdentures. This study included 395 subjects. Dropouts were identified as persons who did not respond to letters or telephone calls after participating in the study for up to 2 years, could not be located, or did not wish to return to the study. Participants (N=273) and Dropouts (N=84) were compared by evaluating a series of factors: sociodemographic, medical, health, and some oral health behaviors. The population was divided into two very similar cohorts for analysis based on years of recruitment: Group I (1974–1984) and Group II (1985–1993). Significant differences were found between them, including vision problems and risk of oral soft tissue problems related to medical diagnosis. Dropouts were significantly younger than Participants, had fewer hearing and vision problems, tended to brush their teeth more often and were more likely to use daily topical fluoride in their overdentures. The differences between the Dropouts and the Participants may be that younger persons are more mobile and have fewer vision and hearing problems, but this does not help predict their commitment to a study. Health behaviors such as brushing overdenture abutments or fluoride use may be more predictable but are harder to assess until persons have been study participants for some time.

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Introduction

Longitudinal studies and clinical trials are designed to compare rates of change over time in one or more outcome variables in a group of patients. Longitudinal studies help define and measure the incidence of disease and identify the risk factors associated with treatment outcomes [9, 11, 15]. These data can be used to develop preventive programs. Most longitudinal studies, [1, 13, 23] especially those which include older adults, have incomplete data because patients die, become ill or drop out before completing the study. The missing data may introduce bias into the study and may threaten the validity of the treatment outcome of a study. When elderly persons participate in a longitudinal study there is always a risk of mortality, morbidity or relocation to a supportive housing environment or nursing home [14].

Very few studies, [3, 12, 16] especially in dentistry, have examined the characteristics of subjects who were retained in a study or were lost to follow-up. Osterberg et al. [17] followed a Swedish 70-year-old population longitudinally and examined the gender and dental status of subjects who were lost to follow-up in their 5-year study. Married males and persons who were dentate were more likely to return than the edentulous. Payne et al. [19] reported on the characteristics of their Dropouts at the 3-year recall of the Ontario Study of the Oral Health of Older Adults. They found that those who remained in the study were healthier, more likely to use dental services on a regular basis and had better periodontal health.

In a longitudinal study, being able to predict which individuals will remain in the study is important when recruiting subjects who will commit to the study and respond to recall appointments.

This paper examines the characteristics of "dropouts" in a longitudinal study of patients who received overdentures by comparing a series of variables, which were

recorded at baseline, to subjects (participants) who remained in the study.

Materials and methods

All patients solicited for the study were scheduled for overdenture treatment in the prosthodontics student clinic at The University of Iowa College of Dentistry from 1974 to 1996. Patients who agreed to participate were asked to return for recall at least once every 6 months after placement of the dentures. The inclusion criteria at the time of recruitment were:

1. They were able to give informed consent.
2. They were ambulatory and able to return to the clinic for recall.
3. They were physically able to clean their teeth or abutments independently.

There were initially 395 patients enrolled in this study, which was approximately 90% of all subjects who received overdentures.

Prior to the reduction of the abutment teeth, the teeth were scaled and cleaned and the patient was taught how best to clean the remaining teeth. If necessary, the patient was referred to the Department of Periodontics for more extensive care to establish optimal gingival health. For most patients, root canal therapy was completed in one visit and the access opening was restored with a restorative material. All of the abutment teeth were reduced to a level of 1.5–2.0 mm above the gingival margin.

At the time of denture placement, baseline measurements and photographs were made for all patients by a single examiner. These measurements included abutment height above the gingival margin and periodontal probing depth. Plaque levels, bleeding on probing and horizontal mobility were also recorded.

Recall

Patients were asked to return to the Department of Prosthodontics at 6-month intervals. At these recall appointments the single examiner evaluated the overdenture abutment teeth for the condition of the restorations, dental caries, and periodontal problems. Appropriate maintenance care and/or treatment was performed on the dentures, the abutments, and the soft tissues.

All patient charts were held in the department in a locked filing cabinet. Six months after the last appointment, the department's clerical staff sent out a recall card asking patients to call the department to make an appointment. If no communication was received from the patient, another card was sent within 2 months. If again there was no response or the letter was returned "address unknown," the clerical staff would try to contact the patient by telephone.

Dropouts

Dropouts in this study were individuals who did not respond to letters or telephone calls after having been in the study for at least 1 year and who did not return for their 2-year recall after receiving their overdentures. Dropouts either could no longer be contacted or told us they did not wish to return to the study. Dropouts did not include patients who had died (N=9) or who had lost all their overdenture abutments (N=3) within 2 years of having been recruited into the study (Table 1). Although this study ran from 1974 to 1996, persons who were recruited into the study in 1994, 1995, and 1996 were not included in the evaluation of Dropouts. Because of the study's 22-year span and the changing characteristics of people, the study population was divided into two cohorts based on the year they were recruited into the study: Group I, 1974–1984, and Group II, 1985–1993.

To characterize the differences between the two groups of Dropouts and the Dropouts and the Participants, a number of independent variables, which could influence the ability to wear overdentures, were measured at baseline and were compared between the groups. These variables are shown in Fig. 1.

Table 1 Disposition of subjects recruited for the overdenture study

Died within the first 2 years	9
Had all overdenture abutments extracted within the first 2 years	3
Recruited 1994, 1995, 1996	8
Incomplete data	18
Dropouts	84
Participants	273
Total population recruited	395s

Statistical analysis

SAS software was used for the data analyses of each specific aim. The assessment of associations for contingency tables and for bivariate analyses were performed by the Chi-Square Test, the Fisher's Exact Test for small sample sizes, or Cochran-Mantel-Haenszel Test for stratified analyses, and analyses of ordinal outcomes. The Nonparametric Wilcoxon-Mann-Whitney Test, based upon ranks, was used to compare the distribution of age between groups. Multivariate Logistic regression models were developed. To identify factors associated with the two populations of Dropouts and two matching groups of Dropouts and Participants, only those variables which were found to have a significant association in bivariate analyses were considered as candidates for forward model selection analyses. All tests had a 0.05 level of statistical significance.

Results

There were 395 subjects who agreed to participate in the study and who were evaluated. The mean age was 55.5 years at the time the overdentures were fitted and the age range was from 15 to 92 years of age.

The overall disposition of the Dropouts, compared with Participants at the end of the study in 1996, is shown in Table 2. We had no response to our written communications or our telephone calls from 60.9% of the Dropouts in Group I compared with 17.5% of the Participants. In Group II, the numbers were 73.7% compared with 11.2%. Nearly 20% of Group I Dropouts told us they were moving compared with 3.0% of Participants, while no Group II Dropouts gave us that information. The next most common reasons subjects did not return to the study were either because they were going to a dentist near their home, were unhappy because we were too far away or just did not want to return. Fewer than 3% of the Dropout groups and 6% of the Participants had become too frail to travel to see us or were now living in a long-term care institution.

The age and gender distribution of Group I of the Dropouts and Participants is shown in Tables 3 and 4. The Dropouts were younger—their mean age was 50.0 years compared with 59.6 years for Participants, which was a significant difference ($p<0.001$). Although there were some differences in the percentage of males (67.4%) in the Dropout group compared with Participants (59.0%), these differences were not significant ($p=0.304$).

Age – Age Groups <50, 51-60, 61-65, 65+ – Age as a continuous variable	**Gender** – male, female	**Mental status** – alert, semi-alert, non-communicative	**Level of cooperation** – very, somewhat, uncooperative
Hearing – normal, aided, impaired	**Vision** – normal, corrected, impaired	**Speech problems** – normal, speaks with difficulty, unintelligible	**Ability to ambulate** – ambulatory, walks with aid, transport required, e. g., wheelchair
Medical problems which could potentially cause: oral soft tissue lesions, e.g., leukemia, anemia, lupus, diabetes, etc. – yes, no hard tissue changes, e.g., osteoporosis, rheumatoid arthritis – yes, no neurological control, e.g., stroke, Parkinson's disease, trigeminal neuralgia – yes, no	**Number of medications being used**, e. g., 0, 1-3, 4+	**Medications which could potentially result in:** anticholinergic effects, e.g., diuretics, tricyclics, phenothiazines, etc. – yes, no inflammatory lesions, e.g., NSAIDS, gold salts, Phenytoin, Ca/channel blockers, etc. – yes, no increase the risk of local infection, e.g., corticosteroids, chemotherapy – yes, no dyskinetic movements, e.g., tricyclics, phenothiazines – yes, no	**Smoking** – never, past smoker, currently smoking

The following three variables were taken from the last appointment with the subjects.

Brushing habits – 2 or more X daily, once daily, occasionally	**Use of fluoride daily** – once daily, every 2nd day, occasionally/none	**Use of chlorhexidine** – daily, occasionally, none

Fig. 1 Independent variables which could influence the ability to wear overdentures

The age and gender distribution of Group II of the Dropouts and Participants is shown in Tables 5 and 6. The mean age of the Dropouts was 48.4 years compared with 59.9 years for Participants and like Group I these differences were statistically significant (p<0.001). There was a lower percentage of males (60.5%) in the Dropout group compared with the Participant group (67.3%) but again, these differences were not statistically significant (p=0.451).

To determine if there were any important cohort differences in the Dropout population, since the study spanned more than 20 years, we compared 21 population characteristic variables between the two Dropout groups (using recruitment year as previously described). Bivariate analyses (Tables 7 and 8) indicated that only two of the 21 characteristic variables displayed statistically significant differences. Group I had a higher percentage of Dropouts with corrected vision compared with Group II (93.5 vs. 73.7; p<0.01) and Group II had a higher

Table 2 Disposition of subjects

	Dropouts				Participants			
	1974–1984		1985–1993		1974–1984		1985–1993	
	N	%	N	%	N	%	N	%
No response	28	60.9	28	73.7	29	17.5	12	11.2
Moved	9	19.6	0	-	5	3.0	2	1.9
Gone to other dentist	4	8.7	6	15.8	15	9.0	3	2.8
Does not want to return	4	8.7	3	7.9	11	6.6	4	3.8
Too frail	1	2.1	1	2.6	9	5.4	1	0.9
All teeth extracted	NA*	NA	NA	NA	22	13.3	15	14.0
Died	NA	NA	NA	NA	35	21.1	6	5.6
On recall	NA	NA	NA	NA	40	24.1	64	59.8
Total	46	100.0	38	100.0	166	100.0	107	100.0

If subjects had all their abutments extracted or died prior to being in the study for 2 years, they were by definition not included in the Dropout population. *NA* not applicable

Table 3 Dropouts (1974–1984) by age group and gender

Age in years	Male		Female		Total	
	N	%	N	%	N	%
<50	17	54.8	7	46.7	24	52.2
51–60	5	16.1	2	13.3	7	15.2
61–65	3	9.7	1	6.7	4	8.7
65+	6	19.4	5	33.3	11	23.9
Total	31	67.4	15	32.6	46	100.0

Table 4 Participants (1974–1984) by age group and gender

Age in years	Male		Female		Total	
	N	%	N	%	N	%
<50	16	16.3	16	23.5	32	19.3
51–60	27	27.6	20	29.5	47	28.3
61–65	21	21.4	16	23.5	37	22.3
65+	34	34.7	16	23.5	50	30.1
Total	98	59.0	68	41.0	166	100.0

Table 5 Dropouts (1985–1993) by age group and gender

Age in years	Male		Female		Total	
	N	%	N	%	N	%
<50	12	52.2	8	53.3	20	52.6
51–60	5	21.7	4	26.7	9	23.7
61–65	1	4.4	0	0.0	1	2.6
65+	5	21.7	3	20.0	8	21.1
Total	23	60.5	15	39.5	38	100.0

Table 6 Participants (1985–1993) by age group and gender

Age in years	Male		Female		Total	
	N	%	N	%	N	%
<50	18	25.0	10	28.6	28	26.2
51–60	12	16.7	13	37.1	25	23.4
61–65	12	16.7	3	8.6	15	14.0
65+	30	41.6	9	25.7	39	36.4
Total	72	67.3	35	32.7	107	100.0

percentage of Dropouts with medical problems associated with soft tissue problems compared with Group I (44.7 vs. 23.9; $p<0.05$). These differences were maintained in the logistic regression model controlling for the other variable with minimal change in significance levels. Therefore, despite the length of the study, the Dropout population was similar in most of the measured characteristics. However, since there were significant differences in two variables and there could be important differences in characteristics not measured in this study, we continued to compare Participants and Dropouts using the established Dropout groups.

Participants remained in the study as long as their overdenture abutments remained healthy and their general health allowed them to return for recall and as long as they believed that we could help them. The distribution of the length of time participants remained in the study by their age at which the overdentures were delivered is

Table 7 Bivariate differences between dropouts. Group I N=46 (1974–1984) and Group II N=38 (1985–1993)

			Chi square	*P*
% with corrected vision	Group I	93.5	6.23	<0.01
	Group II	73.7		
% with medical problems which affect soft tissues	Group I	23.9	4.06	<0.05
	Group II	44.7		

Table 8 Bivariate differences between dropouts. Final logistic regression model

Parameter	Beta	*P*	Odds ratio	Maximum	Minimum
Intercept	–4.47	0.006	-	-	-
% with corrected vision	1.65	0.021	5.21	21.17	1.28
% with medical problems that affect soft tissues	0.96	0.051	2.62	6.88	1.00

Table 9 Length of time participants remained in the study by age group

Time in the study in years	Total N(%)	Age at delivery of overdentures in years			
		50 or Less N (%)	51–60 N (%)	61–64 N (%)	65+ N (%)
5 or Less	74 (27.1)	16 (5.9)	12 (4.4)	14 (5.1)	32 (11.7)
6–10	104 (38.1)	24 (8.8)	25 (9.2)	16 (5.9)	39 (14.3)
11–15	67 (24.5)	17 (6.2)	22 (8.1)	7 (2.6)	21 (7.7)
16+	28 (10.2)	3 (1.1)	13 (4.8)	7 (2.6)	5 (1.8)
Total	273 (100.0)	72 (26.4)	72 (26.4)	44 (16.1)	97 (35.5)

Table 10 Bivariate differences between dropouts Group I (1974–1984) and time matched participants

			Chi square	*P*
Mean age in years	Dropouts Participants	50.0 59.6	12.38	<0.001
% brushing (×2)	Dropouts Participants	82.6 62.1	6.50	<0.01
% using fluoride at least daily	Dropouts Participants	76.1 56.0	18.17	<0.001

Table 11 Bivariate differences between dropouts Group I (1974–1984) and time matched participants. Final logistic regression model

Parameter	Beta	P	Odds ratio	Maximum	Minimum
Intercept	–2.11	2.20	-	-	-
Age	–0.01	0.50	0.99	1.03	0.95
% brushing (×2)	0.94	0.017	2.57	5.56	1.19
% using fluoride daily	2.50	0.033	12.13	120.24	1.22
Interaction between age and fluoride	–0.05	0.027	0.96	1.0	0.91

Table 12 Bivariate differences between dropouts Group II (1985–1993) and time matched participants

			Chi square	*P*
Mean age in years	Dropouts Participants	48.4 59.9	13.42	<0.001
% with corrected vision	Dropouts Participants	73.7 88.8	4.97	<0.02
% brushing (×2)	Dropouts Participants	81.6 60.8	5.04	<0.02

shown in Table 9. Over one third (38.1%) of the subjects were in the study between 6–10 years; another third (34.7%) were in the study for more than 11 years. There were only four subjects who remained in the study for over 20 years and these have been included in the 16 years and longer time group.

Bivariate comparison of characteristics between time-matched Participants and Group I Dropouts indicated significant differences in mean age and oral care habits (Tables 10 and 11). Dropouts were significantly younger than study participants (50 vs. 59.6 years; $p<0.001$). A higher percent of Dropouts reported brushing their overdenture abutments at least twice daily and using fluoride at least once daily compared with Participants. These differences maintained significance in a logistic regression model predicting Dropout status. Higher levels of oral care and younger age were associated with Dropout status. An interaction term of age and fluoride use was also important in the model and indicated that age is more strongly predictive of Dropout status than reported fluoride use.

Bivariate comparison of characteristics between time-matched Participants and Group II Dropouts indicated significant differences in mean age, corrected vision, and tooth brushing frequency (Tables 12 and 13). Similar to the findings with Group I, Group II Dropouts were significantly younger than study Participants (48.4 vs. 59.9 years; $p<0.001$), and a higher percent of Group II Dropouts reported brushing their overdenture abutments at least twice daily. Significantly fewer Group II Dropouts reported having corrected vision compared with time-matched Participants and fluoride use was not an

Table 13 Bivariate differences between dropouts Group II (1985–1993) and time matched participants. Final logistic regression model

Parameter	Beta	P	Odds ratio	Maximum	Minimum
Intercept	0.67	0.59	-	-	-
Age	–0.05	0.003	0.95	0.98	0.92
% with corrected vision	–0.02	0.969	0.98	3.16	0.30
% brushing (×2)	0.71	0.084	2.03	4.52	0.91

important difference between Participants and Group II Dropouts. All three variables maintained independent significance in a logistic regression model predicting Dropout status and there were no significant interaction terms.

Discussion

A study including older populations requires an adequate sample size and should be sufficiently similar to the community to allow study findings to be generalized to the community population. Recruiting older subjects is difficult because it takes longer than planned, can cost more, and fewer persons meet the inclusion criteria and give consent compared with younger persons [4, 10, 18, 23]. Also, because older persons become frail and die, one must compensate for this loss during the study by oversampling. In a longitudinal study it is important to successfully profile and recruit participants who will stay the length of the study.

There were several handicaps that influenced participants in this study. First, the study was not funded externally because the National Institute of Dental and Cranial Research (NIDCR) infrequently funds single site clinical studies and we were not directly testing a material or a product, so the study was not attractive to manufacturers. Therefore, funds were not available to reimburse subjects for participating or even for parking. Additionally, the coordinating clerical staff, who were not paid as research assistants but helped out of goodwill as an extension of their job description, conscientiously recalled patients.

When patients returned on recall, they were given a free examination and cleaning and were required to pay only for their maintenance needs such as replacing restorations or repairing or relining dentures. This was attractive for these subjects as the majority had sought treatment in our student clinics at reduced fees because they had limited income, lacked dental insurance, or were retired and living on a fixed income, which did not allow for many discretionary expenses. In retrospect, it would have been interesting to collect more data on income and education and previous occupation as this has been shown in other studies [2, 5, 22] to influence utilization. The study subjects' only motivations for returning were their personal relationships with the author and believing that overdentures were beneficial to them and improved their function with dentures.

Payne et al. [19] have suggested that loss to follow-up can be reduced by maintaining annual contact with subjects by sending birthday cards, etc. Although the recall schedules for the subjects were individualized after the first year and we tried to have them come back at 6-month intervals, for many the recalls occurred no more than once a year. Because Payne et al. [19] also suggested that calling the subjects directly helped to reverse refusals, we utilized this method but had a high frequency of telephone numbers that were incorrect, not being answered or out of service. The Payne group also suggested obtaining the names and addresses of two close relatives during the initial interview who could be contacts if the subject moved during the study. This approach was not considered when we began the study.

Patients keeping teeth as overdenture abutments are similar to patients who have terminal dentitions. They have lost many of their teeth due to caries and periodontal disease and now the dentist is asking them to change their behaviors radically. These patients may represent individuals who have avoided dental care for a variety of reasons, which may explain why more men than women accepted this treatment. Numerous studies [6, 24] have shown that because men utilize dental care less than women, they tend to have more teeth.

This study began in 1974 and ended in 1996. Because people are influenced by the economy and politics, they change over time. To take into account some of these cohort effects, the population in the study was divided into two 10-year cohorts: 1974–1984 and 1985–1993. The two Dropout cohorts were compared with each other as well as with the Participants.

The only profile we established on our Dropout population was that they were younger and possibly more mobile. It is not surprising that they had fewer vision problems, which are age-associated changes. The smoking data is flawed because we did not begin collecting information on this population until 1979. For the first cohort we did not have smoking data on 56.5% of the Dropouts and 20.3% of the Participants. For the second cohort it was 5.3% of the Dropouts and 3.7% for the Participants. Although we found some differences with the smoking data between Dropouts and Participants, we did not report it because of our general concern about the data. A surprising predictor for becoming Dropouts was better brushing and topical fluoride use after receiving the overdentures.

The integrity of an overdenture abutment requires the patient to clean the teeth daily with a toothbrush and use a high concentration topical fluoride gel (5000 ppm F) [8, 20, 21]. In this study the oral health behaviors do not reflect well on the Participants. An explanation may be that when we began the study in 1974, the only fluoride gel available was Karigel, an acidulated phosphate fluoride (5000 ppm) at pH 5.6 (Young Dental Company, Earth City, MO, USA). As this was an acid gel, we were worried about irritating the gingiva and initially advised our patients to use one drop in each overdenture depression in the denture every second day after cleaning and not to eat or drink anything for 1/2 h. In 1985 Karigel-N became available to us, and as this is a neutral fluoride, we switched our patients to using this home-use fluoride on a daily schedule. Clinically, we found that not brushing daily or using fluoride were significant predictors for caries and tooth loss [7, 8]. Therefore, it was surprising that so many of the early cohort Group I, especially among the Dropout group, reported that they used the fluoride daily as this is not a behavior non-compliant subjects would engage in.

Conclusions

We have no explanation why our Dropout population seemed to be reporting that they were more conscientious about home care than the Participants. Thus, we have no clear markers except age to differentiate between Dropouts and Participants. However, compared with older subjects, younger people who have reached this terminal stage of tooth loss may be persons who avoid dental care until they can no longer do so or are persons who indulge in risky health behavior until it catches up with them. We must design studies to identify this population and develop an intervention which prevents them from becoming edentulous. However, as in any longitudinal study evaluating persons with terminal dentitions, our study suggests we need to compensate for losing younger persons from the study, as well as older persons, by oversampling them.

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