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ABSTRACT

Implementation of new therapies is usually governed by financial considerations, so efficacy studies should also include cost comparisons. The cost and effectiveness of mandibular conventional dentures (CD, n = 30) and two-implant overdentures (IOD, n = 30) were compared in elderly subjects. Effectiveness (Oral Health Impact Profile, OHIP-20) and cost were measured up to one year post-treatment. Data for subsequent years were estimated by the Delphi method. Using an average life expectancy of 17.9 years, the equalized annual costs (in Canadian dollars) were $399 for CD and $625 for IOD ($p < 0.001$), and the equalized annual values for the outcome (OHIP-20) were 47.0 for CD and 31.3 for IOD treatment ($p < 0.05$). These values translate into a yearly additional cost for IOD treatment of $14.41 *per* OHIP-20 point. These results are key to the implementation of programs to provide this form of therapy for edentulous adults.

KEY WORDS: cost-effectiveness, healthcare economics, elderly, mandible, edentulous, dental prosthesis, dental implants.

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INTRODUCTION

Mandibular overdentures on 2 anterior implants provide significantly greater satisfaction, quality of life, and better mastication than do conventional dentures in edentulous subjects (Boerrigter *et al.*, 1995; Meijer *et al.*, 1999; Naert *et al.*, 1999; Awad *et al.*, 2000, 2003; Heydecke *et al.*, 2003). Millions of people throughout the world, particularly the elderly, could benefit from this treatment. The prevalence of edentulism in seniors (aged 65+) has been estimated to be 26% in the USA, 15-78% in Europe, 24% in Indonesia, and 11% in China (Petersen, 2003). However, even the simplest overdentures cost more than conventional dentures, and few health programs pay for implant-supported prostheses. Although a panel of experts recently recommended that mandibular overdentures become the standard of care for edentulism (Feine *et al.*, 2002), this will not occur until the true cost and benefits of conventional and overdenture treatments can be compared.

Walton *et al.* (1996) estimated the cost of providing mandibular implant prostheses in British Columbia, but used the fees charged by clinicians rather than their costs. Resource-based micro-costing gives a better approximation of the true cost of treatment. It is based on measuring all resources used (materials, time, etc.) and the best estimate of their true costs (opportunity costs) (Gold *et al.*, 1996).

The usual denominator in economic analyses of treatments is years of life gained (Gold *et al.*, 1996), but for a non-fatal condition, it is appropriate to use an index of the disease-specific health-related quality of life (Barkun *et al.*, 1997; Sevick *et al.*, 2000). Therefore, we measured oral-health-related quality of life with the 20-item Oral Health Impact Profile (OHIP-20) (Allen and Locker, 2002; Awad *et al.*, 2003; Heydecke *et al.*, 2003), together with resource-based micro-costing of treatment (Takanashi *et al.*, 2004), during a randomized controlled trial (RCT) to compare conventional and implant-supported mandibular overdentures in 60 elderly edentulous patients in Montreal, Canada. We used these data to derive the cost associated with the improvement brought by the overdentures.

MATERIALS & METHODS

Trial Characteristics

Sixty independently living males and female, aged 65-75 yrs and edentulous for at least 5 yrs, were enrolled. The RCT was approved by the McGill University Institutional Review Board, and informed written consent was obtained from all subjects. Inclusion and exclusion criteria have been described (Heydecke *et al.*, 2003).

Sample size was based on the primary outcome of the study, general satisfaction, measured on 100-mm visual analogue scales (Awad *et al.*, 2003). Subjects were randomly assigned to the groups in blocks of ten, by means of computer-generated random numbers.

Subjects received either mandibular overdentures (IOD; n = 30) retained by ball attachments on 2 implants (ITI 048.242/243, Straumann, Waldenburg, Switzerland) or conventional dentures (CD; n = 30), both opposed by new conventional maxillary dentures. All dentures were constructed by one prosthodontist.

Economic Assessment

Cost

Direct and indirect costs of treatment and maintenance were calculated, in Canadian Dollars-CAN $, for each patient up to 1 yr after delivery of the prostheses in 1999 (Takanashi *et al.*, 2004). Direct costs included labor, materials, drugs, laboratory work, and radiography. The time spent by the clinicians and the surgical assistant was measured, and opportunity costs for labor were estimated with the use of census data and other sources. A record of all drugs and disposable and re-usable materials was kept, and market prices were obtained. Indirect costs included the patients' transportation and cost of their time while receiving treatment. Overhead costs were calculated as a percentage of the 'clinician time' cost. A detailed description of the techniques has been published (Takanashi *et al.*, 2002, 2004).

Since there were no data on cost and frequency of consultation from the trial, beyond those collected for fabrication and maintenance during the first year post-treatment, a literature search was conducted in MEDLINE (1970-2002) using key words to identify publications on the maintenance, repair, and replacement of complete dentures and implant-supported overdentures: for CD [(Denture*, complete OR complete denture* OR denture*, full OR full denture*) AND (maintenance OR repair OR service)]; and for IOD [(Denture*, complete OR complete denture* OR denture*, full OR full denture* OR denture*, removable OR removable denture* OR overdenture* OR cover denture*) AND dental implant* AND (maintenance OR repair* OR) service*)]. Data from 7 studies of overdentures were found (Hemmings *et al.*, 1994; Davis *et al.*, 1996; den Dunnen *et al.*, 1997; Watson *et al.*, 1997; Davis and Packer, 1999; Naert *et al.*, 1999; Payne and Solomons, 2000). However, no data were found for conventional dentures or for implant overdentures for observation periods greater than 5 yrs.

Therefore, the Delphi group opinion technique (Dalkey, 1969) was used to generate approximations of the frequency of required maintenance, repairs, and replacements for the period beyond the trial follow-up. Questionnaires based on the published maintenance data were sent by electronic mail to a panel of 30 experts who were asked how often maintenance, replacement, and repair of the 2 types of prostheses would be necessary during a ten-year period. Following the Delphi principle (Dalkey, 1969), means and standard deviations were calculated from the first-wave responses, and the survey was continued with a second set of questionnaires. The respondents were asked to indicate agreement or disagreement with these mean values. In case of disagreement, they provided their current estimate. The survey was stopped when overall agreement across all questions reached 80% (Green *et al.*, 1999). The second questionnaire was sent to the 21 responders, and 13 replied (61.9%). Agreement for the maintenance questions was > 85%, and for differences in outcome, > 94%. We calculated yearly maintenance costs by multiplying the cost *per* procedure obtained from the first-year data with the frequency. Separate estimates of costs were calculated based upon the literature values for expected maintenance requirements of IODs.

Effectiveness

Subjects completed the OHIP-20 survey at the one-year follow-up appointment, and subscale and total sum scores were calculated without item-weighting (Awad *et al.*, 2003; Heydecke *et al.*, 2003). Lower scores represent better outcomes. Group opinions were also used to estimate changes in outcome over a ten-year period. The expert panel was provided with the one-year between-group difference for the OHIP-20, and were asked to give the expected between-group difference in five-year intervals up to 20 years post-treatment.

Cost-effectiveness Analysis

We assumed that no implants would be lost before death (Adell *et al.*, 1990; Zarb and Schmitt, 1996), and that treatment would not alter longevity. From census data, we calculated that the average life expectancy of a 65-year-old Quebec-Canadian from the greater Montreal area would be 17.9 yrs. We also tested the effect of decreasing life expectancy by 5 yrs, and compared cost-effectiveness separately in males and females, assuming remaining life expectancies of 15.7 and 19.8 yrs, respectively (Statistics Canada, 1996).

It is recommended that all costs and outcomes be discounted, starting with the second year, to reflect loss of capital (Gold *et al.*, 1996). There is some debate about the rate of this 'social discount' that should be applied (Gold *et al.*, 1996); 3% is often used, but we also calculated the effect of using a discount rate of 5%.

To express the accumulation of costs and outcomes over the remaining life of the patient, we computed the present discounted value (PDV) of both costs PDV_c and outcomes PDV_o. The PDV is the weighted sum of a given variable discounted over time. The standard formula (Drummond *et al.*, 1997) to compute the PDV is:

$$\sum_{i}^{\text{LEXP}} \frac{X_i}{(1+\text{r})^{i-1}}$$

where LEXP is the life expectancy in years, X_i is the value of the variable (cost or outcome) in year i, and r is the discount rate. We converted PDV_c and PDV_o into their respective constant annual flows, referred to as the equivalent annual value for cost (EAV_c) and for outcome (EAV_o), using the formula

$$E = \frac{K}{A(n,r)}$$

where E is the equivalent annual cost/outcome, K the purchase price, and $A(n,r)$ the annuity factor (n expected life years at interest rate r) (Drummond *et al.*, 1997). To calculate the cost-effectiveness ratio, we divided the between-group difference in EAV_o by the difference in EAV_c.

Statistical Analyses

Between-group comparisons of the effectiveness outcome (one-year post-treatment OHIP scores) as well as of the present discounted values of outcome (PDV_o) and cost (PDV_c) and the respective equalized annual values (EAV_o, EAV_c) were made with independent *t* tests (SPSS 10.0, SPSS Inc., Chicago, IL, USA). An alpha level of 0.05 was set for significance.

Table 1. Age and Sociodemographic Variables for the Two Treatment Groups

		Treatment			
		CD		IOD	
		Mean	SD	Mean	SD
Age		70.5	2.9	69.7	3.2
Total		n	%	n	%
		23	100	25	100
Gender	Male	8	36.4	14	63.6
	Female	15	57.7	11	42.3
Marital status	Single	3	75.0	1	25.0
	Married	11	40.7	16	59.3
	Separated/divorced	3	75.0	1	25.0
	Widowed	6	46.2	7	53.8
Domestic status	Living alone	10	58.8	7	41.2
	Living with family	11	42.3	15	57.7
	Living with other persons	2	100.0		
Education	Primary	1	33.3	2	66.7
	Secondary	13	52.0	12	48.0
	Technical/college	6	54.5	5	45.5
	University degree	2	33.3	4	66.7
Employment	Part time	2	66.7	1	33.3
	At home	1	100.0		
	Retired	21	47.7	23	52.3
Income (CAN $)	< 20,000	8	50.0	8	50.0
	20,000-30,000	7	63.6	4	36.4
	30,000-40,000	4	44.4	5	55.6
	40,000-50,000	3	42.9	4	57.1
	> 50,000	1	20.0	4	80.0

Table 2. Between-group Comparison of the Oral-health-related Quality-of-Life Scores (OHIP-20)

OHIP Category	CD Mean	CD SD	IOD Mean	IOD SD	Mean Difference	95% CI lower	95% CI upper	p-value*
Functional limitation	10.0	4.5	6.8	2.5	3.20	1.0	5.4	0.005
Physical pain	12.0	5.1	7.5	2.4	4.48	2.1	6.9	0.001
Psychological discomfort	4.8	3.0	2.9	1.2	1.86	0.5	3.2	0.009
Physical disability	9.5	4.2	5.7	2.0	3.80	1.9	5.7	0.0001
Psychological disability	3.9	2.0	2.8	1.2	1.07	0.1	2.0	0.029
Social disability	4.0	2.5	3.1	0.4	0.92	-0.2	2.0	0.089
Handicap	3.2	1.7	2.2	0.6	0.97	0.2	1.7	0.014
Total	47.3	19.7	31.0	8.3	16.30	7.3	25.4	0.001

* Independent *t* tests.

RESULTS

Forty-eight of the 60 original subjects attended the one-year follow-up appointment. Seven subjects with CD and five with IOD did not attend; three could not be found, seven had general health problems, and two refused because of general dissatisfaction. The missing subjects had lower income than the participants ($p = 0.022$, Mann-Whitney-U-test), but pre-treatment OHIP values were not significantly different. No significant differences between treatment groups for any of the demographic variables were found (Table 1).

Outcome and Cost during the First Year

At baseline, no differences in OHIP-20 score were found between groups (Heydecke *et al.*, 2003). One year post-treatment, the implant overdenture group had significantly lower (better) scores on all 7 OHIP-20 domains ($p < 0.03$) except social disability (Table 2). The post-treatment mean total OHIP-20 score was significantly lower in the IOD (16.3 OHIP-20 units; $p < 0.001$) than in the CD group. Mean cost of treatment was $2057 for CD and $3650 for IOD treatment (Takanashi *et al.*, 2004).

Estimates of Cost after First Year

Predicted costs were based on the current cost of the procedure and the mean frequency of the procedure, as estimated by the expert panel. They predicted that prostheses will need to be replaced during the average lifetime of the subjects, resulting in an annualized cost of $167 for IODs and $134 for CD (Table 3). Relining the CD denture was expected to occur 0.3 times *per* year at an annual cost was $47. Although the reline procedure was more expensive for IOD, the annual cost was lower because of the frequency. The general check-up for IOD was more expensive and more frequent than for CD. The third most expensive procedure was the replacement of the IOD attachment clips ($45).

The between-group differences in OHIP-20 units at 5, 10, 15, and 20 yrs post-treatment were predicted to be 12.8, 12.5, 13.4, and 14.2, respectively.

Costs and Outcomes

Based on an average life expectancy of 17.9 yrs and a discount rate of 3%, the total established lifetime cost (PDV_c) was $5646 for conventional treatment and $8852 for implant overdentures. The corresponding EAV_c was $399 for CD and $625 for IOD. The lifetime PDV_o was 666 OHIP-20 points for CD and 443 for IOD; the EAV_o was 47 units for CD and 31 units for IOD treatment (Table 4). Between-group differences were all significant ($p < 0.001$).

Cost-effectiveness

Between-group differences in EAV_c and EAV_o were $226 and 15.7 OHIP-20 points. This means that it costs $14 *per* year to improve oral-health-related quality of life by one OHIP-20 point through IOD treatment (Table 4).

Sensitivity analysis showed that these results were relatively robust in the face of changes in life expectancy and discounting. Additional annualized costs for the IOD group as a whole ranged from $226 (assumed life expectancy of 17.9 and 3% discount) to $271 (life expectancy 12.9, 5% discount) for an improvement of approximately 16 OHIP-20 points. Separate calculations for males and females increased the range from $208 for females with an average lifespan of 19.9 yrs and a 3% discount rate, to $282 for males with a 15.7-year life span and 5% discount rate (Table 4).

Table 3. Maintenance Costs *per* Procedure (CAN $)

Procedures	Cost/procedure (CAN $)	IOD Treatment Events/year Experts	IOD Treatment Events/year Literature	IOD Treatment Cost/year (CAN $) Experts	IOD Treatment Cost/year (CAN $) Literature	CD Treatment Cost/procedure (CAN $)	CD Treatment Events/year Experts	CD Treatment Cost/year (CAN $) Experts
General check	37	1.06	Not reported	39.27	39.27†	24	0.85	20.44
Reline base	172	0.22	0.10	37.47	17.70	157	0.30	46.83
Adjust base	30	0.53	0.30	16.03	9.10	31	0.84	26.06
Adjust occlusion	30	0.33	0.07	9.85	2.02	31	0.34	10.44
Repair base	115	0.19	0.03	21.67	3.59	101	0.20	20.29
Denture tooth replacement	90	0.17	0.02	14.91	1.64	91	0.15	14.09
Replacement of denture	1433	0.12	0.04	167.18	60.63	896	0.15	134.40
Adjust attachment clip	32	0.57	0.27	18.20	8.53	*	*	*
Replace attachment clip	184	0.25	0.14	45.29	25.54	*	*	*
Retighten ball attachment	10	0.43	0.32	4.31	3.23	*	*	*
Replace ball attachment	104	0.13	0.15	13.44	15.64	*	*	*
Scaling of peri-implant mucosa	8	0.93	0.07	7.47	0.56	*	*	*
Total cost of maintenance from 2nd year				395.11	187.45			272.55

† Value from expert survey used.
* Does not apply.

However, analysis of published data suggests that the annual IOD maintenance cost is much lower than that predicted by the experts ($33 *vs.* $130, Table 4). Over 17.9 yrs, the mean difference between the two estimates is $2733.

DISCUSSION

One yr after treatment, those in the group that received the mandibular implant overdenture had significantly better oral-health-related quality of life than those who received mandibular conventional dentures. The post-treatment OHIP total mean score was approximately 33% better in the IOD group than in the CD group, at an additional expense of $1593.

This is the starting point for the calculation of lifetime benefits and costs. Cost *per* quality-adjusted life-years (QALYs) saved is computed for durable health interventions (Gold *et al.*, 1996). Although this method has previously been applied to oral health interventions (Birch and Ismail, 2002), it is not an appropriate way of assessing treatments that may not prolong life. Therefore, we used cost *per* quality-of-life unit, an approach that has been used to assess the benefit of treatments for heart disease (Hamilton *et al.*, 1995), gall stones (Barkun *et al.*, 1997), and osteoarthritis of the knee (Sevick *et al.*, 2000).

At the end of the first year, the average cost of the IOD was about $1600 more than that of the CD because of the cost of the implants and surgery. However, analysis of the data suggests that implants in the intra-foraminal area of the mandible will last for more than 20 yrs. It is therefore appropriate that their costs be amortized over the remaining lifetime of the subjects. We did not estimate costs associated with other common variables, such as masticatory efficiency. However, there was an improvement of 32% in the 'functional limitations' OHIP-20 subscale and 40% in 'physical disability', *vs.* 33% in the total OHIP score. This suggests that the cost of unit improvements in function is similar to those of overall improvements.

We used modeling to project costs and benefits for the estimated lifetime of subjects, as is usually done (Buxton *et al.*, 1997). However, we had to use the Delphi group-opinion approach (Dalkey, 1969) to provide estimates for maintenance costs of both prostheses, because of the lack of published cost data. The model predicted that the additional cost of IOD over a lifetime of 17.9 yrs was $226 *per* year for an average between-group difference of 15.7 OHIP-20 points, compared with CD treatment, or $14.41 *per* OHIP point *per* year.

If implant-supported overdentures became the 'standard of care', as has been proposed, the effect of not providing implants to a patient would be to increase the number of annual negative impacts by approximately 50% [(31.0-47.3)/31.0].

We used total OHIP-20 score as the measure of the effectiveness of oral prostheses, and therefore our results cannot be directly compared with specific measures such as chewing ability. The Delphi analysis estimated an annual maintenance cost for IODs ($395 without discounting) that was $122 greater than that for CDs ($273). However, analysis of data from published studies predicts much lower annual costs for IODs ($187) than those derived from expert opinion. This suggests that the real annual cost difference between the IOD and CD groups may be similar to, or even smaller than, our current best estimate. Therefore, it is important to continue the analysis of maintenance costs of these prostheses for at least one decade.

Provision of two-implant-supported mandibular overdentures instead of a conventional mandibular denture improves oral-health-related quality of life by approximately 33%, approximately one standard deviation. Compared with this substantial improvement, the estimated incremental cost of the overdenture of $226 *per* year seems relatively modest. Although the dearth of studies of the cost-effectiveness of other oral health interventions prevents us from concluding that the implant therapy would be considered 'cost-effective' or acceptable to payers, it does provide important information to decision-makers and patients about the costs and benefits of

Table 4. Between-group Comparisons[a] of PDV_c/PDV_o and EAV_c/EAV_o

Life Expectancy (yrs)	Discount Rate (%)	Treatment	PDV_c (CAN $) Mean	SD	Between-treatment Increment	PDV_o (OHIP points) Mean	SD	Between-treatment Increment	EAV_c (CAN $) Mean	SD	Between-treatment Increment	EAV_o (OHIP points) Mean	SD	Between-treatment Increment	Cost/Effectiveness Ratio (CAN $/OHIP point/yr)
17.9*	3	IOD	8852.09	304.02	-3205.88*	443.3	117.4	222.6**	624.88	21.46	-226.31*	31.3	8.3	15.7**	14.41
		CD	5646.22	748.80		666.0	278.8		398.57	52.86		47.0	19.7		
	5	IOD	8104.53	304.02	-2973.99*	383.9	101.7	193.3**	660.30	24.77	-242.30*	31.3	8.3	15.8**	15.38
		CD	5130.54	748.80		577.2	241.5		418.00	61.01		47.0	19.7		
12.9	3	IOD	7582.97	304.02	-2812.20*	341.9	90.8	174.0**	692.26	27.75	-256.73*	31.2	8.3	15.9**	16.16
		CD	4770.76	748.80		515.9	215.6		435.53	68.36		47.1	19.7		
	5	IOD	7152.00	304.02	-2678.52*	307.7	81.7	156.9**	725.12	30.82	-271.57*	31.2	8.3	15.9**	17.08
		CD	4473.48	748.80		464.6	194.1		453.55	75.92		47.1	19.7		
Influence of maintenance frequency based on literature only or an average of literature and expert estimates															
Literature only	3	IOD	6118.07	304.02	-471.85***	443.3	117.4	222.6**	431.88	21.46	-33.31***	31.3	8.3	15.7**	2.12
17.9		CD	5646.22	748.80		666.0	278.8		398.57	52.86		47.0	19.7		
Average literature/experts		IOD	7485.08	304.02	-1838.86*	443.3	117.4	222.6**	528.38	21.46	-129.81*	31.3	8.3	15.7**	8.26
17.9		CD	5646.22	748.8		666.0	278.8		398.57	52.86		47.0	19.7		

[a] Sensitivity analyses were carried out with different discount rates and life expectancies. In addition, the influence of using maintenance frequencies based on literature and expert panel estimates was calculated.
* $p < 0.0001$.
** $p < 0.001$.
*** $p < 0.01$.

these therapies. It also provides an important first contribution to a body of evidence from which a consensus on critical criteria could emerge.

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