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Original Article

A comparison of the effect on oral health quality life by two attachment designs used with implant supported removable overdentures

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ABSTRACT

Aim: The purpose of this study was to investigate the impact on oral health related quality of life by ball and magnet attachments within implant supported mandibular overdentures (ISMOD) using patient-centred outcome measures (OHIP-20). Our a priori hypothesis was that there is no difference in patient oral health related quality of life between the two attachment types.

Materials and Methods: The study was designed as a within-subject crossover randomized clinical trial with initially twenty-two edentulous patients lately using complete dentures were recruited. Sixteen patients completed the study; nine female patients with a mean age 62 years and a mean of 22 edentate years; seven male patients with a mean age 67.8 years and a mean of 20 edentate years completed both arms of the crossover study. Each patient completed an OHIP-20 questionnaire at baseline before had two implants placed in the intraforaminal region of the mandible then randomly selected to receive a implant supported mandibular overdenture retained by either magnetic or ball attachment. After three months of using the overdenture, patients repeated the OHIP-20 questionnaires before having their attachments replaced by the other design. After a further 3 months of using the second attachment, patients completed the final questionnaires. The outcome variables of OHIP scores were compared between baseline and the two attachment types using paired t-tests.

Results: The impact of denture wearing on patients oral health related quality of life decreased significantly between baseline and both prostheses designs for all domains of the OHIP -20 and total OHIP-20 ($p < 0.05$).

Conclusion: The significant reduction in impact of denture wearing on patients oral health related quality of life with ball attachments is greater than that for magnetic attachments however both designs provide significantly improved oral health related quality of life than conventional dentures

Keywords: Implants, overdenture, ball attachments, magnets

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INTRODUCTION

Until recently, replacement of missing teeth and their associated structures by conventional complete dentures was considered as the only reliable treatment of edentulousness. The success of this treatment is however not predictable and is highly dependent on patient's adaptability [(1)]. Significant lack of denture retention and stability in patients with problems adapting to conventional compete dentures is attributed to denture quality [(2, 3)] and poor anatomical conditions [(4, 5)].

Different approaches are used by patients and prosthodontists to facilitate the successful wearing of complete dentures. Patients may try to adapt to their dentures by developing the muscular skills or reflexes to control dentures in position, but with increasing age some functional elements in the

central nervous system may be diminished and as a result there will be a decrease of neurophysiologic adaptive capacity for wearing complete dentures [6].

One treatment method directed toward the improvement of complete denture support and retention in elderly edentulous patients is the use of a fully implant-supported, or mucosa-and implant supported complete overdenture. Of these two approaches the mucosa and implant-supported dentures is perhaps used more frequently. The encouraging patient responses to their provisional implant-supported overdentures prolonged wearing suggested that their lack of adaptability had been eliminated, and that by obtaining adequate denture retention and stability patients were able to adapt to complete dentures [7].

There are two basic designs of implant-supported prostheses: a fixed prosthesis that is screwed onto the implants by the dentist (FP) [8] and a removable type that is retained by means of precision attachments on the individual implants, or onto a bar attached to them (RP) that usually requires only two implants and commonly utilizes a ball and 'O' ring or stud or magnetic attachment [9].

The successful use of attachment systems with implant-supported overdentures has proven both clinically predictable and effective approach of obtaining improved retention [10]. Selection of the optimum attachment design for implant-supported overdentures, particularly in elderly patients, should allow; ease of placement and removal of prostheses; maintenance of oral hygiene; a traumatic and even distribution of stress to both the mechanical and biologic supporting structures [11].

While almost all aspects of mandibular supported overdentures are relatively well investigated using patient centred outcome measures such as the impact on quality of life, this has not been widely applied to retentive attachment designs [12].

A comprehensive dental treatment to some extent can be technically assessed, but it is more complex to assess the consequences of such treatment on a patient quality of life. Therefore, using the OHIP in clinical trials would be suitable for establishing an objective baseline against which the assessment of dental care program can be evaluated [13].

Oral Health Impact Profile (OHIP) is currently the most comprehensive and sophisticated measure for oral health [14]. OHIP has been shown to be reliable [15], sensitive to changes [16, 17] and exhibit suitable cross-cultural consistency [18]. In addition, the OHIP possess a highly significant advantage that statements are generated from a true representative patient group thus increasing the ability of the measure to recognize social consequences of oral problems which are regarded important by patients [19]. OHIP-20 item version was developed by analyzing data from the Ontario study and data from a longitudinal clinical trial of OHRQL in edentulous patients with removable denture wearing problems [20, 21]. The Satisfactory, validity, and sensitivity of the OHIP-20 have been confirmed [22]. Shorter versions of OHIP still provide a basic overall health despite the loss of some comprehensiveness and sensitivity [20].

There is sufficient evidence to indicate that significant improvements in OHRQoL can be achieved by mandibular prostheses supported by two implants in edentulous patients compared with a conventional denture [22]. These improvements were recorded in all OHIP sub-scales [23] and numerous studies reported similar supporting results [24, 25].

Although numerous randomized crossover trials (RCTs) evaluated impacts of wearing implant supported mandibular overdentures (ISMODs) on patient's quality of life, there are, few studies comparing the impact of different attachment systems used to retain implant over dentures on patient's oral health quality of life.

The aim of this study was to determine the impact of two designs of retainer (magnet or ball attachment) on oral health related quality of life 3 months after placement. The null hypothesis being that there is no difference in OHRQoL between the two forms of attachment.

MATERIALS AND METHODS

The study was a randomized crossover within-subject clinical study with three data gathering stages comparing; ball and magnet attachments used with ISMOD prescribed for the edentulous mandible. The sample size (n=18) calculation was based on data previously collected from subjects with conventional and long bar overdentures (LBOs). The number of subjects initially recruited was increased to twenty two in order to compensate for potential subject withdrawal.

Subjects were recruited from edentulous patients referred by their general dental practitioners for the provision of replacement complete dentures. All

the patients were experiencing difficulty in wearing conventional complete dentures and received a full clinical assessment by a specialist prosthodontist in order to evaluate their eligibility for implant treatment. They were all experienced denture-wearers of at least five years and had not previously been treated with dental implants. Additional clinical inclusion criteria to participate in the study included a good general medical condition and adequate mandibular alveolar bone to receive the dental implants without the need for ridge augmentation procedures.

Detailed written information, informed consent, and demonstration aids were provided to all subjects regarding the study, different treatment options, possible risks, and the method used for treatment assignment. Patients were treated with a new maxillary conventional complete denture and implant-supported overdenture in the mandible. Full details of the clinical trial used in this study are available in a previously published article by the main author [26]. The study design is shown in (Figure 1).

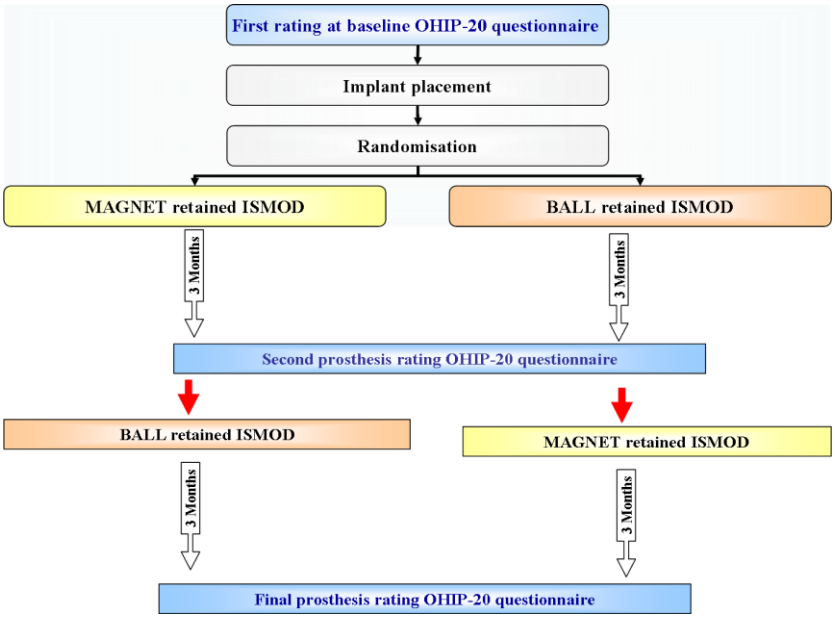

Figure 1: Overview of study design

DATA RECORDING AND STATISTICAL ANALYSES

Following recruitment to the study and prior to ISMOD placement patients completed baseline OHIP-20 questionnaires. The sequence of allocation was randomly assigned by a computer program, so that half of the patients received the ball attachment overdentures first.

Following ISMOD insertion patients of the two experimental groups wore the initial ISMOD design for a period of three months and then completed further assessment OHIP-20 questionnaires. Patients were then provided with the alternative design of ISMOD (as described above) and wore their ISMOD for a further 3 months before completing final patient OHIP-20 questionnaires.

Items of the OHIP-20 were recorded on five-point Likert scales (never, hardly ever, occasionally, fairly often, very often, always), which were transferred into numerical values between zero (never) and five (always) higher scores indicating a worse oral health related quality of life condition. Totaling responses to these items gave scores for the six OHRQoL domains; physical pain (4 items, score can range from 0-20); psychological discomfort (2 items, score can range from 0-10); physical disability (4 items, score can range from 0-20); psychological disability (2 items, score can range from 0-10); social disability (4 items, score can range from 0-20); and handicap (1 item score

can range from 0-5). The scores on all six domains were further summed to obtain a 100 maximum total OHIP score.

Data were transcribed onto a spread sheet and checked for errors. The statistical analyses were carried out using SPSS statistical software (SPSS for Windows: Version 14.0, 2006) utilizing the baseline data (with the previous conventional dentures) to assess comparability of the two retentive designs used in this study. Mean and standard deviation scores were calculated for each attachment type and at baseline for each domain of the OHIP-20 questionnaire. As the data were normally distributed, comparison between baseline scores with each prosthesis design and between the two designs was carried out using paired t-tests. It was accepted that differences were statistically significant if alpha was less than 0.05.

A distribution-based measure of change, effect size (ES) [27], was also calculated to evaluate the size of clinical change of patient satisfaction offered by each attachment. Effect sizes from baseline to post-treatment and between attachments were calculated using the following equation:

$$\mathbf{ES=}\ \frac{\text{Mean baseline score - mean (ball or magnet attachment) score}}{\text{Standard deviation of mean baseline score}}$$

The difference in scores for each attachment recorded at baseline to 3 months were calculated and divided by the standard deviation at baseline to give ES. The scale of change is considered of small clinical magnitude if ranged 0.2-0.5, moderate 0.5–0.8, and above 0.8 are large.

RESULTS

Six patients out of the twenty-two patients who recruited into the study were unable to complete the study. All patients who withdrew were female resulting in a final sex ratio of 9:7 (female : male).

The mean scores for total OHIP-20 and the OHIP-20 subscales at baseline and 3 months post-treatment for both prosthesis designs are presented in (Table 1, 2, 3 and Figure 2). The greater OHIP scores signify a greater impact on quality of life. Significant improvements in OHRQoL had occurred, as measured by a decrease in OHIP score, for both attachment systems compared to those of the previous conventional dentures at baseline ($p < 0.05$).

Table 1: Mean differences in OHIP-20 when comparing between baseline and 3 months post-delivery of each retainer ISMOD design.

Variable	Baseline Mean ±SD	Ball ISMOD Mean ±SD	Magnet ISMOD Mean ±SD
Total OHIP-20	64.88 ±22.37	16.19 ±18.29	28.31 ±20.74
Physical pain	13.06 ±04.86	04.12 ±03.72	06.125 ±04.65
Psychological discomfort	07.06 ±03.15	01.12 ±01.71	02.75 ±01.88
Physical disability	14.44 ±06.04	03.12 ±04.26	06.19 ±05.29
Psychological disability	07.87 ±02.58	01.44 ±02.53	02.56 ±02.78
Social disability	04.50 ±04.02	01.50 ±04.47	03.25 ±04.96
Handicap	03.44 ±02.22	00.56 ±01.26	01.12 ±01.67

Table 2: Mean differences in OHIP-20 when comparing between baseline and 3 months post-delivery of ball retained ISMOD.

Variable	Mean difference ±SD (Ball retainer-baseline)	95% CI	*P*-value
Total OHIP-20	48.69 ±25.39	35.16, 62.22	**0.001**
Physical pain	08.94 ±06.62	5.41, 12.46	**0.001**
Psychological discomfort	05.94 ±03.11	4.28, 7.59	**0.001**
Physical disability	11.31 ±07.18	7.49, 15.14	**0.001**
Psychological disability	06.44 ±03.52	4.56, 8.31	**0.001**
Social disability	03.00 ±03.81	0.97, 5.03	**0.007**
Handicap	02.87 ±02.31	1.65, 4.10	**0.001**

Table 3: Mean differences in OHIP-20 comparing between baseline and 3 months post-delivery of magnet retained ISMOD.

Variable	Mean difference ±SD (Magnet retainer-Baseline)	95% CI	*P*-value
Total OHIP-20	36.56 ±25.68	22.88, 50.25	**0.001**
Physical pain	06.94 ±05.79	3.85, 10.02	**0.001**
Psychological discomfort	04.31 ±03.52	2.44, 6.19	**0.001**
Physical disability	08.25 ±07.50	4.25, 12.24	**0.001**
Psychological disability	05.31 ±03.30	3.55, 7.07	**0.001**
Social disability	01.25 ±04.80	-1.31, 3.81	0.314
Handicap	02.31 ±02.15	1.17, 3.46	**0.001**

Comparison of OHIP scores between the two prosthesis designs shows significantly lower OHRQoL impact for the ball attachment than with the magnet attachment. This was seen not only for the total OHIP score (p=0.036) but also with the sub-domains of psychological discomfort (p=0.017) and social disability (p=0.024) (Table 4 and Figure 2).

Table 4: Mean differences in OHIP-20 when comparing between ball and magnet retained ISMOD 3 months post-delivery.

Variable	Mean difference ±SD	95% CI	***P*-value**
Total OHIP-20	12.1 ±21.12	-23.38, -0.87	**0.036**
Physical pain	02.0 ±05.57	-4.97, 0.97	0.172
Psychological discomfort	01.6 ±02.42	-2.91, -0.34	**0.017**
Physical disability	03.1 ±05.95	-6.23, 0.11	0.060
Psychological disability	01.1 ±02.31	-2.35, 0.10	0.07
Social disability	01.7 ±02.79	-3.24, -0.26	**0.024**
Handicap	00.6 ±01.31	-1.26, 0.14	0.108

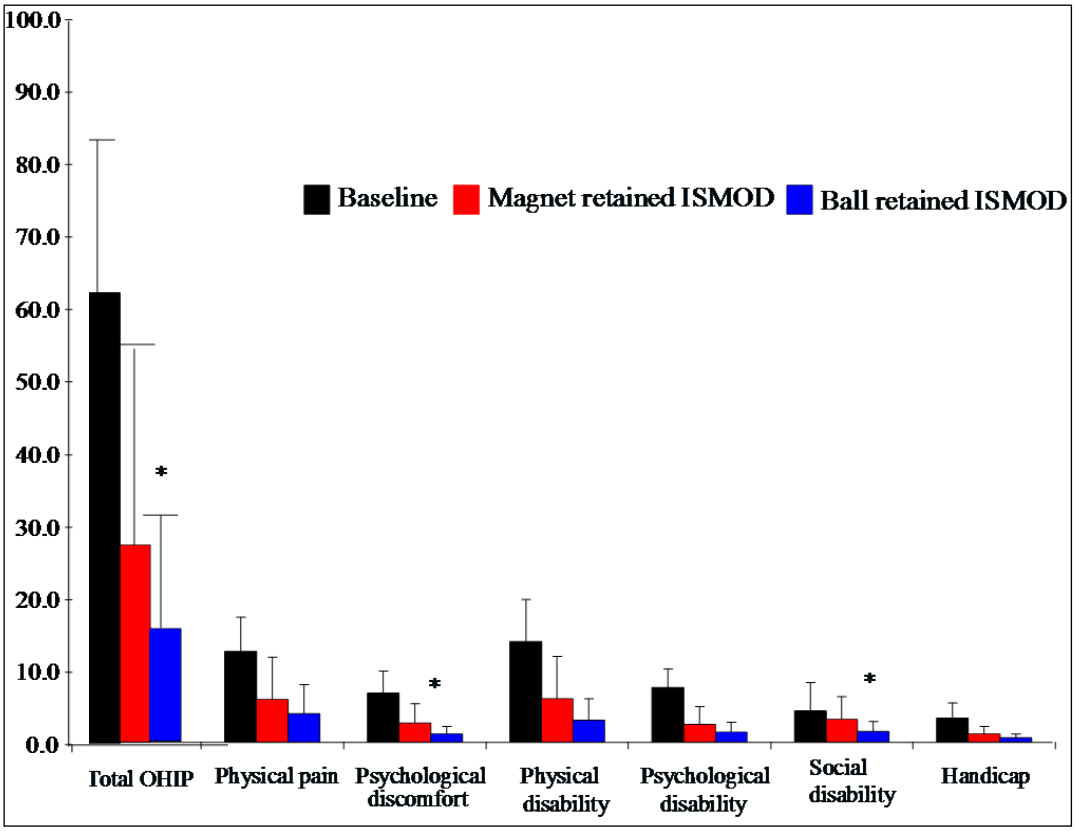

Figure 2: Histogram showing mean OHIP-20 and domain scores for baseline and ISMOD attachment designs. (*=p<0.05)

When comparing both attachment systems with baseline, the ES for the OHIP-20 were far above the threshold value of 0.8 for total OHIP scores and most of the OHIP subscales except for social disability. The ES for the two attachments were generally moderate (0.5-0.8) except for psychological discomfort that showed a large magnitude (1.0) (Table 5 and Figure 3).

Table 5: Effect sizes (ES) of OHIP-20 domains when comparing baseline and 3 months post-delivery of the two attachments.

	Baseline-ball	Baseline-magnet	Magnet-ball
Total OHIP-20	**2.2**	**1.6**	0.7
Physical pain	**1.8**	**1.4**	0.5
Psychological discomfort	**1.9**	**1.4**	**1**
Physical disability	**1.9**	**1.4**	0.7
Psychological disability	**2.5**	**2.1**	0.4
Social disability	0.7	0.3	0.4
Handicap	**1.3**	**1**	0.4

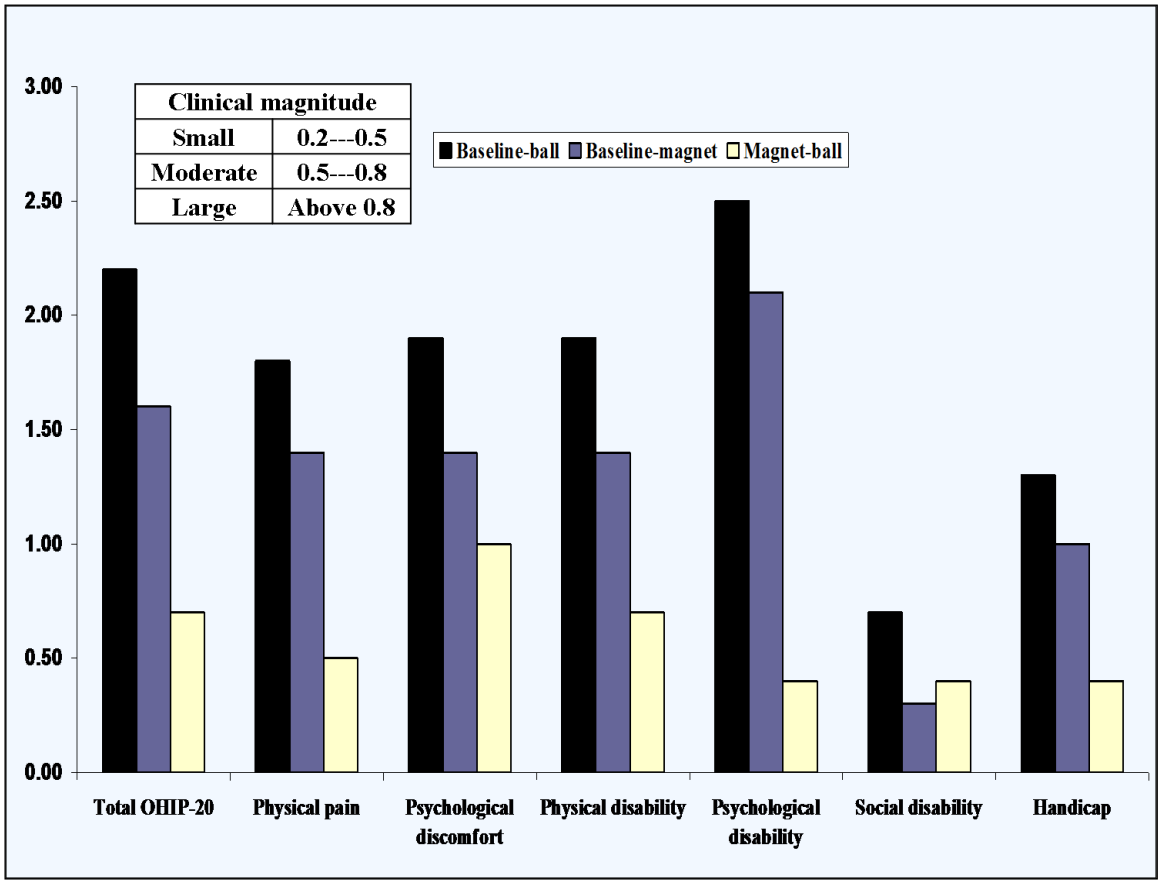

Figure 3: Histogram showing mean Effect sizes (ES) of OHIP-20 domains when comparing baseline and 3 months post-delivery of the two attachments.

DISCUSSION

Numerous studies have aimed to compare conventional dentures with implant supported dentures using these outcome measures [2, 9, 17].There are fewer studies investigating oral rehabilitation of edentulous patients using patient quality of life outcomes to compare attachment designs; however, patients recruited to this study were aware that they would be provided with a mandibular implant supported overdentures with the ultimate retainer design being their choice. This is likely to reduce any bias that may have occurred if patients were randomly allocated to receive a treatment for which they had a preference at the outset.

In comparison to baseline data both ball attachments and magnets when used in conjunction with implant supported mandibular overdentures resulted in a significantly reduced impact on oral health related quality of life. Significantly lower impact scores were observed at three months post-treatment with both designs of attachment across all six domains of the OHIP-20 except for the domain of social disability and the magnet attachment which showed no significant difference to the baseline values. Moreover, the post-treatment ratings of the 20 items were predominantly zeros (never) for the ball attachment (n = 184 [57.5%]) compared to magnet (n = 118 [36.9%]), and baseline (n = 36 [11%]) out of possible 320 demonstrating that for the ball and magnet attachments no negative impact on OHRQoL was recorded more frequently than any other category.

Comparison between attachments shows that the ball attachment had significantly lower scores for total OHIP-20 and four of the six domains (psychological discomfort, physical disability, and social disability). Regardless of the attachment used, the reduced impact on OHRQoL observed in this study is consistent with the findings of previous studies' [2, 28, 29].

In comparison to baseline data, the effect size analysis detected similar changes of large clinical magnitude by the two attachment designs for the impact on OHRQoL domains (except for social disability). This confirms that the a simple two implants-supported mandibular overdenture, retained by either attachment system tested in this study, offers much-improved and better patients' quality of life compared with conventional complete dentures.

In comparison to baseline data, the results of this study demonstrate that the sensitivity to change was high for most of the OHIP-20 subscales, as confirmed by the large effect sizes. This is in turn confirms that OHIP-20 exhibits good psychometric properties, and therefore it is a very useful measure for clinical trials of oral prostheses.

CONCLUSIONS

In conclusion, regardless of retainer design, mandibular implant-supported overdenture achieved a greater positive effect on oral health related quality of life compared to the previous conventional mandibular denture. The ball attachment improved significantly better the patients' perceived oral health status than the magnet attachment for total OHIP-20 scores as well as significantly lowers scores of three domains.
The results of this study supported by the established literature prove that implant supported mandibular overdentures (regardless of retainer design) may provide a suitable treatment modality for the edentulous mandibular patients who present with persistent difficulties wearing conventional mandibular dentures.

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