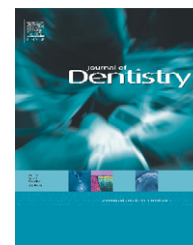


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Two implant retained overdentures—A review of the literature supporting the McGill and York consensus statements

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ABSTRACT

The McGill consensus statement on overdentures (14) was published following a symposium held at McGill University in Montreal, Canada in 2002. A panel of relevant experts in the field stated that: The evidence currently available suggests that the restoration of the edentulous mandible with a conventional denture is no longer the most appropriate first choice prosthodontic treatment. There is now overwhelming evidence that a two-implant overdenture should become the first choice of treatment for the edentulous mandible (14). In 2009, a further consensus statement was released as a support and follow-up to the McGill consensus statement. This report was jointly created by members of the BSSPD (British Society for the Study of Prosthetic Dentistry) Council and the panel of presenters at the BSSPD conference in York, UK in April 2009 (15). This report also highlighted that since the McGill statement in 2002, uptake by dentists of implant technology for complete denture wearers has been slow.

The York statement concluded that ‘a substantial body of evidence is now available demonstrating that patients’ satisfaction and quality of life with ISOD mandibular overdentures is significantly greater than for conventional dentures. Much of this data comes from randomised controlled trials (15).

Whilst it is accepted that **the two-implant overdenture is not the gold standard of implant therapy it is the minimum standard that should be sufficient for most people, taking into account performance, patient satisfaction, cost and clinical time.**

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1. Introduction

The default treatment for the edentulous patient is conventional dentures (complete removable maxillary and mandibular dentures).^{1,2} However, such prostheses, especially the mandibular denture, have well-documented problems such as lack of stability and retention.³ This can be affected by the height and shape of the mandibular ridge. Continued loss of

alveolar bone can occur over time, and cause previously stable dentures to become ill-fitting. It has been reported that more than 50% of those with mandibular complete dentures may have problems with stability and retention.^{4,5}

These factors cause a range of problems. Many patients experience pain when eating and chewing and are often concerned about the denture moving when eating, speaking or laughing and report fears about the negative effect of dentures on social situations.^{6–8} Movement of the denture can lead to

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concerns about aesthetics and patients also report that because of difficulty eating foods that are difficult to bite or chew they have to adapt their food choices, especially when eating out and in social situations. In some cases, people avoid social situations completely.^{7,8}

Implant-supported overdentures (ISOD's) offer better stability and retention of the mandibular denture and better chewing function. Patients also report greater satisfaction with aesthetics because the denture is not visibly moving.³ Implants reduce further bone resorption and the long-term success rate of implants in the lower mandible is at least 95%³ and there are few serious complications.⁵

In 1998, 13% of adults overall and 58% of adults aged 75 and over in the UK were edentulous⁹. In the most recent US oral health survey (1999–2004), 31.3% of adults aged over 75 and 23.9% of those aged 65–74 years were edentulous.¹⁰ In Germany in 2005,¹¹ 22.6% of those in the 65–74 years age group had no natural teeth. Overall, over the past two decades, the trend has been for edentulousness to decrease. In the UK the proportion of edentulous adults was 30% in 1978 falling to 21% in 1988 and 13% in 1998. Similar trends were seen in the US in those aged 65–74 years, there were 28.6% edentulous 1994 falling to 23.9% in the 2004 survey. A similar trend was seen in the over 75 age group.

Whilst rates of edentulism are falling in most Western countries population demographics are changing; as people live longer there will be an increasing proportion of people in the older age group, the group most likely to need dentures.^{10–12} Despite this, it does seem likely that the absolute number of people who need complete dentures in the developed world will decrease over the next few decades but this will still leave a substantial number of edentulous patients requiring treatment. In the UK this is likely to be half the number required at the end of 1999.¹³

1.1. The McGill and York consensus statements on overdentures

The McGill consensus statement on overdentures¹⁴ was published following a symposium held at McGill University in Montreal, Canada in 2002. A panel of relevant experts in the field stated that: 'The evidence currently available suggests that the restoration of the edentulous mandible with a conventional denture is no longer the most appropriate first choice prosthodontic treatment. There is now overwhelming evidence that a two-implant overdenture should become the first choice of treatment for the edentulous mandible'.¹⁴ In 2009, a further consensus statement was released as a support and follow-up to the McGill consensus statement. This report was jointly created by members of the BSSPD (British Society for the Study of Prosthetic Dentistry) Council and the panel of presenters at the BSSPD conference in York, UK in April 2009.¹⁵ This report also highlighted that since the McGill statement in 2002, uptake by dentists of implant technology for complete denture wearers has been slow.

The York statement concluded that 'a substantial body of evidence is now available demonstrating that patients' satisfaction and quality of life with ISOD mandibular overdentures is significantly greater than for conventional dentures. Much of this data comes from randomised controlled trials'.¹⁵

Whilst it is accepted that the two-implant overdenture is not the gold standard of implant therapy it is the minimum standard that should be sufficient for most people, taking into account performance, patient satisfaction, cost and clinical time.

This paper aims to present the current evidence and rationale to support the McGill and York consensus statements.

2. Materials and methods

2.1. Critical appraisal of the evidence

Patient perceptions of treatment outcome are one of the most important factors to take into account when planning treatment programmes.¹⁶ Evidence from high quality sources such as systematic reviews and randomised controlled trials (RCTs) which have assessed patient-centred outcomes such as patient satisfaction and quality of life are presented below. The studies discussed are all comparisons where patients received either new complete conventional dentures in both the maxilla and the mandible or ISOD mandibular overdentures opposed by a new conventional denture in the maxilla. The data from objectively measured outcomes such as masticatory efficiency and bite force is also reported below.

Additionally, the in-depth data obtained from qualitative interviews with patients about their experience of edentulousness and prosthetic rehabilitation with either CD's or ISOD's is presented, along with information about nutritional and economic factors.

3. Results

3.1. Patient assessed satisfaction and quality of life (QoL) outcomes

A recently published systematic review and meta-analysis of randomised controlled trials¹⁷ reports on the patient-assessed outcomes of general patient satisfaction, oral health-related quality of life and general health quality of life as primary outcomes.

A total of 10 manuscripts on 7 randomised controlled trials were included in the meta-analyses. The sample sizes in these trials varied from 60 to 157 participants. The age range of those involved in the studies was 35–80 years. All patients wore conventional maxillary complete dentures and either mandibular implant-retained or conventional complete dentures. Outcomes were included with a follow up period of at least 2 months.

General satisfaction of participants in the studies was measured using 100 mm visual analogue (VAS) or Likert-type response scales. Six studies that measured general satisfaction were included in the meta-analysis. The pooled effect size from the meta-analysis was 0.80 [$z = 3.56$, 95% CI 0.36–1.24, $p = 0.0004$] and significant in favour of the implant overdentures compared to conventional dentures.

For the effect of mandibular prostheses on patient-assessed oral health-related quality of life the meta-analysis

included only studies using OHIP as the measurement instrument.^{17,18} Three trials that used OHIP-49 and OHIP-20 were combined in the meta-analysis. The pooled effect size (ES) was -0.41 ($z = 131$, 95% CI -1.02 – -0.20 , $p = 0.19$). In 2 of the 3 trials the 95% CI did not include an ES of zero. When the analysis was restricted to studies including populations who were recruited from the general population via advertisement, the pooled ES values declined from -0.41 to -0.71 ($z = 4.37$, 95% CI -1.03 to -0.39 , $p < 0.0001$), the negative value for their ES were consistent with a significantly positive effect in favour of the implant overdenture treatment.

By contrast for the effect of treatment on perceived general health QoL only one article was found which used a general measurement instrument. The SF-36 questionnaire was used but no differences were found between groups on any subscale. As no other study used a similar scoring method no further processing of the data was undertaken.

The analyses illustrate that patient general satisfaction and oral health related quality of life is greater with mandibular ISODs than conventional dentures. However, the authors comment that the studies included ranged greatly in factors such as population, length of the study and assessment of outcomes and that heterogeneity of outcomes was observed.¹⁷ For general satisfaction as an outcome, the p -value for heterogeneity ($\chi^2 = 31.63$, $df = 5$) was $p < 0.00001$ and $I^2 = 84\%$. For oral health-related quality of life, the p -value for heterogeneity ($\chi^2 = 11.53$, $df = 2$) was $p = 0.003$ and $I^2 = 83\%$.

The systematic review discussed above¹⁷ only examined studies with general satisfaction, oral health related quality of life and general health related quality of life measured using standardised and validated instruments as outcomes. Data and outcomes from other RCT's comparing conventional dentures and ISOD's with patient-assessed outcomes are listed in Table 1. Some of the papers listed in Table 1 are reports of different outcomes from the same study. The implant attachment method, i.e. ball, magnet, bar, may also be different between studies, and a comparison of ISOD attachment systems has previously been reported and discussed.¹⁹ It should be noted that patients dissatisfied when not assigned to their preferred treatment group may be a potential confounder in RCTs of this nature, nevertheless, numerous non-randomised studies also support the view that ISOD's are perceived by patients to be preferable to CD's.¹⁹

3.2. Masticatory function/chewing ability

A systematic review of studies with objectively measured masticatory performance as an outcome was published in 2007.²⁰ Studies between 1996 and 2007 were included if the masticatory performance of implant-supported or retained dentures was assessed objectively with standardised masticatory tests and compared with the performance of conventional dentures. Ratings of the evidence in each article followed US Agency for Healthcare Research and Quality recommendations.

This review looked at all studies regardless of the number of implants used for support. In 7 studies, ISOD's were retained by two implants^{21–27} and in three studies, ISOD's were

supported by between 4 and 6 implants. Of the studies that evaluated systems retained by two implants, 2 were RCTs (4 papers)^{21–24}, 3 were prospective studies with within-subject evaluation and 1 was a retrospective study.

This systematic review concluded that ISOD's provide significant improvements in masticatory performance compared to CD's for both the mandible and maxilla for those having persistent functional problems with an existing mandibular CD due to a severely resorbed mandible.

As the McGill and York consensus statements solely relate to two-implant retained overdentures, data from the individual RCT's that have assessed masticatory function with ISOD's have been separated out are presented in Table 2 and they support the overall conclusions of the systematic review.

The review also reported that the type of implant and attachment system for mandibular ISOD's has limited impact on masticatory function. This conclusion was based on 2 RCT's (3 papers)^{23,24,28} and 1 randomised crossover trial.²⁹

3.3. Qualitative data

The benefits of combining both quantitative and qualitative data in health care research are now well-established.³⁰ Quantitative studies can measure the relative merits of different treatments but sometimes only measure a limited part of patients' experiences. Qualitative interviews can help to elucidate a fuller and more in-depth understanding of patients' experiences of treatment and how such treatment impacts on the lives of patients.

Trials that have used patient-based assessment of outcomes usually use instruments developed by clinicians so that the outcomes measured are those that are assessed as important by clinicians, not necessarily by patients. Sometimes, the instruments used to measure outcomes have not specifically been developed for populations with dentures. For example, the SF-36 questionnaire³¹ was developed for people with a wide range of health conditions, not specifically for oral health, so may not be sufficiently sensitive to fully measure the concerns of people with dentures.

The qualitative data that has been published in relation to edentulousness and prosthetic rehabilitation highlights in particular the social restrictions that dentures can impose on patients.^{6–8,32} In a recent qualitative study that reported in-depth interviews with patients who received conventional dentures or ISOD's, patients were often concerned about embarrassment when eating amongst strangers, friends or even family.⁸ Those who had extensive problems avoided social situations completely. Patients who had received ISOD's were much more likely than those with CD's to report a major improvement in what they could eat and how they felt about eating, particularly in social situations. For patients who had received replacement CD's only marginal improvements were usually reported, although a few did report larger improvements. Typical comments of ISOD patients are below and highlight the real improvements that ISOD's can bring to the everyday life of patients.⁸

'I really have got my life back. . . . because I wouldn't go out anywhere to dinners. . . it was so embarrassing so I just

Table 1 – RCT's with patient-based outcomes comparing conventional mandibular dentures and implant-supported mandibular overdentures.

	Comparison (if not ISOD vs CD)	Population	Sample size randomised	Follow-up	Outcomes
Boerrighter et al. ⁵⁵		Ages 35–84 Pts ref by dentist or physician because of dissatisfaction with lower denture. Mand height 16–25 mm.	n = 90 (30 ISOD, 30 CD, 30 pre-pros surgery) Dropouts at 1 yr = 4.	12 months	Denture complaints and chewing ability questionnaires. At 1 year, 5 of 7 factors showed significantly better scores for the ISOD and pre-pros groups than conventional dentures ($p < 0.05$). The same was found for the overall denture satisfaction rate ($p < 0.05$).
Bouma et al. ⁵⁶	Comparison between mandibular ISOD and maxillary denture; new complete dentures following interforaminal vestibuloplasty and new complete dentures grp.	Age 55 ± 11 Pts ref by dentist or physician because of dissatisfaction with lower denture.	ISOD, n = 30 CD, n = 30 Pre-pros surgery, n = 30.	12 months	Psychosocial impact assessed using Groningen Activity Restriction scale; Psychological well-being scale for denture patients; Hopkins symptom check-list inc. scale for psychological complaints. Scores in all groups improved for almost all scales, however there was no difference between groups.
Raghoobar et al. ⁵⁷	(1) New complete dentures (CD). (2) New dentures following pre-prosthetic surgery to enlarge the denture bearing area (PPS). (3) Implant-retained mandibular overdentures (ISOD).	Patients with mean mandibular height 20.7 mm (Cawood class IV and V).	n = 90 ISOD = 40 Pre-pros surg = 30 CD = 30.	5 years	Patient assessment of functional ability (chewing, speaking), satisfaction and psychosocial functioning. Better scores were seen in the 2 surgical groups. At 5 yrs 'complaints' of the lower denture less in ISOD grp and no differences between the PPS and CD grps.
Raghoobar et al. ⁵⁸	(1) New complete dentures (CD). (2) new dentures following pre-prosthetic (PPS). (3) implant-retained mandibular overdentures (ISOD).	Patients with mean mandibular height 20.7 mm (Cawood class IV and V).	n = 90 ISOD = 40 Pre-pros surg = 30 CD = 30.	10 years	10 year follow up of Raghoobar et al. ⁵⁷ At 10 year evaluation, the intention to treat analysis showed no significant differences between the groups but the per protocol analysis showed that the ISOD group was the most satisfied.
Boerrighter et al. ⁵⁹		Age range 35–84 Patients referred because of severe dissatisfaction with their lower denture. Total height of mandible <15 mm.	n = 157 9 patients refused the allocated treatment ISOD, n = 86 CD, n = 56.	1 year Dropouts at 1 year follow up = 6	Denture satisfaction assessed using questionnaires on denture-related complaints and 'general satisfaction rate'. At 1 yr, 3 out of five factors and general satisfaction significantly better for implant group. Functional complaints lower denture ($p < 0.001$); functional complaints in general ($p < 0.001$); items concerning accidental lip, tongue and cheek biting ($p < 0.001$).

Table 1 (Continued)

	Comparison (if not ISOD vs CD)	Population	Sample size randomised	Follow-up	Outcomes
Kapur et al. ⁵³		Diabetic patients, treated with or without insulin.	102 randomised, 89 completed the study.	6 and 24 months	Patient perceptions of the use of dentures for eating, chewing comfort and satisfaction with dentures assessed by questionnaire. No significant difference between two groups at baseline or at 6 months. At 6 months, the change from baseline score showed significantly higher percentages of patients with improvements in their overall satisfaction in the ISOD group ($p = 0.028$).
Kapur et al. ⁶⁰		Diabetic patients, treated with or without insulin.	102 randomised, 89 completed the study.	6 and 24 months	2 questionnaires were used for patients assessments of dentures at baseline and at 6 and 24 months. Questionnaire 1 - patients absolute assessment of denture- no sig difference. Questionnaire 2 - relative change perceived by patients. A significantly higher percentage of patients in the ISOD group perceived improvements or chewing ability.
Heydecke et al. ⁶²		35–65 years, recruited from a pool of respondents to newspaper advertisements.	102 randomised; ISOD, $n = 54$ CD, $n = 48$.	2 months	Impact of different types of dentures on social and sexual activity assessed using a two-part Social Impact Questionnaire. Patients asked about avoidance of conversation, refused invitations, sport and unease when kissing and in sexual relationships. OHRQoL measured using OHIP 49. Significant improvement in the ISOD group; looseness when eating, speaking, yawning and kissing ($p < 0.0001$). ISOD subjects less uneasy kissing and during sexual activity ($p < 0.002$).
Awad et al. ⁶³	Maxillary CD and mandibular ISOD (bar attach), cf CD's.	35–65 years, respondents to advertisements.	102 randomised; ISOD, $n = 54$ CD, $n = 48$.	2 months	OHRQoL measured using OHIP. Implant group had lower post-treatment scores on all subscales ($p < 0.002$).
Awad et al. ⁶⁴		35–65 years, respondents to advertisements.	102 randomised; ISOD, $n = 54$ CD, $n = 48$.	2 months	General satisfaction, comfort, stability, ability to chew, speech aesthetics, ability to clean assessed on VAS. Gen satisfaction, comfort, stability and ease of chewing higher in the ISOD group.

Table 1 (Continued)

	Comparison (if not ISOD vs CD)	Population	Sample size randomised	Follow-up	Outcomes
Awad et al. ⁶⁵	Conventional maxillary denture opposing implant supported mandibular overdenture or conventional mandibular denture.	Age 65–75, respondents to advertisements.	n = 60 randomised ISOD = 30 CD = 30.	2 months	Implant group higher OHRQoL, lower scores for physical pain domain of OHIP-49. Lower OHIP-20 scores functional limitations, physical pain and physical disability problems. General satisfaction, comfort, stability and ability to chew significantly better.
Heydecke et al. ⁶⁶		Age 65–75, respondents to advertisements.	n = 60, random ISOD = 30 CD = 30.	2 and 6 months	OHIP-20, SF-36. Patients provided with ISOD had fewer impacts OHRQoL. No differences with SF-36
Thomason et al. ⁶⁷	Comparison was mandibular conventional denture or an overdenture supported by 2 implants with ball retentive anchors.	Age 65–75.	n = 60 randomised ISOD = 30 CD = 30.	6 months	General satisfaction, comfort, stability, ability to chew, speech aesthetics, ability to clean rated on VAS. General satisfaction higher in the implant group by 36% (p = 0.005). Comfort, stability, and ability to chew also rated higher.
Heydecke et al. ⁶⁸			n = 60.		Patients rated satisfaction before and after treatment on VAS and the treating prosthodontist rated the dentures for the same categories.
Meijer et al. ⁶⁹		Edentulous patients with dentures problems, mand bone height 8–25 mm, no pre-pros surgery. Ages: ISOD 56.9 ± 11.6 CD 57.8 ± 10.9	n = 121, ISOD, n = 61 CD, n = 60.	5 years. 1 year after treatment CD pts given implant opportunity	14 of CD group (23%) chose an ISOD after 1 year. Patients in the IOD group were significantly more satisfied than those in the CD group though the score at 5 years was lower. The mean satisfaction score of the CD group, including those who later received implants, was still lower than that of the IOD group.
Meijer et al. ⁷⁰		As above	As above	10 year follow-up.	24 patients chose an ISOD between 1 and 10 years. ISOD group more satisfied after 1, 5 and 10 years. The mean satisfaction score of the CD group (including patients who later received implants) was still lower than that of the ISOD group.

Table 1 (Continued)

Comparison (if not ISOD vs CD)		Population	Sample size randomised	Follow-up	Outcomes
Allen et al. ⁵⁰		<80 years Patients referred because of complaints about existing dentures. Patients had no knowledge of implants and expected to receive CD's on referral.	n = 118 randomised ISOD = 62 allocated (45 participated, then 12 refused implants and were given CD's. CD = 56 allocated (46 participated).	3 months	Results were analysed on an 'intention to treat basis' so those originally allocated to the ISOD group were analysed in that group even if they eventually received CD's. Both groups reported improvement in OHRQoL (OHIP-49) and satisfaction. Concluded that any treatment effect may be masked by the 'intention to treat' analysis. The pre/post treatment change scores were significantly higher for those who had implants than those who refused ($p = 0.02$).
Assuncao et al. ⁷¹	Seven patients received 2 implants, 3 patients received 3 implants, five received 4 and two received 5. The mandibular overdentures were supported by ball attachment for patients with 2 implants, bar-clip attachments for those with 3, patients with 4 or 5 implants bar-clip was used.	Age 49 to 84, mean age 68. Details of population or recruitment not supplied.	n = 34, ISOD = 17, CD = 17.	2 months	Questionnaire based on OHIP and OHRQoL though details not given. Satisfaction was assessed on a 3 point scale. Implant patients had higher levels of satisfaction for stability of the denture ($p = 0.039$). There were no differences between the groups for comfort, aesthetics, ability to chew, overall satisfaction, pain, functional, social and psychological limitations. Expectations of satisfaction with implant and conventional denture treatment were compared with ratings of satisfaction after treatment onVAS. Post-treatment satisfaction with CD treatment was lower than pre-treatment satisfaction for CD patients in both middle-aged ($p < 0.0001$) and senior ($p = 0.036$) patients. There was no or only borderline significant difference between pre-treatment and post-treatment satisfaction for patients receiving ISOD's in both middle-aged ($p = 0.078$) and senior ($p = 0.057$) patients.
Habill et al. ⁷²		Middle-aged and senior patients. (MA, n = 102; senior, n = 60)	n = 162.	6 months	

Table 1 (Continued)

	Comparison (if not ISOD vs CD)	Population	Sample size randomised	Follow-up	Outcomes
Esfandiani et al. ⁷³	(1) conventional dentures (2) ISOD Subjects were randomised to treatment groups as above, but also to be treated by an experienced prosthodontist or inexperienced newly graduated dentists.	Aged > 65 years, completely edentulous for a minimum of 5 years, wishing to replace existing CD's.	n = 140 randomised ISOD, n = 79 CD, n = 61.	6 months	General satisfaction was assessed using 100 mm visual analogue scales (VAS). Change in satisfaction between baseline and six month post-delivery scores were compared. Satisfaction was significantly higher with ISOD's than for CD's whether delivered by experienced prosthodontists ($p = 0.006$) or inexperienced dentists ($p = 0.009$).

didn't. It was really bad. But after this I go out, you know, I've got so much confidence'

'...basically it's changed my whole way of life, ...to take a sandwich used to be embarrassing when I was say not in the house, somewhere. That's why I hated restaurants, cafes, things like that. ...so I just didn't go out because I got into problems you know. But I can just eat anything.'

The increased social confidence that ISOD's can provide is the major benefit of ISOD's as perceived by many patients. Being able to eat foods they wish to eat, with people they wish to eat with and in places where they wish to eat are fundamental to day to day life. This is important to patients as it has been well documented that lack of social interaction is related to serious health problems including depression³³ and even mortality.^{34,35}

3.4. Nutrition

Those with conventional dentures often avoid certain foods because of difficulties with chewing and biting.^{7,8} The 1998 adult dental health survey in the UK found that edentulous people had a lower daily intake of protein, fibre, calcium, iron and vitamin C than the dentate.^{9,36} Intake of dietary fibre is also lower in the edentulous.³⁷ In the US, the edentulous have been shown to consume fewer vegetables, less fibre and carotene, and more cholesterol, saturated fat and calories than participants with 25 or more teeth.³⁸

Poor diet in older people is implicated in cardiovascular disease, arthritis, osteoporosis and cognitive decline.^{39,40} Poor diet may not solely be related to the functional ability to eat, and, established eating habits, personal preferences and knowledge about nutrition may all affect dietary intake. However, there is preliminary evidence that implant overdentures may improve nutrition in patients. It has been reported that intakes of carrots, salads and serum levels of beta carotene, folate and vitamin C are higher for those with ISOD's compared to complete dentures.⁴¹ In a randomised trial of people aged 65–75 years, Patients who received ISOD's showed improved measures of serum albumin, haemoglobin and vitamin B12 and body fat and a decrease in waist circumference compared to those who received CD's although no between group difference was found.⁴²

Other studies have shown no differences in food selection between those who received ISOD's or CD's⁴³ and concurrent dietary intervention may be required to maximise the capacity of ISOD's to enhance nutritional status. Patients with ISOD's reported increased satisfaction and chewing ability compared to those with CD's after a programme of individual dietary advice that challenged patients to eat a wider range³⁶ of foods including more fruits, vegetables and fibre rich foods⁴⁴ and that included foods considered to be difficult to bite or chew.

3.5. Economic factors

Whilst the cost of ISOD's is more than that of CD's the difference is less when the overall lifespan of the dentures and indirect costs are considered. In a RCT of 60 edentulous

Table 2 – RCT's with objectively assessed masticatory performance outcomes comparing IOD's supported by two implants with CD's.

Masticatory performance	Population desc	Sample size randomised	Follow-up	Outcomes
Geertman et al. ²³	Mean age 57 (39–75) Patients with severely resorbed mandibles and problems wearing conventional dentures.	n = 95 3 groups – transmandibular bar, 2 implants linked with a bar, CD's	1 year (n = 84)	Masticatory performance was assessed by the comminution of a standardised artificial test food. The test food was collected after 60 chewing strokes and median particle size assessed. The masticatory performance was reported to be substantially better for the implant groups but no significant differences between the two implant groups.
Garrett et al. ²¹	Diabetics with clinically acceptable metabolic control Mean age ISOD group 65.7; CD group 64.2	n = 102 randomised ISOD, n = 53 completed CD, n = 37 completed	2 years	Masticatory performance was assessed by 4 previously validated tests, using a set number of chewing strokes, with peanuts and raw carrots. Particle size of chewed material assessed using standard mesh. The post-treatment performance scores for the two groups were similar, but higher gains between baseline and post-treatment seen with ISOD group. Post treatment change in masticatory performance between the two groups for peanuts was significant for implants when assessed by t-test but not when assessed by MANOVA at 12 months. The ISOD group had lower starting scores but showed greater gains.
Fontijn-Tekamp et al. ²⁴	Mean age 59 (range 41 to 71) Patients referred for persistent problems wearing CD's. Severely resorbed mandibles (symphyseal bone height 8–15 mm)	2 cylindrical implants, n = 27 Transmandibular implant, n = 24 CD, n = 16 (10 received implants during 4 yr follow up)	Masticatory performance assessed 4 years after initial trial.	No statistical difference was observed in the number of chewing strokes, time till swallowing and median particle size at swallowing. However, both implant groups had a significantly higher chewing rate than the CD group.
Kimoto and Garrett ²²	Patients divided into 3 subgroups according to mandibular ridge height: Low (≤ 21 mm) Mod (21–28 mm) High (≥ 28 mm)	n = 65, ISOD, n = 38 CD, n = 25	6 months after dentures fitted	Significantly better masticatory performance for ISOD's for peanuts ($p = 0.05$) and carrots ($p = 0.03$). However in post-hoc tests there was significantly better masticatory performance only for patients with low mandibular ridge height. Although no significant differences were found in swallowing threshold performance, the mean change scores for subjects with low bone height were greater with the ISODs than those with CD for swallowing threshold performance, strokes, and time.

patients aged 65–75 (ISOD, $n = 30$; CD, $n = 30$) ISOD's were found to be 1.6 times more expensive than CD's (based on a life expectancy of 17.9 years), taking into account aftercare, check-ups, relining and prosthesis replacement. The between group difference was significant ($p < 0.001$). This equated to a difference (in 2005) of 226 Canadian dollars per year additional cost for ISOD's.⁴⁵ In an earlier RCT, that took into account both direct and indirect costs, the cost ratio of implant to conventional dentures was found to be 1.8.⁴⁶ Direct costs included the cost of labour, materials, medications, lab fees and radiography fees. Indirect costs included the patients' time costs and out of pocket expenses.⁴⁵

It has been shown that the time taken for the prosthodontist to treat a patient with ISOD's is not significantly different from the time to treat a patient with CD's.⁴⁷ The differences in overall costs are therefore related primarily to the provision of the implants themselves. Costs of mandibular overdentures retained by 2 implants are significantly lower than those using 4 implants.⁴⁸ No significant differences were observed for direct costs of aftercare. ISOD's retained by two implants therefore offer a less complex and less expensive option than implants retained with four or more implants for an edentulous patient.

Arguably ISOD's will have more long term maintenance cost than conventional dentures but conventional denture wearers seek denture replacement more frequently.⁴⁵ Additionally, some of the more recently introduced systems are designed in such a way that an easy to replace component is 'sacrificially' worn so that more expensive and difficult to replace elements are 'protected'. There remains a lack of long term follow-up studies that could inform the effect of new developments on the life-time costs of ISOD's and as new systems are introduced this presents opportunities for further research in this area.

4. Discussion

There is now a large body of evidence that supports the proposal that a 2-implant supported mandibular overdenture should be the minimum offered to edentulous patients as a first choice of treatment. There is evidence from systematic reviews and a large number of RCT's that have used patient-based assessment of outcomes such as patient satisfaction and oral-health related quality of life that consistently shows that patients perceive ISOD's to have benefits over conventional complete dentures. Additional evidence comes from in-depth qualitative interviews with patients. This evidence also shows clearly the real benefits of improved confidence in social situations for patients with ISOD's as well as in eating function.

Other evidence for the benefits of ISOD's comes from objective measures of masticatory efficiency that show that ISOD's provides significant improvement in masticatory performance compared to CD's for both the mandible and maxilla for those having persistent functional problems with an existing mandibular CD due to a severely resorbed mandible.

There are some methodological limitations in trials of implant therapy versus conventional dentures.¹⁷ These

include the difficulties in blinding patients to their treatment group [49,451], lack of reporting of allocation concealment¹⁷ and lack of statistical power in some studies. There are also difficulties in conducting trials because of treatment preferences of patients and subsequent allocation to treatment groups that they would not have chosen⁴⁹. Where this design of study has been used the potential for confounding variables to exist should be considered, and some researchers have used the intention to treat principle in order to overcome this problem. The studies listed in Table 1 vary widely in study design, the outcome measures used, the clinical settings in which the implant therapy was provided, the oral status of patients included in the study and the type of implant therapy provided. As discussed previously, there may also be limitations in the sensitivity of the instruments used to assess patient quality of life or satisfaction. With less sensitive measures, the sample sizes studied may be too small to accurately detect differences in outcome.

However, taking into account these limitations, there are sufficient studies now using satisfaction and oral-health-related quality of life outcomes to demonstrate that the evidence consistently points to real advantages of ISOD's for rehabilitation of the edentulous mandible compared to CD's as assessed by patients. The evidence supports the McGill and York consensus statements that mandibular implants should be the first choice of treatment for the edentulous mandible. Whilst patient choice should be taken into account,⁵¹ for example, some patients are uneasy about implant surgery, the McGill and York consensus statements propose that all patients who would prefer them and are likely to benefit clinically should at least be offered the choice of ISOD's.

4.1. Minimum standards of training and experience

The minimum standards of training recommended for dentists wishing to undertake implant treatment have been set out in the document 'Training Standards in Implant Dentistry for General Dental Practitioners'.⁵² The report states that placement of implants should only be carried out by a dentist who has received suitable training and has been assessed as competent to do it.⁵² The dental surgeon should be trained in appropriate clinical assessment, treatment planning, placement and restoration of the implants. When training, the dentist should work closely with a mentor in association with a training course in implant dentistry. The report acknowledged that appropriate training can be obtained from a variety of sources, including universities, Royal Colleges, hospital in-post training and also from privately run or commercial courses.

There is also a need to fully incorporate the teaching of the skills required for delivering and maintaining implant retained prostheses into the undergraduate dental curriculum so that newly qualified general dentists are confident and competent in the treatment and maintenance of patients with implant retained prostheses.⁵³ If dentists receive training in implant therapy as part of undergraduate training it has been shown that implants are more likely to be offered to patients.⁵⁴ However this will require financial resources and appropriate training for teaching staff.

5. Conclusions

There is now overwhelming evidence to support the proposal that a two-implant overdenture should become the first choice of treatment for the edentulous mandible. The next task is to identify and overcome barriers for the delivery of this care for the benefit of edentulous patients.

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