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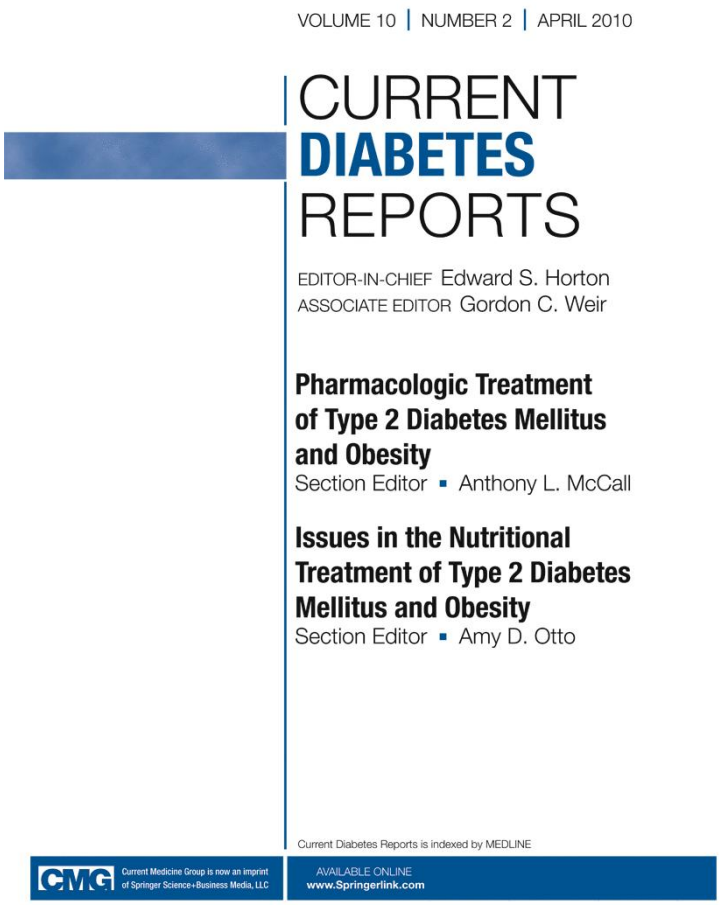

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Weight Management Using a Meal Replacement Strategy in Type 2 Diabetes

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Abstract The growing prevalence of diabetes parallels the increased prevalence of obesity. Overweight and obese individuals with diabetes who attempt weight reduction face considerable challenges. However, several recent studies showed that weight reduction in patients with diabetes is feasible using a multidisciplinary approach that incorporates structured dietary intervention and meal replacements (MRs). Nutritionally complete MRs are shown to be useful at the start of weight reduction programs and for weight maintenance because of their nutrition adequacy. However, patients using this approach need to monitor their blood glucose levels closely and may need to adjust their diabetes medications. Most commercial MRs are currently fortified with vitamins and minerals to prevent long-term deficiency in essential micronutrients that are commonly seen in low-calorie diet plans. They also come in different flavors and formats that improve their general acceptability. To successfully initiate weight loss, MRs are generally used as absolute replacement of an agreed upon number of meals/snacks. This article covers the use of MRs for patients with diabetes for short-term and long-term weight reduction in clinical trials and real-world clinical practice.

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Introduction

Obesity is known to be directly linked to type 2 diabetes mellitus (T2DM) and, not surprisingly, the growing prevalence of diabetes parallels the increased prevalence of obesity [1]. From 1991 to 2001, the prevalence of obesity increased by 74% among the US population [1]. Data from two NHANES (National Health and Nutrition Examination Survey) surveys show that among adults 20 to 74 years of age, the prevalence of obesity increased from 15.0% (in the 1976–1980 survey) to 32.9% (in the 2003–2004 survey) [2]. After a quarter century of increases, obesity prevalence has not measurably increased in the past few years, but levels are still high, with a combined prevalence of overweight and obesity reaching 64.5% [1, 3].

Multidisciplinary weight management approaches, including the use of meal replacements (MRs) within a structured dietary plan, are emerging as viable and potentially cost-effective solutions to overweight and obesity management in T2DM. Applying weight reduction as a T2DM treatment can delay or reduce the need for medications, reduce cardiovascular risk, and improve quality of life [4]. Modest weight reduction of about 7% over a 6-month period through caloric reduction and increased physical activity improves insulin sensitivity, endothelial function, and several markers of inflammation and coagulation in obese patients with and without diabetes [5, 6].

However, individuals with T2DM who attempt weight loss face considerable challenges. A near-universal barrier

is that weight gain is a side effect of many diabetes medications, including insulin, sulfonylurea, glinides, and thiazolidinediones. Over a 10-year treatment period, participants in the United Kingdom Prospective Diabetes Study gained weight, particularly patients treated with insulin [7]. Not surprisingly, Look AHEAD (Action for Health in Diabetes) study patients receiving insulin therapy were less likely to lose weight compared with other participants [8••]. A second challenge is physicians' reluctance to urge weight loss as a treatment. Surveys indicate that one third to one half of physicians do not recommend weight management to their overweight and obese patients, with some research indicating that physicians may not believe their patients are adequately motivated to achieve weight loss [9]. Further, because insurance plans do not typically cover antiobesity medications, MRs, or weight management programs, physicians often view these options as impractical and costly [9, 10]. The authors note that medical nutrition therapy for patients with T2DM is a covered benefit by Medicare and most third-party private insurers and few insurance plans provide small incentive to those enrolled in weight management programs.

Structured Dietary Plan for Weight Reduction

Several recent studies showed that weight reduction in patients with diabetes is feasible using structured dietary intervention that includes a level of caloric restriction to create negative energy balance [11••, 12 , 13]. However, evidence-based dietary guidelines should be used to design individualized patient plans in consultation with a registered dietitian or qualified health care provider. In general, several factors should be included in a successful long-term weight reduction dietary plan for people with diabetes. First, daily caloric intake should be reduced by a modest 250 to 500 calories to enhance dietary compliance. Reasonable and paced calorie reductions can help patients continue on the recommended dietary plan for a longer duration rather than a dramatic reduction of 750 to 1000 calories per day. Daily calories from carbohydrate should be also reduced to about 40% of intake, with a total daily intake of no less than 130 g/d [14, 15]. Except in patients with renal impairment or significant microalbuminuria (creatinine clearance<60 mL/min), protein may comprise up to 20% to 30% of daily caloric intake (to minimize lean muscle mass loss during weight reduction) [15]. The remaining 30% should come from fat. Trans fats should be eliminated completely and saturated fat should be reduced to 10% or even 7% in patients with elevated low-density lipoprotein cholesterol (> 100 mg/dL) [15, 16]. Meal plans should also focus on increased soluble fiber (eg, from fresh fruits and vegetables) and healthy carbohydrate consumption, especially foods high in fiber and with a low glycemic index [14]. Finally, caloric intake should be adjusted over time until weight loss is achieved [11••]. Underlying all of these steps should be the goal of designing individualized plans that can be maintained over the long term.

Many patients find it helpful to receive a structured reduced calorie intervention that includes specific suggestions for daily meals. This structured intervention may increase adherence and can be easier to follow than a list of general guidelines [11••, 12, 13]. Nutritionally complete MRs (eg, in the form of shakes or bars) may be useful for some patients at the start of the weight reduction program; however, patients using this approach need to monitor their blood glucose levels closely to avoid hypoglycemia. MRs generally will provide the balance of protein, fat, and carbohydrate, including fiber, as described above within a 190-to 350-calorie serving. MRs designed for patients with diabetes and with a favorable carbohydrate profile are preferable. If an MR is used, 100-to 200-calorie snacks (eg, fruits and nuts) may be added at breakfast, lunch, or in between as needed to reach targeted total daily calories.

MRs as Useful Tools for Diabetes Weight Management

As part of a comprehensive diabetes management program, MRs can be effectively used to facilitate initial weight loss and help with weight maintenance in some individuals [8••, 11••]. To reduce daily caloric intake and to deviate the focus off the stimulus of food choice, commercial MRs in the form of shakes, bars, and ready-to-mix powders are frequently used to replace one or two meals or snacks each day.

A once fairly limited MR category now has seemingly endless choices. Besides being a balanced source of macronutrients, an MR should provide fiber and a substantial level of the daily requirements of essential vitamins and minerals. The MR components of weight management programs (self-help and structured) take on all types of food format, from bars to beverages to soups or complete meals. The cost for an MR is often directly correlated with where it is acquired (eg, program vs retail) and how convenient it is to use (eg, mix vs ready to eat). The price of an MR purchased at retail usually ranges from $0.50 (add your own milk) to $3.25+ for ready-to-consume items. The convenient ready-to-drink MR shakes usually average around $1.50 for the typical 8 to 11 fl oz serving. Table 1 summarizes some commercially available MRs tried for weight management in overweight and obese patients with diabetes.

Blood glucose patterns frequently change with the initiation of MRs. Consequently, diabetes medications

Table 1 Common ready-to-drink meal replacements[a]

Meal replacements	Unit	DV	BOOST Nutritional Energy Drink (chocolate)[b]	% DV	BOOST Glucose Control Nutritional Drink (chocolate)[b]	% DV	Ensure Shake (creamy milk chocolate)[c]	% DV	Glucerna Shake (creamy chocolate delight)[c]	% DV	Medifast Shake (Dutch chocolate)[d]	% DV	Optifast Shake (chocolate)[b]	% DV	Slim-Fast Original (creamy milk chocolate)[e]	% DV	Slim-Fast Optima (creamy milk chocolate)[e]	% DV
Size			8 fl oz		8 fl oz		8 fl oz		8 fl oz		8.25 fl oz		8 fl oz		11 fl oz		11 fl oz	
Calories			240.00		190.00		250.00		200.00		90.00		160.00		190.00		190.00	
Fat	g	65	4.00	0.06	7.00	0.11	6.00	0.09	7.00	0.11	1.50	0.02	3.00	0.05	6.00	0.09	6.00	0.09
Saturated fat	g	20	0.50	0.03	1.00	0.05	1.00	0.05	0.50	0.03	–	–	0.50	0.03	2.50	0.13	2.00	0.10
Trans fat	g		–		–		–		–		–		–		–		–	
Cholesterol	mg	300	5.00	0.02	10.00	0.03	5.00	0.02	< 5	< 2%	–	–	–	–	5.00	0.02	5.00	0.02
Sodium	mg	2400	130.00	0.05	180.00	0.08	190.00	0.08	210.00	0.09	190.00	0.08	220.00	0.09	200.00	0.08	220.00	0.09
Potassium	mg	3500	400.00	0.11	65.00	< 2%	390.00	0.11	400.00	0.11	480.00	0.14	460.00	0.13	600.00	0.17	600.00	0.17
Total carbohydrate	g	300	41.00	0.14	16.00	0.05	41.00	0.14	27.00	0.09	12.00	0.04	20.00	0.07	25.00	0.08	25.00	0.08
Fiber	g	25	–	–	3.00	0.12	3.00	0.12	5.00	0.20	3.00	0.12	–	–	5.00	0.20	5.00	0.20
Sugars	g		25.00		4.00		22.00		6.00		6.00		17.00		18.00		18.00	
Protein	g	50	10.00	0.20	16.00	0.32	9.00	0.18	10.00	0.20	11.00	0.22	14.00	0.28	10.00	0.20	10.00	0.20
			25% or more of 24 essentials vitamins and minerals		25% or more of 22 essentials vitamins and minerals		25% or more of 24 essentials vitamins and minerals		25%or more of 24 essentials vitamins and minerals		20% or more of 23 essentials vitamins and minerals		20% or more of 24 essentials vitamins and minerals		25% or more of 21 essentials vitamins and minerals		25% or more of 21 essentials vitamins and minerals	
Flavors			Vanilla, chocolate, strawberry		Vanilla, chocolate, strawberry		Homemade vanilla, creamy milk chocolate, rich dark chocolate, strawberry and cream, butter pecan, coffee latte		Homemade vanilla, creamy chocolate delight, strawberry and cream, butter pecan		French vanilla, dutch chocolate		Vanilla, chocolate, strawberry		French vanilla, creamy milk chocolate, rich chocolate royale, strawberry and cream		French Vanilla, milk chocolate, rich chocolate royale, strawberry and cream, cappuccino delight	

[a] Information provided is based on manufacturer's printed information available at the time of publication and is subject to change. Information is for comparison purposes only

Percent daily values (DVs) are based on a 2000-calorie diet

[b] Nestlé Nutrition, Minnetonka, MN

[c] Abbott Nutrition, Abbott Laboratories, Abbott Park, IL

[d] Medifast, Owings Mills, MD

[e] Unilever, London, UK and Rotterdam, Netherlands

may need adjustment. Use of MRs did not appear to significantly change the glucose or insulin area under the curve versus natural food; however, long-term use of MRs results in reduction of fasting plasma glucose and body weight compared with natural food of the same caloric level [17–19]. Patients using MRs should be told to monitor their blood glucose carefully to identify hypoglycemia.

MRs and Micronutrients Adequacy

Because MRs are frequently fortified with vitamins and minerals, it is justifiable to use them as part of calorie-controlled weight management plans to achieve micronutrient adequacy. In a recent trial designed to evaluate individuals' ability to adjust to diet routines, free-living overweight and obese adults were able to adapt to four different popular commercial diet programs with fairly minimal, if any, professional guidance [20]. All intervention groups showed variable micronutrient inadequacies, except for the diet plan that included MRs. That arm showed only a decline in niacin (95% of recommended), but adequate other micronutrients similar to baseline. The authors concluded that overall nutrient adequacy of popular diet plans should not be of particular concern to health care professionals; however, over extended time, micronutrient deficiencies may be expected and should be carefully monitored. An acknowledged limitation of the study is that it was for relatively short duration and the dietary intakes were self-reported; however, a comparison between pre-dietary versus post-dietary intake indicated significant diet compliance and caloric reduction.

This proposition that a commercial MR can enhance nutrient adequacy is also supported by another recent randomized clinical trial [21]. The study compared the nutrient adequacy between a diet plan using MRs versus another that used traditional food. Both groups had dietary composition (carbohydrate:protein:fat) within the recommended ranges (55:16:29 in the MR plan and 50:19:31 in traditional plan). Because food choices always affect overall nutrient adequacy, the traditional food group was significantly lower for nine essential vitamins and minerals versus the MR group after 1 year.

Across several studies that evaluated micronutrient adequacy, many of the micronutrients that consistently fell short of the recommended daily intake are essential for metabolism, energy, and bone health (B vitamins, iron, calcium, and magnesium) [20–22]. The caveats of these studies are that food records were often self-reported and the studies included selected groups (ie, overweight, obese) who usually tend to inaccurately report their true food intakes. Wisely, most commercial diet plans encourage supplemental use of vitamins and minerals that may minimize the risk of micronutrient deficiencies. Regardless of the diet plan recommended for weight management, MRs offer an easy and effective way to avoid nutrient inadequacy, especially of micronutrients, while reducing caloric intake.

MRs and Initial and Long-Term Weight Reduction

It is recommended that MRs be used as part of a comprehensive multidisciplinary weight management program. The key role of an MR is to limit food choices and possibly bad food selections. MRs usually offer a structured, well-measured dietary composition that is easier to use within a diet strategy that aims at controlling portions and high caloric consumption. To successfully initiate weight loss, MRs are generally used as absolute replacement of an agreed upon number of meals/snacks (usually one to two/day) as part of a structured diet plan [11••]. For long-term weight maintenance, MRs in combination with exercise can be used to get patients back on track if they start to regain weight. In contrary to some popular beliefs, today's commercial MRs are mostly palatable and are offered in different flavors and formats that are generally accepted [22, 23].

Although long-term weight reduction is rarely achieved using nonsurgical weight management plans, major advances in the techniques used for medical weight management in patients with diabetes made it possible to achieve significant improvement in metabolic outcomes and significant reduction in diabetes medications together with sustainable weight loss beyond 6 months [8••, 11••]. Heymsfield et al. [23] published a meta-analysis of six clinical trials that compared diet plans that incorporated MRs versus those that only used natural food. At 1 year, participants in the MR plans achieved approximately 7% to 8% weight reduction versus approximately 3% to 7% in those using natural food. The dropout rate was also significantly lower in the MR plans [23]. In a recent study, Vázquez et al. [24•] randomized 62 adult patients, who initially lost at least 5% of their initial body, over 6 months to diet alone or diet plus MRs during a weight maintenance phase. The diet plus MR group lost an additional−3.2%± 3.7% compared with the diet only group who lost an additional 1.3% ± 3.6% after another 6 months.

MRs for Weight Management in Patients With Diabetes

In the previously mentioned meta analysis [23], approximately 20% of the pooled study population had diabetes. At the 1-year evaluation point, 60% of nondiabetic subjects on natural foods had dropped out compared with 35% of those

on MRs. In contrast, the dropout rate of diabetic subjects was not significantly different between the two groups (77% vs 79%, P=0.78). However, weight loss in diabetic subjects was less at 1 year than at 3 months, indicating that lifestyle relapse is more frequent in people with diabetes than in healthy overweight and obese individuals even with the use of MRs. It may also be related partially to diabetes progression and the probable need for weight-promoting diabetes medication such as insulin [25]. A possible insight might be that to maintain weight goals, people with diabetes may require more redirection and encouragement over time than people without diabetes.

One of the largest diabetes weight management studies that used MR strategy for weight reduction is the ongoing Look AHEAD study. The study aim is to investigate the health outcomes and mortality among patients with diabetes who lose and maintain weight loss for up to 10 years. The 5145 participants of the Look AHEAD study were randomly divided into two intervention groups: one uses intensive lifestyle intervention (ILI) including possible use of MRs (Glucerna [Abbott Laboratories, Abbott Park, IL]; HMR [Health Management Resources Corp., Boston, MA]; Optifast [Nestlé, Vevey, Switzerland]; and Slimfast [Unilever, London, UK and Rotterdam, Netherlands]); another receives standard diabetes support and education (DSE). MRs are used as one to two servings per day. The research groups published their first year results that showed significant weight loss of an average of−8.6% in the ILI group versus−0.7% in the DSE group [8••]. This amount of weight loss resulted in significant improvement in diabetes control (absolute hemoglobin A_{1c} [HbA_{1c}] reduction of −0.64% in the ILI versus−0.14% in the DSE from a baseline of~7.3 in both groups [P<0.001]). Notably, HbA_{1c} lowering was observed in the context of decreased glucose-lowering medication use in the ILI group and increased medication use in the DSE group. These observations were maintained after 4 years of intervention [26]. In addition to the significant weight loss, the ILI group showed better attendance to the use of MRs, better physical fitness, and better adherence to their diabetes treatment. The higher the reliance on MRs, the higher the odds were of achieving weight loss goals. Participants in the highest quartile of MR usage had a 4.0 times greater odds of reaching a 7% weight loss and a 4.1 times greater odds of reaching the 10% weight loss mark (Fig. 1) [27••]. The three indicators—session attendance, activity, and MR consumption—were also highly intercorrelated. A systematic review of 11 other long-term studies with a follow-up of more than 2 years showed that mortality risk was reduced by 25% in patients with diabetes who intentionally lost a significant amount of weight [4].

In clinical practice, MRs have been used in the Why WAIT (Weight Achievement and Intensive Therapy) program dietary intervention [11••]. Participants in this 12-week weight management program are instructed to consume two MRs (each of 190 calories) plus two snacks of 100 to 200 calories for their breakfast and lunch and natural food for their dinner. After the initial 12 weeks, participants are instructed to continue the same dietary principals on their own, with the option of continuing the use of MRs if the participant prefers. Other intervention procedures used in the Why WAIT include change of diabetes medications to enhance weight loss, dietary composition that is lower in calories (~ 500 kcal/d) and carbohydrates (~ 40%) and higher in protein (~ 20% to 30%) derived from natural foods and commercial MRs (BOOST Glucose Control; Nestlé Nutrition, Minneapolis, MN), graded strength exercise, and weekly didactic and behavioral support sessions. Thus far, 130 obese patients with diabetes have been followed up for an average of 552 days and have successfully maintained at least a 7% weight loss on their own. In addition to weight loss, HbA_{1c} decreased significantly and was kept lower in those who maintained the weight loss within 5 lb [11••].

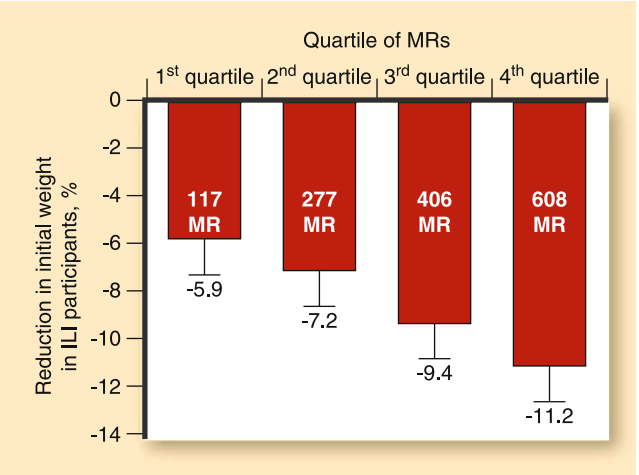

Fig. 1 Shows the percentage reduction in initial weight at 1 year in the Look AHEAD (Action for Health in Diabetes) study based on quartile of meal replacement (MR) product used. The number within each *bar* shows the mean number of products used in that quartile. ILI—intensive lifestyle intervention. (*From* Wadden et al. [27••]; with permission.)

Conclusions

Given the current epidemic of overweight and obesity and the associated increase of diabetes prevalence among adult Americans, weight management becomes an imperative necessity. In many recent studies, incorporation of MRs within a structured dietary plan was successful for short-and long-term weight reduction among overweight and obese patients with diabetes. The micronutrient adequacy of many

of the currently available MRs can help prevent long-term essential micronutrient deficiencies that are commonly seen with a low-caloric diet plan. MRs come in different flavors and formats that improve acceptability and compliance. Many of the commercially available MRs follow the current dietary guidelines and are suitable for people with diabetes. Monitoring of blood glucose and adjustment of diabetes medications are needed with initiation of dietary plans that include MRs.

Disclosure Debbie Zwiefelhofer works for Nestlé HealthCare Nutrition, which manufacturers three products mentioned in this article (BOOST Glucose Control, BOOST Nutritional Energy Drink and Optifast Shake). The material presented about these products is based on the best-known clinical evidence and is not affected by this financial relationship. No other potential conflicts of interest relevant to this article were reported.

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