

Original article

## Aspiration therapy for the treatment of obesity: 4-year results of a multicenter randomized controlled trial

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**Abstract**

**Background:** The AspireAssist is the first Food and Drug Administration–approved endoluminal device indicated for treatment of class II and III obesity.

**Objectives:** We earlier reported 1-year results of the PATHWAY study. Here, we report 4-year outcomes.

**Setting:** United States–based, 10-center, randomized controlled trial involving 171 participants with the treatment arm receiving Aspiration Therapy (AT) plus Lifestyle Therapy and the control arm receiving Lifestyle Therapy (2:1 randomization).

**Methods:** AT participants were permitted to continue in the study for an additional year up to a maximum of 5 years providing they maintained at least 10% total weight loss (TWL) from baseline at each year end. For AT participants who continued the study, 5 medical monitoring visits were provided at weeks 60, 68, 76, 90, and 104 and thereafter once every 13 weeks up to week 260. Exclusion criteria were a history of eating disorder or evidence of eating disorder on a validated questionnaire. Follow-up weight, quality of life, and co-morbidities were compared with the baseline levels. In addition, rates of serious adverse event, persistent fistula, withdrawal, and A-tube replacement were reported. All analyses were performed using a per-protocol analysis.

**Results:** Of the 82 AT participants who completed 1 year, 58 continued to this phase of the trial. Mean baseline body mass index of these 58 patients was  $41.6 \pm 4.5 \text{ kg/m}^2$ . At the end of first year (at the beginning of the follow-up study), these 58 patients had a body mass index of  $34.1 \pm 5.4 \text{ kg/m}^2$  and had achieved an  $18.3 \pm 8.0\%$  TWL. On a per protocol basis, patients experienced 14.2%, 15.3%, 16.6%, and 18.7% TWL at 1, 2, 3, and 4 years, respectively ( $P < .01$  for all). Forty of 58 patients (69%) achieved at least 10% TWL at 4 years or at time of study withdrawal. Improvements in quality of life scores and select cardiometabolic parameters were also maintained through 4 years. There were 2 serious adverse events reported in the second through fourth years, both of which resolved with removal or replacement of the A tube. Two persistent fistulas required surgical repair, representing approximately 2% of all tube removals. There were no clinically significant metabolic or electrolytes disorders observed, nor any evidence for development of any eating disorders.

**Conclusions:** The results of this midterm study have shown that AT is a safe, effective, and durable weight loss alternative for people with class II and III obesity and who are willing to commit to using the therapy and adhere to adjustments in eating behavior. (*Surg Obes Relat Dis* 2019;15:1348–1354.) © 2019 Published by Elsevier Inc. on behalf of American Society for Bariatric Surgery.

**Keywords:**

Obesity; Endoscopic bariatric therapy (EBT); Aspiration therapy; Metabolic; Diet

Obesity is a major public health problem in the United States and throughout most of the world because of its high prevalence and adverse effects (AEs) on health, quality of life, and healthcare costs [1]. Conservative therapies (diet and exercise, cognitive behavior therapy, and pharmacotherapy) are minimally invasive but with limited long-term effectiveness [2–5]. Although bariatric surgery is highly effective, it suffers from low utilization because of its relative invasiveness [6].

In recent years, there has been a growing interest in endoscopic bariatric and metabolic therapies. The U.S. Food and Drug Administration recently approved the AspireAssist System (Aspire Bariatrics, King of Prussia, PA, USA) [7]. This is an endoscopic bariatric and metabolic therapies that is approved for adults,  $\geq 22$  years, with a body mass index (BMI) of 35 to 55  $\text{kg/m}^2$  who have not been successful with conservative therapies. It is indicated for long-term use, with continuous monitoring and lifestyle therapy.

The AspireAssist consists of a modified percutaneous endoscopic gastrostomy tube (A tube), with a fenestrated 15-cm long intragastric portion and an external port to facilitate partial drainage of gastric contents. Patients are instructed to aspirate 20 to 30 minutes after a meal up to 3 meals per day. Sullivan et al. [8] showed that optimal aspirating technique resulted in removal of up to 30% of the total ingested calories.

In an earlier report, we described the 1-year results of the U.S. pivotal study (PATHWAY trial), which was a prospective, randomized, controlled, 10-center study. The study randomized 171 patients in a 2:1 fashion to AspireAssist with lifestyle intervention (AT group) versus lifestyle intervention alone. At 1 year, the AT group experienced a 12.1% total weight loss (TWL), whereas the lifestyle intervention alone group experienced a 3.5% TWL ( $P < .001$ ) [9].

In this report, we provide longer-term results of the primary outcomes with post hoc analysis of the AT patients from the PATHWAY Trial.

## Methods

### Study design

The PATHWAY trial was a 52-week, randomized, controlled trial conducted at 10 sites in the United States from November 13, 2012, to June 17, 2015, under the guidelines of the Declaration of Helsinki ([ClinicalTrials.gov](https://www.clinicaltrials.gov) NCT01766037). The study protocol was previously described in detail [9]. In brief, patients in both groups were provided a 10-session behavioral and diet education weight loss program and were seen for 13 medical monitoring visits during the first year. For AT participants who continued the study, 5 medical monitoring visits were provided at weeks 60, 68, 76, 90, and 104 and thereafter once every 13 weeks up to week 260.

All participants provided written informed consent. The study was approved by the institutional review board at each institution. All authors were involved in the preparation of the manuscript, agreed to submit it for publication, and assumed responsibility for the accuracy and completeness of data from their respective site. The sponsor, Aspire Bariatrics, funded this clinical trial and provided support for statistical analyses.

### Study participants

Inclusion criteria were ages 21 to 65 years old and a BMI of 35.0 to 55.0 kg/m<sup>2</sup>. Exclusion criteria were a history of eating disorder (binge eating disorder, bulimia nervosa, or night eating syndrome) or evidence of an eating disorder evaluated by the Questionnaire on Eating and Weight Patterns-Revised (QWEP-R) or on an Eating Disorder Examination (EDE), which provide a self-reported measure and an interview-based assessment of binge eating, purging, and disordered attitudes and behaviors related to eating, body-shape, and weight [10,11]. Of 282 patient screens, there were 8 (2.8%) screening failures owing to Night-Eating Disorder and 13 (4.6%) screening failures owing to bulimia or binge-eating disorder. Details regarding subject eligibility were provided in our earlier paper [9].

### Statistical analysis

Continuous variables were reported using mean  $\pm$  standard deviation. Categorical variables were reported using proportion (%). A Student's *t* test was used to compare continuous variables and Pearson's  $\chi^2$  test was used for comparison of categorical variables. TWL was calculated using the following formula: (initial weight before AT – follow-up weight) / initial weight before AT  $\times$  100%. Excess weight loss (EWL) was calculated using the following formula: (initial weight before AT – follow-up weight) / (initial weight before AT – ideal weight)  $\times$  100%. Clinical success was defined as achieving at least 10% TWL. A per protocol analysis was used for all

calculations in this follow-up study. A Kaplan Meier Survival analysis was used to assess median survival time of an A tube. All statistical analysis was performed using SAS version 9.4 software (Cary, NC, USA). Statistical significance was defined as a 2-sided *P* value  $\leq$  .05.

## Results

Of 111 patients randomized into the AT group in the PATHWAY trial, 29 elected to have the A tube removed for a variety of reasons (Fig. 1) and 82 had the A tube in place at 1 year, with a TWL of 14.2%. Of 82 patients, 58 patients elected to continue in this follow-up study. Of these, 55 (94.8%) had achieved at least 10% TWL at the end of the first year. Mean baseline age of these 58 patients was  $43.7 \pm 9.7$  years and mean baseline BMI was  $41.6 \pm 4.5$  kg/m<sup>2</sup>. At the end of first year (at the beginning of the follow-up study), these 58 patients had a BMI of  $34.1 \pm 5.4$  kg/m<sup>2</sup> and had achieved an  $18.3 \pm 8.0\%$  TWL.

### Weight loss and device usage

Of 58 patients who enrolled in the follow-up study, 15, 21, and 7 patients elected to have the A tube removed (i.e., withdrew from the study between years 1 and 2, 2 and 3, and 3 and 4, respectively). There was no loss to follow-up. As a result, the numbers of patients who had the A tube in place and reported for follow-up at the end of years 2, 3, and 4 were 43, 22, and 15, respectively. Of 43 patients who withdrew from the study between years 2 and 4, 25 (58.1%) achieved at least 10% TWL at the time of withdrawal (Fig. 1). On a per protocol basis, patients experienced 14.2%, 15.3%, 16.6%, and 18.7% TWL at 1, 2, 3, and 4 years, respectively (*P* < .01 for all). This corresponded to 37.1%, 40.8%, 44.7%, and 50.8% EWL (Table 1). Mean ( $\pm$  standard deviation), %EWL, from baseline, of AT participants at years 1, 2, 3, and 4 was  $37.1 \pm 27.6$  (n/N = 81/110),  $40.8 \pm 25.3$  (n/N = 42/55),  $44.7 \pm 29.7$  (n/N = 22/55), and  $50.8 \pm 31.9$  (n = 15/55), respectively (Table 1). Clinical success rate for patients participating in the follow-up study was 40/58 (69%) at 4 years from A-tube placement. The average number of tube connections, or device uses per day, was approximately 2.2 over the first year and 1.5 over the fourth year.

### Quality of life

As shown in our prior paper [9], the total Impact of Weight on Quality of Life score increased at year 1 by  $16.3 \pm 17.7$  points from a  $63.8 \pm 17.9$  baseline. The score increased across all 5 measures (physical function, self-esteem, sexual life, public distress, and work) at year 1. The improvement observed at year 1 from baseline in mean total Impact of Weight on Quality of Life score trended even greater in years 2 to 4 (eTable 1 in Supplementary Appendix).

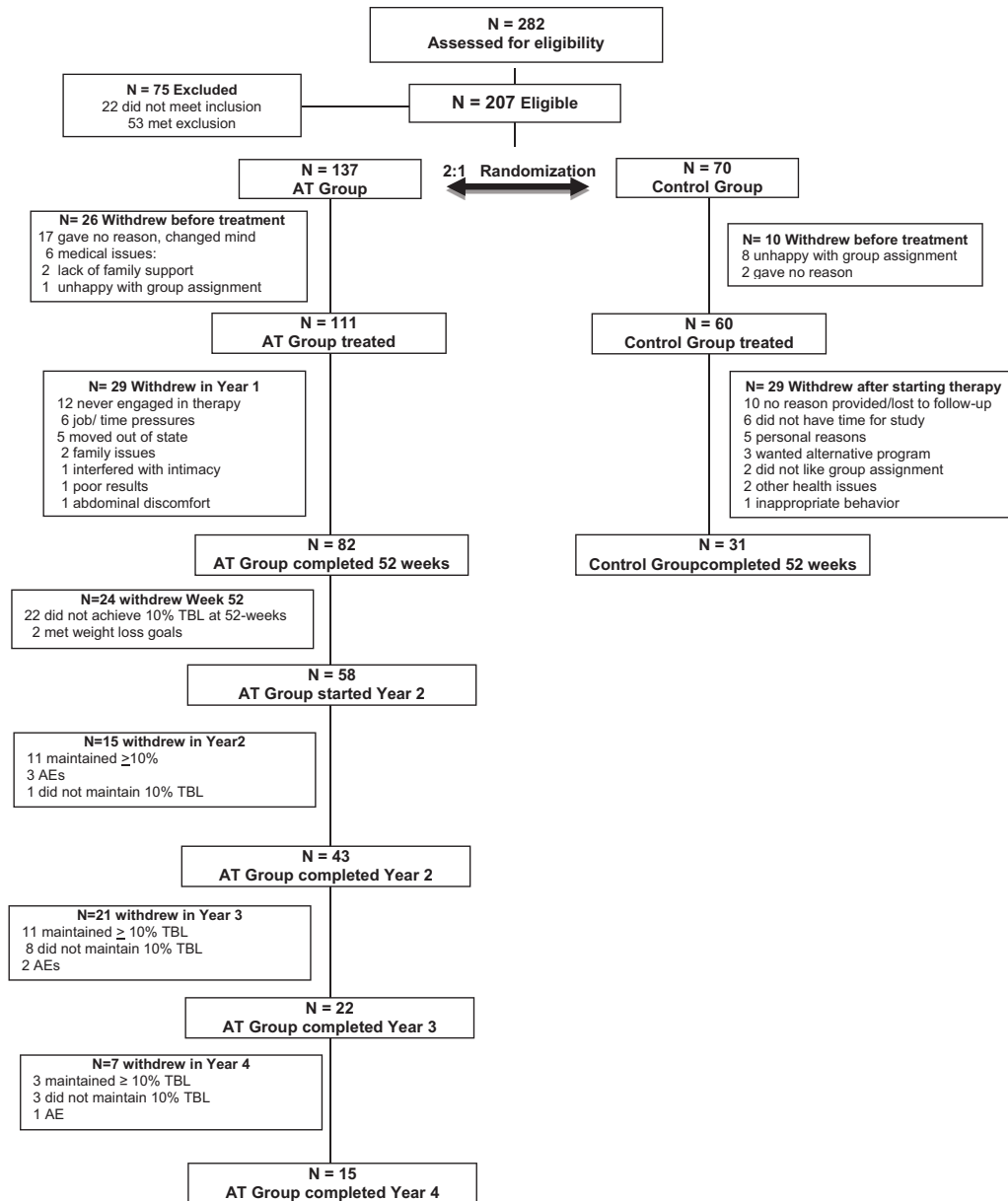


Fig. 1. PATHWAY trial study disposition through year 4.

### Co-morbidities

At year 1 compared with baseline, glycated hemoglobin, blood lipids, blood pressure, plasma alanine aminotransferase, and plasma aspartate aminotransferase had improved, and this improvement was maintained through 4 years (eTable 2 in the Supplementary Appendix). In the subset of patients with abnormal or near-normal baseline levels of these parameters, a greater improvement was observed (eTable 3 in the Supplementary Appendix).

Medications to treat hypertension, dyslipidemia, and diabetes were not fixed throughout the study: the participants' primary physicians changed such medications as they saw fit. Nonetheless, there was a reduction in medications and

the number of participants on medications at year 1 from baseline, and a trend for further reductions in years 2 to 4 (eTable 4 in the Supplementary Appendix).

### Electrolytes and minerals

Data on electrolytes (potassium, sodium, chloride, calcium, and  $\text{CO}_2$ ) and other analytes (vitamin D, 25-OH, iron, total protein, blood urea nitrogen, creatinine, and bilirubin) at baseline and for years 1 to 4 are provided in eTables 5 and 6, respectively, in the Supplementary Appendix. In general, there is little remarkable about these data in the tables. The mean values at years 1 to 4 were not clinically or statistically different than the baseline levels

Table 1

Mean ( $\pm$  standard deviation), %TWL, %EWL, and absolute weight loss (kg), relative to baseline and at years 1 to 4, with 95% CIs and the percentage of patients who achieved at least 25% EWL at years 1 to 4

	N	%TWL	%EWL	WL, kg	% EWL >25%
Year 1	82	14.2 $\pm$ 9.8 95% CI: 12.1–16.4	37.1 $\pm$ 27.6 95% CI: 31.0–43.1	16.6 $\pm$ 11.5 95% CI: 14.1–19.1	68.3%
Year 2	43	15.3 $\pm$ 8.8 95% CI: 12.6–18.0	40.8 $\pm$ 25.3 95% CI: 32.9–48.7	17.9 $\pm$ 10.8 95% CI: 14.5–21.3	72.1%
Year 3	22	16.6 $\pm$ 10.5 95% CI: 12.0–21.3	44.7 $\pm$ 29.7 95% CI: 31.5–48.7	19.6 $\pm$ 13.3 95% CI: 13.7–25.5	63.6%
Year 4	15	18.7 $\pm$ 11.7 95% CI: 12.2–25.2	50.8 $\pm$ 31.9 95% CI: 33.1–68.5	22.1 $\pm$ 15.9 95% CI: 13.3–30.9	73.3%

%TWL = percent total weight loss; %EWL = percent excess weight loss; CI = confidence interval.

and almost all assessments over this 4-year period, except for a small percentage, remained in the normal range. There were no clinical manifestations of any abnormality.

### Eating behaviors

Participants were assessed for potential maladaptive eating behaviors with the QEWP-R, a self-administered test, and the EDE, a test administered by a qualified health-care professional. The QEWP-R was given at screening and weeks 14, 26, 52, 104, 156, 208, and 260. The EDE was given at screening and weeks 14, 26, and 52.

One participant in the control arm who showed no evidence of binge-eating behaviors at screening demonstrated evidence of binge eating at week 28, when evaluated by using the both the QEWP-R and the EDE, and hence was withdrawn from the study. One AT participant showed no evidence of any maladaptive eating behavior at week 52 with either her QEWP-R or EDE assessment, but reported excessive eating at night at week 60 and was withdrawn from the study. No AT participant ever showed any abnormal eating behaviors in any of the EDE or QEWP-R assessments over the 4-year period of this study.

### Withdrawals

Of 58 AT participants who continued in the study after year 1, 43 participants withdrew before completion of year 4. Of these, 25 of 43 patients (58%) met their weight loss goal or had lost >10% of their initial weight. Eighteen of 43 patients (42%) had insufficient weight loss. Of these 18 patients, common reasons for withdrawal included lack of time or motivation and recurrent site irritation.

### Adverse events

Two serious adverse events (SAE) were reported in years 2 through 4 of the study; both resolved with conservative interventions. In the first SAE, a participant at 14 months who had lost 45 kgs from baseline developed a secondary fistula just superior to the A-tube fistula. The A tube was removed and the secondary fistula closed without additional intervention, by the second postexplant visit. In the second SAE, a

participant developed a hole in the A tube 20 months after placement. The A tube was replaced.

A total of 57 AEs, including the 2 SAEs discussed in the previous paragraph, occurred in years 2 through 4 (eTable 7). In aggregate, there were .6 AEs per patient-year in years 2 through 4, compared with a rate of 1.37 AE per patient-year in the postprocedural period of year 1. The 3 AEs with the greatest frequency were peristomal irritation (12 events), persistent fistulas (12 events), and peristomal granulation tissue (8 events). In addition to the 1 persistent fistula reported at 6 months in our prior report, 12 persistent fistulas occurred in years 2 through 4 (4 at 2 years, 5 at  $\sim$ 2.5 years, 2 at 3 years, and 1 at 4 years); an additional persistent fistula was reported at 5 years. All persistent fistulas ultimately closed with 1 to 3 additional interventions (argon plasma coagulator, cytology brush, clips, or sutures); 2 of 14 persistent fistulas were closed with a surgical intervention, representing 2% of all removed A tubes (eTable 8, Supplementary Appendix).

### Special patient population: participants $\geq$ 55 years at baseline

We looked at weight loss and safety in participants  $\geq$ 55 years old at baseline versus participants <55. Weight loss at each time period trended slightly higher in the  $>$ 55 group than <55 group, although the difference is not statistically significant (eTable 9). AEs were similar between the 2 groups (eTable 10).

### A-tube replacements

Over the 4 years of this study, a total of 27 A tubes have required replacement. Reasons for A-tube replacement include (1) a defect developing within the tube ( $\sim$ 50%), (2) leaks around the tube ( $\sim$ 30%), and (3) miscellaneous (diagnostic endoscopy, buried bumper, etc.; 20%). According to a Kaplan Meier survival analysis, one can expect 50% of the A tubes to be replaced within approximately 3.5 years postgastrostomy.



## Discussion

The results of this study show that AT can provide significant and durable weight loss over 4 years in people with class II and III obesity. Mean %TWL for those continuing in the trial improved from 14.2% at 1 year to 18.7% at 4 years. Quality-of-life scores at year 1 also showed significant improvement from baseline and trended to greater improvement in each subsequent year. In addition, the decrease in daily device usage from years 1 to 4 for those continuing in the trial suggests adherence to lifestyle modification and not sole dependence on the device, even for those requiring longer-term therapy.

The study withdrawal rate reported in this study over a 4-year period was higher than that reported by Nystrom [12] in which 91%, 76%, 64%, and 57% of the participants who started AT completed 1, 2, 3, and 4 years of therapy. One possible explanation is that most of the sites in the Nystrom study provided more patient-to-patient support than what was provided in the PATHWAY study (e.g., group therapy session and Facebook groups).

At year 1, compared with baseline, improvement was seen in systolic blood pressure, diastolic blood pressure, high-density lipoprotein, low-density lipoprotein, triglycerides, glycated hemoglobin, plasma alanine aminotransferase, and plasma aspartate aminotransferase. These improvements over baseline were maintained, or trended toward greater improvement, for the 3 subsequent years as well. In addition, with a subset of baseline values that were abnormal or near-abnormal, at 1 year even greater improvement was seen. In addition to the improvement in these cardiometabolic parameters, there was also a reduction in hypertensive and dyslipidemia medications. This study offers no evidence that AT has any effect on cardiometabolic parameters beyond those secondary to weight loss.

AEs recorded in years 2 through 4 were no different than the postprocedural AEs reported in prior studies reporting PEG tube complications, except for the secondary fistula as reported above. The majority of AEs in this study were effectively treated with conservative therapies (short-term antibiotics, analgesics, topical ointments), resolved without any treatment, or in some cases required removal or replacement of the A tube. With few exceptions, the AEs reported in years 1 to 4 of this study were known complications of percutaneous endoscopic gastrostomy tubes, as reported in the literature. Of note, the rate of persistent gastrocutaneous fistulas rose from approximately 2% in the first 2 years to roughly 33% for tubes in place for longer than 2 years. The high rate of persistent fistulas after 2 years suggest that interventions should be taken prophylactically at the time of A-tube removal for those removed 24 months or later postgastrostomy. All persistent fistulas eventually closed with conservative interventions, apart from 2 that closed with surgical interventions, representing 2% of all tube removals. The optimal approach for managing this potential AE warrants further study.

There have been no deaths or permanent disabilities over the course of this study. In aggregate, 6 participants in this study experienced a SAE as follows: 2 in the periprocedural period, 2 in year 1, and 2 in years 2 to 4. These SAEs resolved with the following conservative therapies: (1) a 2-night hospital stay in which antibiotics were administered, (2) 2, 1-night hospitalizations in which analgesics were administered, (3) 2 A-tube replacements, and (4) 2 A-tube removals.

In this study, patients with a diagnosis of current or previous eating disorder were not enrolled. Nevertheless, 1 subject developed increased eating at night. This did not meet criteria for an eating disorder, but the device was removed. The concern expressed by some practitioners is that the ability to aspirate or remove food may be seen as a compensatory behavior and lead to the development of bingeing in patients treated with AT, consistent with bulimia nervosa. Binge eating disorder by itself has a lifetime prevalence of .855% to 2.6% and a 12-month prevalence of .44% to 1.6% in the general population and is the most common eating disorder [13–16]. In a population of patients with obesity who are seeking weight loss treatment, prevalence of binge eating disorder may be as high as 16% to 52% [17]. Therefore, it would be expected for a small percentage of patients with obesity to develop binge eating over the course of 4 years. Moreover, the rate at which an abnormal eating behavior occurred in this population of patients with obesity treated with AT is likely at or below what would be expected, suggesting that AT does not increase the risk of developing an eating disorder.

This therapy has the potential of being significantly less expensive than traditional bariatric surgery, particularly when the cost of long-term complications is considered. AT is a 15-minute endoscopic procedure that is performed in an outpatient setting and typically under conscious sedation. Furthermore, the complications associated with AT are relatively few and minor and typically resolve with conservative therapies. As such, it may provide an important option to risk adverse patients that do not wish to undergo surgical intervention.

Limitations of this study are the relatively small number of participants in the fourth year and the absence of weight loss data after A-tube removal, although some participants stopped using the device for an extended period of time before A-tube removal without weight regain because the adoption of new healthy eating behaviors is encouraged.

## Conclusion

This randomized controlled study has shown that AT can achieve durable weight loss and provide significant improvement in quality of life and in cardiometabolic metabolic factors, particularly for patients with a diagnosis of hypertension, dyslipidemia, or type 2 diabetes. In addition, the

results of this study support those of prior studies, in addition to the track record for percutaneous endoscopic gastrostomy tubes, to affirm the safety of the intervention. Considering this, we conclude that AT is a safe and effective intervention for people with class II and III obesity who desire a nonanatomy altering procedure and who are willing to commit to using the therapy.

### Disclosures

*CCT, LJA, RK, SS, ABS, AA, CMA, DT, AZ, MDJ, SE, and DLJ all received institutional research support from Aspire Bariatrics for this clinical trial.*

### Supplementary materials

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.soard.2019.04.026>.

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