and overall health by reaching extremes to limit participants' dietary intake, even at the expense of brushing and flossing. The device and its violation of autonomy should be censured by dentists, obesity medicine specialists and the public at large. Rather than promulgate weight stigma and potentially undermine oral health, we encourage dentistry experts and obesity medicine physicians to come together and devise interventions that account for the complexities of obesity and oral care.

L. Tu, S. S. Bajaj, F. C. Stanford, Boston, USA

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A bigger picture

Sir, we laud the efforts of Paul A. Brunton and his research team for designing and assessing tolerability of a novel intraoral device for weight loss.[1]

As the research reported the initial clinical findings, we are giving our input that may be of relevance in light of a bigger picture. The authors state that they intend to aim at short-term weight loss and we agree that it would be motivating to the participants who complied. However, as the tolerability was assessed for only two weeks, it is not clear if the beneficial outcome will be sustainable.

Furthermore, any active intervention should give due consideration to patients' preferences and should not cause deviation from acceptable patterns of lifestyle – including dietary practices. The intervention in the present study caused a deviation from the normal form of dietary consumption of food/nutrients. In the study, all the patients with BMI >30 were subject to only liquid diet. In order to optimise patients' choice and the clinician's intent of therapy on an acceptability scale, we suggest that a gradient in stringency in approach and mechanics of the device could be developed for the varied ranges of obesity.

Another important observation made by us was that the effect on temporomandibular joints (TMJ) was assessed only on changes in occlusion. Adequacy of a 15-day period for assessment needs to be substantiated if the risk of development of a chronic TMJ problem in the long term is to be considered. In the given premise, it becomes questionable to include obese patients with pre-existing TMJ disorders for the intraoral device intervention in future research on a larger number of subjects. Nevertheless, the research has shown a new direction and method by which general health and oral health can be integrated through a dental therapeutic approach.

R. R. Iyer, R. Sethuraman, Vadodara, India

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https://doi.org/10.1038/s41415-021-3736-y

Irregularities

Sir, further to the paper by Brunton *et al.*, I am writing to formally request that you issue an expression of concern and investigate the irregularities identified below.[1]

Firstly, I was surprised to see that the authors claim to conform to the STROBE statement despite the fact that STROBE (as the name implies) is for observational studies in epidemiology and this is an interventional clinical trial. One of the most important metrics for a trial to assess a device's acceptability and tolerability is patient flow. How many patients were approached but refused consent; how many were recruited but dropped out prior to treatment; and how many dropped out after? If this trial had been correctly identified as a trial by the authors and journal, and reported to the appropriate standard (CONSORT – with the 2016 extension for single arm and pilot trials), the prescribed flow diagram would have given us this information.

An unfortunate coincidence is that the number of patients reported appears irregular. The authors claim to have recruited seven patients, only one of whom dropped out due to reasons unrelated to the device. However, the plan when the trial began was to recruit ten patients. No explanation is given as to the deviation. Did the authors simply run out of money? Or was there some other reason to close recruitment at 70%? Concerningly, the history of changes to the trial registry (ANZCTR) is not reassuring. Despite the research group claiming to have only recruited seven patients publicly in your journal, they informed the registry on 12 December 2018 that they were closing recruitment as 'all 10 participants have been recruited'. What happened to the three mystery patients? Why were they not disclosed in the paper? Why did they pull out of the study (if indeed they did)?

K. Sheldrick, Kogarah, NSW, Australia

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https://doi.org/10.1038/s41415-021-3737-x

The authors respond

Sir, the authors have considered the letters the journal has received in response to our article 'An intraoral device for weight loss: initial clinical findings' (*Br Dent J* 2021; doi: 10.1038/s41415-021-3081-1) and the responses are below.

In response to the critical review (Opinion paper), we feel that the points raised are already covered in the responses below and as such we do not feel any further response is either needed or would be helpful.[1]

We thank you for the concerns raised and your interest in our research. Observational studies are better suited to evaluate the incidence of adverse events of interventions because they have less strict inclusion and exclusion criteria, which allow a broader spectrum of the target population to be included. While RCTs are usually the best option to test efficacy (the effect of the intervention under ideal conditions), observational studies are a valuable option to evaluate effectiveness (the effect of an intervention in real life). The current study was considered as an observational study as it was primarily conducted to both validate and test the tolerability of the device in healthy individuals and therefore we believe the STROBE guidelines to be appropriate. In addition, the results as reported also conform to the CONSORT guidelines as one patient was lost to follow-up and the data for all the remaining patients in the trial are reported. A patient flow diagram would add no additional information given the small number of participants.

In total, 28 obese patients volunteered for the study; however, only seven participants fulfilled the study's inclusion criteria. Initially, we had planned to recruit ten participants for the study, but unfortunately, funding