

A randomised, single-blind comparison of high-level disinfectants for flexible nasendoscopes

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Abstract

Objectives: To compare the microbiological efficacy, turnaround time, cost, convenience, and patient and user tolerance of Tristel Trio Wipes, PeraSafe solution and Cidex OPA solution for the high-level disinfection of flexible nasendoscopes.

Methods: Flexible nasendoscopes were used in routine clinical encounters. They were then disinfected with one of the three disinfectant methods. Surveillance cultures were taken before and after each disinfection process. Data relating to each of the study parameters were recorded.

Results: Positive bacterial cultures were discovered on nasendoscopes disinfected with PeraSafe and Cidex OPA. Tristel Trio Wipes have no capital outlay cost, the lowest running cost, the greatest convenience and the fastest turnaround time. PeraSafe had a faster turnaround time than Cidex OPA, and lower running costs.

Conclusion: Tristel Trio Wipes are equal to PeraSafe and Cidex OPA in terms of microbiological efficacy. Turnaround time and cost are dramatically reduced when using Tristel Trio Wipes compared to the other disinfectant methods.

Key words: Endoscopes; Decontamination; Otolaryngology; Laryngology

Introduction

Flexible nasendoscopy is a routine out-patient procedure undertaken to examine the upper aerodigestive tract, which includes areas such as the pharynx, larynx and nasal cavity. Procedures are regarded as relatively quick and simple, and are frequently carried out in the out-patient departments of general otolaryngology clinics.

Flexible nasendoscopes are expensive, heat-sensitive, delicate instruments. The rate-limiting step in the use of these instruments for patient examination is the speed of the high-level disinfection method used.

There is a significant difference between the design and construction of flexible nasendoscopes and other flexible endoscopes. Most nasendoscopes are shorter, thinner and do not have an internal channel. Many disinfectant guidelines have been written to address the disinfection of endoscopes used for respiratory and digestive tracts. However, far fewer guidelines have been published for the disinfection of nasendoscopes.

The upper aerodigestive tract, in which the nature and quantity of flora present are diverse, serves as a potential route of cross-contamination between patients. It has been demonstrated that instrument insertion into

the upper aerodigestive tract results in the adherence of 3000–5000 colony forming units of micro-organisms to their surface.¹ Many studies agree that nearly all of the infections transmitted to the patient after an endoscopic examination result from the cleaning and disinfection procedure.² This can occur in particular during: the pre-washing step (12 per cent); the washing and disinfection step (associated with exposure time or inappropriate disinfectant procedures) (73 per cent); and drying and storage (12 per cent).² It is therefore imperative that disinfection methods are adequate and reduce the iatrogenic spread of infection in clinics to the minimum possible.

The degree of risk determines the reprocessing level required of an instrument. According to the Spaulding classification, semi-critical devices that come into contact with intact mucosal membranes during use require at least high-level disinfection after each use.³ Nasendoscopes are considered as semi-critical devices that require high-level disinfection between patients.

High-level disinfection is capable of destroying bacteria, fungi, mycobacteria, viruses and some bacterial endospores (although not high numbers of clostridium

and bacillus spp). It is different from sterilisation, which is the process by which all living organisms and viruses on an object are destroyed.⁴

Intact mucous membranes are generally resistant to infection by common bacterial spores, but are susceptible to other organisms, such as bacteria, mycobacteria and viruses.⁵

Endoscope high-level disinfection with a liquid chemical solution involves five steps after leak testing: pre-cleaning, disinfecting, rinsing, drying and storage.⁵

There are numerous chemical solutions available on the market that provide high-level disinfection. Many of these solutions are used in conjunction with automated endoscope reprocessors or are placed in a trough for soaking with a specified contact time. These methods are widely known. Another type of high-level disinfecting system is gaining increasingly wide acceptance:⁶ the Tristel[®] Trio Wipes system. This method eliminates the use of automated endoscope reprocessors and soaking troughs.

The current study aimed to evaluate and compare the high-level disinfection capability (which includes microbiology efficacy and turnaround time), ease of use, patient tolerance, user tolerance and cost effectiveness of the Tristel Trio Wipes system against two more conventional and widely known disinfectant solutions: Cidex[®] OPA and PeraSafe[®].

Materials and methods

Patients were randomised at a ratio of 1:1:1 to undergo nasendoscopy in which the flexible nasendoscopes were disinfected with either Tristel Trio Wipes, Cidex OPA or PeraSafe. Given the logistics associated with organising nasendoscopy clinics, it was not possible to have all three disinfection systems available for use in each clinic. Therefore, clinics were randomised to one of the three disinfectant systems.

Randomisation took place after all participants for clinics had been confirmed. Two clinics could occur on the same calendar day, with one in the morning and one in the afternoon. It was expected that between two and eight participants would attend each clinic. Both examining surgeons and participants were blinded to the disinfectant solution used in the particular clinic.

Out-patient lists were reviewed prior to clinic dates. Those likely to warrant nasendoscopy examination were contacted and verbal consent for participation was obtained. On the day of nasendoscopy, written consent was obtained from patients. Patients also completed a baseline questionnaire at this time.

The study inclusion criteria were: consenting patients aged over 18 years who had an indication for nasendoscopy examination. The exclusion criteria were: patients known to be allergic to co-phenylcaine spray or the disinfecting solutions; those who were on antibiotics or had completed a course of antibiotics within the week prior to nasendoscopy; patients who

had undergone endoscopic sinus surgery within the previous six months; or those known to be hepatitis B or human immunodeficiency virus positive.

High-level disinfection with the Tristel Trio Wipes system⁷ entailed the following: (1) pre-cleaning of the nasendoscope with the pre-clean wipe; (2) high-level disinfection with the sporicidal wipe, activated via two aliquots of the provided foam pump (all parts of the nasendoscope were wiped and left for a contact time of 30 seconds); (3) rinsing with the rinse wipe, to neutralise any chemical residues; and (4) air drying.

High-level disinfection with the PeraSafe system⁸ entailed: (1) pre-cleaning of the nasendoscope using an enzymatic sponge; (2) 10-minute submersion in PeraSafe liquid contained within the PeraSafe cylinder; (3) rinsing of the nasendoscope; and (4) air drying.

High-level disinfection with the Cidex OPA solution⁹ used in conjunction with a Medivators[™] automated endoscope reprocessor entailed: (1) pre-cleaning of the nasendoscope outside of the automated endoscope reprocessor; (2) soaking in detergent solution contained within the automated endoscope reprocessor; (3) 10-minute submersion in Cidex OPA solution contained within the automated endoscope reprocessor; (4) rinsing using the automated endoscope reprocessor rinse cycle with filtered water; and (5) air drying.

Microbiological swabs were taken prior to using the flexible nasendoscope on patients and immediately after high-level disinfection. Two sites were sampled from each flexible nasendoscope: (1) the optic tip, the part of the nasendoscope that is inserted into the nose or oral cavity and pharynx of patients; and (2) the handle of the nasendoscope, which is used by the operator to hold and manipulate the endoscope during examination. Microbiological swabs were also taken from the exit port and inner rim of the lid of the automated endoscope reprocessor used with Cidex OPA solution, and from the PeraSafe cylinder, at the end of the clinic.

After nasendoscopy examination, patients rated the discomfort of the procedure on a visual analogue scale for pain that ranged from 0 to 10 cm, with a 0 cm rating indicating 'no pain' and a 10 cm rating indicating 'worst pain possible'. A further visual analogue scale for pain was provided for patients, to be completed 3–7 days following the procedure, in order to gauge if there was any long-term discomfort from any of the three disinfecting solutions used.

The total cost of each cycle of high-level disinfection was calculated. This included the cost of all disinfecting solutions, disposables, nasendoscope damage (if any) caused by the disinfecting solutions and technician time required to complete the disinfection cycle. The time of reprocessing of each solution was accurately recorded, from the start of the initial pre-cleaning step to the final rinsing step.

The ease of disinfection system use was rated by nursing staff using a Likert scale ranging from 1 to 5,

with 1 being 'very easy to use' and 5 being 'quite difficult to use'. Subjective opinion on odour acceptability and odour strength of the disinfectants were rated by nursing staff and surgeons using the same scale, with possible responses ranging from 'undetectable' to 'moderate'.

Results

We aimed to recruit approximately 65 patients per randomised group, totalling 195 participants. No prior results were available for guidance and therefore it was not possible to determine an appropriate sample size based on available data. A sample of 65 patients per group was estimated to be sufficient, without taking into account any specific end point or recordable safety measures for the experiment.

Microbiological data have been summarised per randomised group as frequencies and as percentages of study days for each randomised group. These figures have been compared between groups using chi-square or Fisher's exact tests where appropriate. Baseline clinical and patient features have been summarised for each randomised group using means, medians, standard deviations, ranges, frequencies and percentages, as appropriate. Cost effectiveness has been calculated from the requisite inputs and is presented with empirically derived estimates of the likely variation in any final estimates. Patient perception, ease of use and acceptability data have been compared between the randomised groups using independent *t*-tests and Mann-Whitney U tests. Safety data for participants, nurses and surgeons have been summarised for randomised groups as frequencies and percentages overall, and in terms of relatedness and severity subgroups.

A two-tailed *p*-value of less than 0.05 has been taken to indicate statistical significance. All the statistical comparisons noted above were undertaken as pairwise comparisons, comparing the Tristel Trio Wipes system with PeraSafe solution and the Tristel Trio Wipes system with Cidex OPA solution.

The disinfecting agents used were randomised over a total of 51 study days: the Tristel Trio Wipes system, PeraSafe solution and Cidex OPA solution were each used for 17 days. This resulted in 203 participants, consisting of 100 males and 103 females, with a collective mean age of 51.7 years. The nasendoscope was disinfected with the Tristel Trio Wipes system for 72 participants, with the PeraSafe solution for 68 participants and with the Cidex OPA solution for 63 participants. Eight participants did not return their questionnaires, resulting in a final sample size of 195 participants.

A total of 541 swabs were taken and sent for microbiological culture analysis. Four samples returned positive cultures from endoscopes disinfected with the Cidex OPA solution and PeraSafe solution (Table I). The PeraSafe solution produced a positive culture of *Stenotrophomonas maltophilia* when the handle of the endoscope was swabbed after disinfection with the solution. The Cidex OPA solution returned three positive cultures. One was from a swab of the nasendoscope optic tip after disinfection with the solution, producing a culture of coagulase-negative staphylococcus sp. The two other positive cultures were obtained from the Medivators automated endoscope reprocessor lid, which grew cultures of pseudomonas sp and coagulase-negative staphylococcus sp. No positive cultures were returned from endoscopes disinfected with the Tristel Trio Wipes system.

The Tristel Trio Wipes system had the fastest turnaround time for endoscope reprocessing, with an average time of 2.7 minutes (Table II). The average reprocessing time was 14.6 minutes when PeraSafe solution was used, and 27.4 minutes when Cidex OPA solution was combined with the Medivators automated endoscope reprocessor.

There were no reports of any nurses or surgeons experiencing any adverse events. A total of 11 adverse events occurred in 8 participants after examination; however, these adverse events were not deemed related to the disinfectants used in the study.

TABLE I
MICROBIOLOGICAL EFFICACY ENDPOINT DATA

Disinfectant	Sample site	Organism grown	Relevance
Tristel Trio Wipes	Optic tip & handle of nasendoscope	No growth	
Cidex OPA	Inner rim of Medivators automated endoscope reprocessor lid	Pseudomonas sp isolated	Likely environmental organism of low pathogenic potential
	Optic tip of nasendoscope	Light growth of coagulase-negative staphylococcus sp	Skin commensal of low pathogenic potential, possibly due to inadequate exposure of disinfectant at this site of Medivators automated endoscope reprocessor
PeraSafe	Handle of nasendoscope	Light growth of <i>Stenotrophomonas maltophilia</i>	Skin commensal of low pathogenic potential
			Environmental organism of low pathogenic potential except in immunocompromised patients; organism is inherently resistant to antibiotics

Disinfectant	Mean disinfectant time (minutes)	Mean preparation time (minutes)	Mean total time (range) (minutes)
Tristel Trio Wipes	2.7	0	2.7 (1.6–4.8)
PeraSafe	10	4.6	14.6 (13.2–16.3)
Cidex OPA	10	17.4	27.4 (25.2–36.3)

There was no significant difference between the three study groups in terms of the patients’ comfort ratings given immediately following nasendoscopy or 3 to 7 days after the procedure.

The acceptability and strength of the disinfectants’ odour was rated by the nurses during the disinfection process and by the surgeons during the nasendoscopy procedure. Nurses reported significantly better odour ratings using the Tristel Trio Wipes system compared to the PeraSafe and Cidex OPA solutions (Mann–Whitney U test $p < 0.05$). The Tristel Trio Wipes odour was rated as ‘quite pleasant’ or ‘neither pleasant nor unpleasant’ by 96.3 per cent of nurses, compared to 88.9 per cent for Cidex OPA solution and 59.3 per cent for PeraSafe solution.

Odour strength was rated as ‘undetectable’ by 55.6 per cent of nurses for the Tristel Trio Wipes system, compared to 14.8 per cent for Cidex OPA solution (Figure 1). There were no undetectable ratings reported by nurses using the PeraSafe solution. These results were statistically significant when the Tristel Trio Wipes were compared with Cidex OPA solution and when compared with PeraSafe solution (Mann–Whitney U test, $p < 0.05$). All surgeons rated the odour strength of all three disinfection systems as undetectable.

Two-thirds of the nurses rated the Tristel Trio Wipes system as ‘very easy to use’ and a further 29.6 per cent rated the system as ‘quite easy to use’ (Figure 2). In

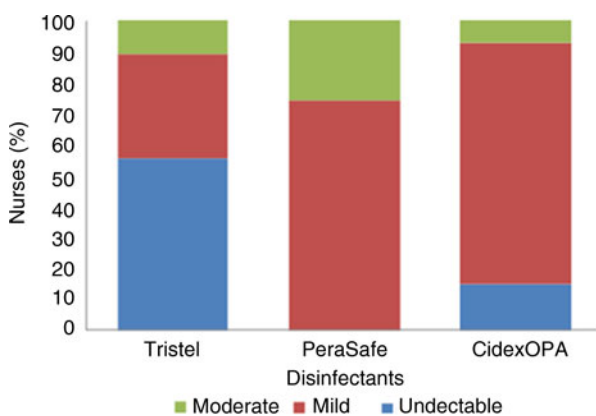


FIG. 1

Nurses’ ratings of odour strength during high-level disinfection.

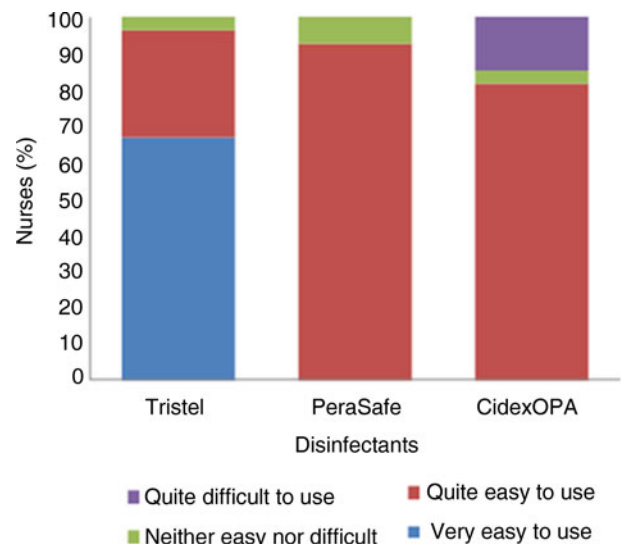


FIG. 2

Nurses’ ratings of ease of use for each of the high-level disinfectants.

comparison, 92.6 per cent of nurses using the PeraSafe solution and 81.5 per cent of nurses using the Cidex OPA solution rated the disinfection systems as quite easy to use. Overall, the Tristel Trio Wipes system was significantly easier to use than Cidex OPA and PeraSafe solution (Mann–Whitney U test, $p < 0.05$).

Of the three disinfection systems used in the study, the Tristel Trio Wipes system is the only high-level disinfection procedure that does not have any capital outlay costs. The total cost for the Tristel Trio Wipes, which includes enzymatic pre-cleaning, high-level disinfectant and rinsing wipes, is NZ\$9.50 per disinfection cycle (Table III). The cylinder containing the PeraSafe solution costs NZ\$227.00. Running costs that include an enzymatic sponge, which is changed every disinfection cycle, and the PeraSafe solution are NZ\$9.62 per cycle (Table IV). The capital cost for the Cidex OPA Medivators automated endoscope reprocessor is NZ\$76 106.25. Running costs for the Cidex OPA system, which include test strips, enzymatic sponges and OPA solution, are NZ\$15.88 per cycle (for every 14 days, this equates to NZ\$568.72 and depends on the OPA solution remaining active for the 14-day period) (Table V). The cost for maintenance of the Medivators machine has not been incorporated into this study.

Item	Frequency	Cost NZ\$
Tristel Pre-Clean Wipe	Each disinfection	2.50
Tristel Sporocidal Wipe	Each disinfection	4.90
Tristel Rinse Wipe	Each disinfection	2.10
Total	Each disinfection	9.50

TABLE IV
PERASAFE COSTS

Item	Frequency	Cost NZ\$
PeraSafe cylinder	Once (single purchase)	227.00
PeraSafe enzymatic sponge	Each disinfection	5.83
PeraSafe solution	Each disinfection	3.79
Total	Each disinfection	9.62*

*Does not include cost of cylinder

Discussion

This risk of nosocomial and iatrogenic infection within the medical arena is a major concern. Within the US healthcare system, it is estimated that \$4.6 billion is spent each year for the diagnosis and treatment of these infections. Human infection spread from patient to patient through procedures using endoscopes should not be underestimated; nearly 300 cases of human infections involving bacteria, fungi parasites and viruses linked to endoscopic procedures have been reported in the literature.¹⁰

The Spaulding system classifies nasendoscopes as semi-critical devices that require high-level disinfection. There are recognised problems associated with high-level disinfection; the methods are often time-consuming, potentially damaging to the instrument in question and often hazardous to the healthcare personnel in charge of the disinfection procedure itself.¹⁰ These factors highlight the need for an appropriate high-level disinfectant that minimises hazards to healthcare workers, instrument degradation and reprocessing time. At present, there is no uniformity in the recommendations set by various government and non-government organisations for the disinfection of nasendoscopes.⁴

The primary objective of this study was to evaluate and compare the high-level disinfectant Tristel Trio Wipes system with the more widely known high-level disinfectants Cidex OPA and PeraSafe.

The microbiological results of this study revealed bacterial growth on nasendoscopes disinfected with Cidex OPA and PeraSafe systems. The *S maltophilia*

isolate cultured (from the nasendoscope handle disinfected with PeraSafe) has high pathogenic potential in immunocompromised patients. It is intrinsically resistant to many antibiotics and disinfectants, thus proving a threat to the patients and clinic if iatrogenic infection occurs. The staphylococcus and pseudomonas isolates from the nasendoscope tip and Medivators automated endoscope reprocessor lid may have been due to contamination during the sampling process. Although these organisms are of lower pathogenic potential, they can still prove a risk to immunocompromised patients.

A smaller study by Bhattacharyya and Kepnes, conducted in 2004, evaluated the microbiological efficacy of another immersion-based high-level disinfectant, and yielded similar results, with a small positive culture occurring.¹⁰ Forty-eight flexible fibre-optic laryngoscopes soaked in 2.5 per cent glutaraldehyde for 20 minutes produced one positive mould culture (2.1 per cent positive culture rate) of rhizopus spp.

Other methods for endoscope cleaning that differ to high-level disinfection merit mentioning, such as the use of sheaths. One study by Elackattu *et al.*, from 2010, compared the high-level disinfection of 50 nasopharyngolaryngoscopes disinfected with Cidex OPA versus 50 nasopharyngolaryngoscopes covered with individually packaged disposable sterile sheaths.⁴ Four samples out of 50 produced positive bacterial cultures on nasopharyngolaryngoscope handles post-disinfection with Cidex OPA, versus 1 positive sample out of 50 with the use of sheaths. No positive samples were cultured from the end of the insertion shaft post-disinfection with Cidex OPA, versus 1 bacterial isolate out of 50 with the use of sheaths.

Although the use of sheaths offers an alternative to high-level disinfection, there are disadvantages. The increase in nasendoscope diameter associated with sheath use has the potential to exacerbate patient discomfort and cause trauma to the nasal mucosa.¹¹ Furthermore, the cost of using sheaths (average cost per use) is expensive.

It has been previously highlighted that the rate-limiting step in the use of nasendoscopes is the speed of the high-level disinfection procedure. In this study, the fastest high-level disinfection procedure was the Tristel Trio Wipes system, averaging at 2.7 minutes per cycle. If used as the sole disinfectant of choice in clinics, the speed at which high-level disinfection can be completed with this procedure will increase patient throughput, thereby reducing the rate-limiting step, which in turn will reduce the time from patient referral to examination. Nurses in the study commented that the fast turnaround time achieved by the Tristel Trio Wipes system made clinics less stressful as there was less pressure to recycle nasendoscopes.

The immersion methods used in this study proved more time-consuming than the Tristel Trio Wipes system. When using the PeraSafe solution, there was little handling time required for pre-cleaning;

TABLE V
CIDEX OPA COSTS

Item	Frequency	Cost NZ\$
Medivators AER machine	Once (single purchase)	76 106.25
Cidex test strip	Daily	2.94
Cidex OPA solution	Every 14 days*	7.11
Enzymatic sponge	Each disinfection	5.83
Total	Each disinfection	15.88 [†]

*Or earlier if the Cidex OPA solution fails testing with test strips. Thirty litres of Cidex OPA are required to fill the Medivators automated endoscope reprocessor machine, with running costs equating to NZ\$568.72 for the 14-day period. [†]This is based on a turnover of 8 disinfections per day, 80 within the 14-day Cidex cycle period, and does not include the cost of the Medivators automated endoscope reprocessor machine. AER = automated endoscope reprocessor

however, the nasendoscopes were inactive for 10 minutes whilst soaking, leading to an average turnaround time of 14.6 minutes.

Cidex OPA solution used in conjunction with the automated endoscope reprocessor proved most time-consuming for nursing staff, averaging a total turnaround time of 27.4 minutes. After nasendoscope pre-cleaning and detergent soaking, there was a further delay in clinics whilst the nasendoscopes were soaked in Cidex OPA solution. The slow turnaround time associated with Cidex OPA means that clinics would need a greater number of nasendoscopes to compensate for the time delay, if this were to be the sole high-level disinfectant used.

In addition to the long turnaround time, Cidex OPA solution proved to be the most expensive to operate for the number of nasendoscopes reprocessed in our clinics. The system was even more expensive when the capital cost of the automated endoscope reprocessor was included, and there are additional costs associated with maintenance of the machine (not assessed in this study). Moreover, the requirement for more nasendoscopes in clinic if only this system is used further increases capital costs. Nasendoscopes are expensive pieces of equipment that have a finite lifetime when used in busy hospital clinics, with rigorous routine cleaning by automated endoscope reprocessors further exacerbating wear and tear.

The use of Cidex OPA has been associated with anaphylaxis-like reactions in bladder cancer patients,¹² and its use has also elicited allergic reactions in healthcare staff via inadequate protective measures.¹³

- **Thorough cleaning of flexible nasendoscopes is crucial to reduce potential infectious disease transmission**
- **Tristel Trio Wipes, Cidex OPA and PeraSafe solutions provide high-level disinfection of nasendoscopes**
- **Patient throughput in clinic is delayed by automated disinfection processes and immersion methods**
- **Tristel Trio Wipes system reduces nasendoscope reprocessing time, thereby increasing patient throughput**
- **Manual disinfection has equivalent microbiological efficacy as immersion and automated processes for high-level disinfection**

One advantage of Cidex OPA when used in conjunction with an automated endoscope reprocessor is that aside from manual pre-cleaning and rinsing, the high-level disinfection process is largely automated. This has similarities with the PeraSafe system, in that the high-level disinfection part of the procedure requires little user input. Nevertheless, various studies have

assessed and demonstrated the effectiveness of the Tristel Trio Wipes system as a manual high-level disinfection process,^{1,11,14–16} and the effectiveness of the system has also been compared against an automated process.¹⁷

Conclusion

The results of this study demonstrate that the Tristel Trio Wipes system is equally as efficacious as the PeraSafe and Cidex OPA systems for the high-level disinfection of nasendoscopes following a 30-second contact time. The fast turnaround time provided by the Tristel Trio Wipes system high-level disinfection procedure reduces the rate-limiting step in clinic, and therefore increases patient throughput, when compared to the turnaround time provided by immersion methods with PeraSafe and Cidex OPA systems. The Tristel Trio Wipes also proved to be less costly, easier to use by staff and less odorous than the other high-level disinfectants tested.

Acknowledgement

This study was supported by a grant from Tristel Solutions, Snailwell, UK, through the Bay of Plenty Clinical School, Tauranga, New Zealand. (Tristel Solutions had no role in the study design, data analysis, interpretation of results or manuscript preparation.)

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Dr B Hitchcock takes responsibility for the integrity of the content of the paper
Competing interests: None declared
