## FEATURES SECTION

# Evidence-based orthodontics Structured Abstracts

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Effect of a self-etching primer on shear bond strength of adhesive precoated brackets *in vivo*. *Angle Orthodontist* 2006; 76: 127–31

Julio P. Cal-Netoa, Jose Augusto M. Miguelb, Eduardo Zanellac.

*Objectives:* To compare shear bond strength of adhesive precoated and uncoated brackets bonded with either conventional acid etching (AE) or self-etching primer (SEP).

Design: Split-mouth randomized controlled trial.

*Setting:* School of Dentistry, State University of Rio de Janeiro, Brazil.

*Participants:* Twenty-three patients each requiring orthodontic extraction of four premolars (92 teeth).

*Interventions:* Each patient's four premolars were randomly allocated for bonding with one of the following four combinations, either a precoated bracket (APCII Victory brackets, 3M Unitek, Monrovia, Clalif) with SEP (Transbond Plus SEP, 3M Unitek) or AE or, an uncoated bracket (Victory brackets, 3M Unitek) with either SEP or AE. Thirty days after bonding the teeth were atraumatically extracted and stored in 0.1% thymol solution until testing.

*Outcome measure:* Shear bond strength was measured after bracket debonding with an Instron Universal Testing Machine.

*Results:* There was no statistically significant difference between the shear bond strength of brackets bonded with conventional etching and primer or SEP (P=0.95). However, the bond strength was a significantly lower with the precoated brackets than with the uncoated brackets (P=0.03). Bond strength was statistically significantly reduced (P=0.03) in the precoated bracket group (10.3 MPa SD  $\pm 2.7$ ) relative to the uncoated bracket group (10.8 MPa SD  $\pm 2.7$ ).

*Conclusion:* Bond strength was unaffected by bonding technique (AE or SEP) but was reduced in precoated

brackets relative to uncoated brackets. This probably was not clinically significant as all the techniques had a bond strength thought to be adequate for clinical use.

*Implications:* The bond strengths of both techniques and types of brackets are probably adequate for clinical use; however, long-term failure/debond data would be more useful from a clinical perspective.

Using written material to support recall of orthodontic information: a comparison of three methods *Angle Orthodontist* 2006 Mar; 76(2): 243–50 Thickett E, Newton JT.

*Objectives:* To assess the effects of three different methods of presenting information on the recall of information in orthodontic patients in the short- and long-term.

Design: Quasi-randomized clinical trial.

Setting: Kings College Hospital, London, UK.

*Participants:* Thirty patients (12–14 years) due to begin orthodontic treatment. All participants had no previous experience of orthodontic appliance wear and had English as their first language.

*Interventions:* All patients were initially given verbal instructions regarding their orthodontic treatment supported by written information in one of the three formats: mind map (Mindmapper 3.4, Sim Tech Systems), information leaflet (British Orthodontic Society) or acronym constructed by the author.

*Outcome measures:* Short-term recall for each patient was assessed by administration of a nine item questionnaire 10–15 minutes after receiving the information. Long-term recall was assessed six weeks later by repeating the questionnaire.

*Results:* Statistically significant differences in recall were found between the three formats in both the short-term (P<0.01) and long-term (P<0.05), with participants

who were given a written information leaflet recalling less information on both occasions. Short-term recall was a good indicator of patient retention of information in the long-term. There was no difference in the rate of forgetting the material between the three methods.

*Conclusion:* Mind maps and acronyms give a small but significant advantage, in patients' recall of information, over written information leaflets.

*Implications:* This study suggests that techniques such as mind maps and acronyms are useful formats for providing information to patients. Clinicians may wish to present information in these formats as an alternative to the conventional written patient information leaflet. Further research into patients' recall of and compliance with the provided information would be useful.

#### Evaluation of preemptive valdecoxib therapy on initial archwire placement discomfort in adults *Angle Orthodontist* 2006 Mar; 76(2): 251–9

Young AN, Taylor RW, Taylor SE, Linnebur SA, Buschang PH.

*Objectives:* To compare the effectiveness of pre-emptive and post-operative administration of a Cox-2 inhibitor (Valdecoxib) in reducing discomfort caused by initial arch wire placement in adults.

Design: Double blind randomized controlled clinical trial.

*Setting:* Baylor College of Dentistry and private practice, Dallas, TX, USA.

*Participants:* Seventy adult patients (>18 years) immediately prior to commencing orthodontic treatment.

Interventions: Participants were randomly allocated to one of three groups prior to fixed appliance bonding: *Group 1* – pre-emptive analgesia 40 mg Cox-2 Inhibitor (Cx) 30 minutes prior to arch wire insertion, placebo at 2 hours, then 20 mg Cx every 12 hours. *Group 2* – pre-emptive placebo, 40 mg Cx at 2 hours, then 20 mg Cx every 12 hours. *Group 3* – placebo at all 6 time points. Ligation technique and initial arch wire sizes were variable, either 0.014", 0.016" NiTi or 0.018" Cu NiTi.

*Outcome measures:* Discomfort levels were recorded on a visual analogue scale at 0, 2, 6, 24, 36 and 48 hours after insertion of initial arch wire.

*Results*: 56 patients completed the trial. Fourteen patients were excluded because they had either used additional analgesia or failed to return the question-naires. Pain scores remained low in the pre-emptive

group as there was no significant increase in discomfort from baseline at any time point. The placebo and postoperative groups showed significant (P < 0.05) increases in discomfort after six hours, with peak discomfort at 24 hours.

*Conclusion:* The addition of pre-emptive analgesia, as well as 12-hourly post-operative analgesia with a Cox 2 Inhibitor, appears to reduce discomfort associated with initial arch wire placement in adults.

*Implications:* Although this study suggests that use of Valdecoxib is effective at reducing orthodontic pain, recent evidence regarding possible adverse effects of this medication has resulted in its withdrawal in Europe and the US and as such its use cannot currently be recommended.

## A clinical trial of Damon 2<sup>TM</sup> versus conventional twin brackets during initial alignment *Angle Orthodontist* 2006 May; 76(3): 480–5

Miles PG, Weyant RJ, Rustveld L.

*Objectives:* To compare the effectiveness and comfort of pre-adjusted edgewise and self-ligating brackets on incisor irregularity during initial alignment.

Design: Split-mouth clinical trial.

Setting: Private practice, Caloundra, Australia.

*Participants*: Sixty patients (40 female, 18 male) requiring a mandibular fixed appliance.

Interventions: Patients were alternately bonded using an indirect technique with Damon two brackets (D2 - Ormco, Glendora, Calif) in one mandibular quadrant and Victory brackets (3M Unitek, Monrovia, Clalif) in the contralateral mandibular quadrant. Initial 0.014" and after 10 weeks  $0.016 \times 0.025$  Cu NiTi arch wires were engaged in all brackets. Silver elastomeric modules were used to ligate the conventional brackets (CB). Appliances were adjusted every 10 weeks for the 20 week duration of the trial.

*Outcome measures:* Alignment of the teeth, from canine to central incisor in each quadrant, was assessed using Little's Irregularity Index (LI) at baseline, 10 and 20 weeks. Patients were questioned regarding discomfort, comfort on the lips and preferred look of each quadrant 1–2 days after initial bonding. Discomfort associated with arch wire insertion and removal was assessed at initial arch wire change at 10 weeks and overall bracket failure rates were recorded for each group.

*Results:* Fifty-eight patients completed the trial. Little's Irregularity Index was statistically significantly reduced by 0.2 mm more in the CB group than D2 at both 10 and 20 weeks (P < 0.01). Statistically significant results (P < 0.0005) were found with more bracket failures and patients disliking the appearance of the D2 brackets. Discomfort was less in the D2 group initially (P < 0.05) but higher upon insertion of the second arch wires at 10 weeks (P < 0.005).

*Conclusion:* It appears that the D2 brackets were less effective than conventional brackets at correcting alignment during the first 20 weeks. Initially, the D2 brackets were less painful but substantially more painful after the insertion of the second arch wire. They were also more likely to debond.

*Implications:* The results of this study should be interpreted with caution due to the internal validity of this trial. Although statistically significant differences were found it is difficult to imply that these are clinically significant, since effectiveness of the SL brackets may become more significant/apparent in the later stages of treatment. A well designed randomized controlled clinical trial, over the whole course of treatment, may address some of these issues.

Orthodontic anchorage: a systematic review Angle Orthodontist 2006 May; 76(3): 493–501 Feldmann I, Bondemark L.

*Objectives:* To examine the types of orthodontic anchorage systems in use and their effectiveness. *Design:* Systematic review.

*Data sources:* The Medline and the Cochrane Clinical Trials Register (www.cochrane.org/reviews) were searched to identify articles published from January 1966 to December 2004 that combined the MeSH terms 'orthodontics' and 'anchorage'.

*Study selection:* Human studies, reported in English, which were RCTs, prospective or retrospective controlled studies or clinical trials comparing at least two anchorage situations, were included.

*Data extraction:* Two reviewers extracted the data independently. Data were extracted on: author, year of publication, study design, material, sex and age, treatment time, anchorage unit used, ratio between anchorage loss and active movement. An assessment of methodological quality of the studies was also conducted.

*Data synthesis:* No data synthesis was possible due to the heterogeneity of study methods. The results were therefore presented in narrative and tabular form.

*Results:* The search strategy identified 494 articles, of which 14 met the inclusion criteria. Three main anchorage situations were identified: anchorage of molars (AM) during space closure after premolar extractions, anchorage loss (ALI) in the incisor  $\pm$  premolar region during molar distalization and studies using temporary anchorage devices (TAD).

AM - 2 RCTs, two prospective and three retrospective longitudinal studies. There was great variation in the methodology of these studies with the ratio of anchorage loss/active movement varying from 0.04 to 1.71.

ALI – 1 RCT, two prospective and four retrospective longitudinal studies. The ratio of anchorage loss/distal molar movement varied from 0.2 to 1.0. Most of the studies had methodological weaknesses including small sample sizes, confounding variables, lack of method error analysis and no blinding in measurements.

*Conclusion:* It was not possible to draw any reliable conclusions on the effectiveness of the different anchorage systems in this systematic review due to the methodological weaknesses of the studies identified.

*Implications:* Further well conducted RCTs are necessary to provide adequate scientific evidence on the effectiveness of anchorage systems including TADs. These studies should also consider patient centred outcomes and cost analysis.

### Forsus Nitinol Flat Spring and Jasper Jumper Corrections of Class II division 1 malocclusions Angle Orthodontist 2006 Jul; 76(4): 666–72

Karacay S, Akin E, Olmez H, Gurton AU, Sagdic D.

*Objectives:* To compare dental and skeletal changes obtained when using two types of spring fixed functional appliances (FFA) for the treatment of Class II division 1 malocclusions.

Design: Randomized controlled clinical trial.

*Setting:* Department of Orthodontics, Gulhane Military Medical Academy, Ankara, Turkey.

*Participants:* Forty-eight adolescent patients (12–16 years) with Class 2 skeletal pattern, increased overjet  $\leq = 7$  mm and minimal crowding requiring upper and lower fixed appliance treatment.

*Interventions:* Participants were randomly allocated to either, observation only or treatment with fixed appliances combined with either Forsus<sup>TM</sup> Nitinol Flat Spring (NFS - 3M Unitek, Monrovia, Clalif) or Jasper Jumper (JJ - American Orthodontics). The FFAs were inserted once

patients were in  $0.017" \times 0.025"$  stainless steel arch wires in a  $0.018" \times 0.028"$  bracket slot. Patients were recalled at 3 weekly intervals, until the molar relationship was corrected to Class I when the FFA was removed.

*Outcome measures:* Dental and skeletal relationships measured from dental casts and lateral cephalograms at baseline, at 6 months for the control group and immediately prior to and after the removal of the FFA for the experimental group.

*Results:* The OJ and molar relationships were corrected in both treatment groups. Statistically significant differences (P<0.05) between both treatment groups and the control group were seen in many variables but there were only differences in ANB and S-GO between the FFAs. The FFAs caused significant expansion (3–4 mm) in both arches relative to the untreated control group. Two JJs and one NFS (8%) were repaired during treatment due to breakages.

*Conclusion:* Both types of FFAs achieved Class II correction by mainly dentoalveolar movement. Arch width control was necessary to prevent over expansion.

*Implications:* Fixed functional appliances are useful as they are less dependent upon patient compliance, however, appropriate patient selection is important as the low frequency of breakages reported in this study, has not been found by the majority of research investigating the use of FFAs.

Soft tissue changes with fixed functional appliances in Class II division 1. A systematic review Angle Orthodontist 2006 Jul; 76(4): 712–20 Flores-Mir C, Major MP, Major PW.

*Objectives:* To evaluate soft tissue changes following fixed functional appliances treatment for Class II division 1 malocclusion.

Design: Systematic review.

*Data source:* PubMed, Medline, Medline In-Process, Cochrane Database, Embase, Web of Science, Lilacs and other non-indexed citations were searched to identify articles published from inception to June/ August 2005.

*Study selection:* Human controlled clinical trials (retrospective or prospective) that evaluated soft tissue changes of fixed functional appliance treatment cephalometrically, with a comparable untreated control group if growth of the study group was expected. Syndromic patients, surgical treatments or treatments with other appliances were excluded. *Data extraction:* Two reviewers extracted the data independently. Data were extracted on: author, year of publication, study design, untreated control group, sex, age, treatment time and type of fixed functional appliance used. The studies were also assessed for methodological quality.

*Data synthesis:* No data synthesis was performed. The results were presented in narrative and tabular form.

*Results:* The search strategy identified 116 studies of which nine initially met the inclusion criteria. Four of these were subsequently excluded, as three contained growing patients but no control group and the final was excluded as measurements were conducted on clinical photographs not cephalograms. The remaining five studies identified two appliances, the Jasper Jumper and the Herbst appliance; however, the methodological quality of these trials was low.

Appliances appeared to cause an improvement in facial profile due to retrusion of the upper lip rather than protrusion of the lower lip, as no change in the anteroposterior position of the lower lip or soft tissue menton were identified. Soft tissue changes produced by appliances were similar in non growing young adults and growing adolescents.

*Conclusion:* This systematic review suggests that treatment with fixed functional appliances leads to an improvement in facial convexity, which may be due to the appliances restricting forward movement of the upper lip.

*Implications:* The results of systematic review indicate the need for further research consisting of long-term randomized clinical trials. It is therefore difficult to conclude from this review whether these small but statistically significant changes are clinically significant, stable or apparent to the lay person.

Six-month bracket survival with a self-etch adhesive Angle Orthodontist 2006 Sep; 76(5): 863–6

Dos Santos JE, Quioca J, Loguercio AD, Reis A.

*Objectives:* To compare bond failure rates over 6 months of preadjusted edgewise brackets bonded with either a self-etching primer (SEP) or conventional acid etch (AE) technique.

Design: Controlled clinical trial.

*Setting:* Orthodontic clinic, University of Oeste de Santa Catarina, Brazil.

*Participants:* Thirty patients (12–18 years) requiring upper and lower fixed orthodontic treatment. Patients had unrestored buccal surfaces and no accentuated occlusal dysfunction.

*Interventions:* A single operator conducted all the treatment. All teeth were pumiced. The teeth were prepared for bonding using AE technique and primer or Transbond Plus SEP (3M Unitek, Monrovia, Calif) with teeth alternately allocated to each bonding technique. The surface agitation time for the SEP was increased (10–15 s) from the manufacturers' recommendation (3 s) in an effort to improve bonding efficacy. All brackets were bonded with Transbond XT adhesive (3M Unitek).

*Outcome measures:* First time bracket failure rate, bracket survival rate and modified adhesive remnant index (ARI).

*Results:* A total of 567 brackets (SEP 283, AE 284) were bonded. By 6 months, 21 SEP (7.4%), and 30 AE (10.6%) brackets failed (OR 0.68, 95% CI 0.38, 1.22). Self-etching primer had a statistically significant higher estimated survival rate (P<0.001) than AE technique.

*Conclusion:* At 6 months there was no difference in the bond failure rate between AE and SEP however, based on these data the SEP had a higher estimated survival rate than conventional acid etching for the whole course of treatment.

*Implications:* This study suggests that that Transbond Plus SEP can be used for orthodontic bonding and that it may have higher survival rates than conventional two stage etching and priming. However, this was an estimated survival analysis based on the first 6 months of treatment. It would be important to see the data for the completed trial prior to making any changes to clinical practice.

Cephalometric facial soft tissue changes with the twin block appliance in Class II division 1 malocclusion patients. A systematic review *Angle Orthodontist* 2006 Sep; 76(5): 876–81 Flores-Mir C, Major PW.

*Objectives*: To evaluate soft tissue changes in Class II division 1 patients treated with the Twin Block appliance.

Design: Systematic review.

*Data source*: PubMed, Medline, Medline In-Process, Cochrane Database, Embase, Web of Science, Lilacs and other non-indexed citations were searched to identify articles published from inception to October 2005.

*Study selection*: Human controlled clinical trials (retrospective or prospective) that evaluated the cephalometric soft tissue changes of patients treated with a Twin Block appliance against a comparable untreated control group. Syndromic patients, patients undergoing concurrent treatment with other appliances or those requiring surgical intervention were excluded. *Data extraction*: Two reviewers extracted the data independently. Data were extracted on: author, year of publication, study design, untreated control group, sex, age, study duration, initial overjet, molar relationship and cephalometric measurements evaluated. Studies were also assessed for methodological quality.

*Data synthesis*: No data synthesis was performed. The results were presented in narrative and tabular forms.

*Results*: The search strategy identified 42 potentially eligible studies of which two fulfilled the inclusion criteria; however, the methodological quality of these reports was low. No significant changes in soft tissues were evident other than the position of labrale superius relative to the aesthetic line which was on average 1.9 mm more retruded than in the control group but in only one of the two studies.

*Conclusion*: This systematic review suggests that treatment with the Twin Block appliance for Class II/1 correction does not produce clinically significant changes in facial convexity or an improvement in facial profile.

*Implications*: It is difficult to generalize the data from this review so clinicians should be cautious about implying that patients' profile will alter significantly as a result of treatment with Twin Block appliances.

#### Changes in the physical properties of human premolar cementum after application of 4 weeks of controlled orthodontic forces *The European Journal of Orthodontics* 2006 Aug; 28(4): 313–8

Chutimanutskul W, Ali Darendeliler M, Shen G, Petocz P, Swain MV.

*Objectives:* To compare the effect of light (25 cN) and heavy (225 cN) forces on changes in physical properties of cementum in an intra-individual sample and to identify sites that may be predisposed to root resorption.

Design: Split-mouth randomized controlled trial.

*Setting:* Sydney Dental Hospital, University of Sydney, Australia.

*Participants*: Eight patients (11.2–17.5 years) undergoing orthodontic treatment requiring bilateral maxillary first premolar extractions (16 teeth).

*Interventions:* Each participant had maxillary premolars randomly assigned to receive either light (25 cN) or heavy (225 cN) orthodontic force. Self-ligating Speed brackets (Strite Industries, Canada) were bonded to the first premolars and first molars to enable the application of a bucally directed force via sectional arch wires and springs. Titanium Molybdenum Alloy springs (Ormco, Glendora, Calif) of 0.016" and  $0.017" \times 0.025"$  dimensions were used to apply light and heavy forces respectively. Glass ionomer cement placed on mandibular molars was used to disengage the experimental teeth.

*Outcome measures:* All teeth were extracted atraumatically 28 days after force application and then stored in saline solution until testing. Hardness and elastic modulus were measured on the buccal and the lingual surfaces of the cementum at the cervical, middle, and apical third of the root using an ultra-micro-indentation system (UMIS) and jig.

*Results:* The hardness and elastic modulus of cementum in the heavy force group were significantly lower than in the light force group (P < 0.01). In both groups the mean hardness and elastic modulus of cementum decreased from the cervical to the apical regions for buccal and lingual surfaces. However, no significant difference was found between the buccal surface compared with the lingual (P < 0.05).

*Conclusion:* This study suggests that heavy orthodontic forces appear to reduce the hardness and elastic modulus of cementum more than light orthodontic forces. Hardness and elastic modulus of human maxillary first premolar cementum gradually decreased from the cervical to the apical regions at both the buccal and lingual surfaces, regardless of the orthodontic force applied.

*Implications:* This study supports the use of light forces during orthodontic treatment to minimize root resorption. However, since the duration of the trial was only 28 days it is difficult to generalize these results to orthodontic treatment that typically lasts 18–24 months.

A thermoplastic mandibular advancement device for the management of non-apnoeic snoring: a randomized controlled trial *The European Journal of Orthodontics* 2006 Aug; 28(4): 327–38 Cooke ME, Battagel JM.

Cooke ME, Battagel JM.

*Objectives:* To assess the effectiveness of a mandibular advancement device (MAD) in the management of non-apnoeic snoring.

Design: Cross-over randomized controlled trial.

*Setting:* Orthodontic Department, Royal London Hospital, London, England, UK.

*Participants:* Twenty-seven adults, (17 males and 10 females) diagnosed with non-apnoeic snoring, who had been referred for treatment with a MAD.

*Interventions:* Each participant received a TheraSnore<sup>TM</sup> (Distar, USA), a chair side adjustable,

thermoplastic MAD. Participants were randomly allocated to wear the appliance in either the non-advanced (placebo) or the advanced (experimental) position at 75% of the patients' maximum protrusion for 4–6 weeks. The activation of the appliance was alternated for the subsequent 4–6 weeks after a one-night wash out period of not wearing an appliance.

*Outcome measures:* Subject questionnaires and visual analogue scales (VAS) were completed at baseline and after each period of appliance wear to assess sleep history, daytime sleepiness, and any side effects of the MAD. Sleeping partners also completed questionnaires to asses snoring loudness, their personal daytime sleepiness and sleep disturbance. Eleven participants had overnight sleep studies at baseline and again with the appliance in each position to assess snoring frequency (snores/hour), oxygen saturation and apnoea hypopnoea index. Supine radiographs were used to examine the oropharyngeal airway at baseline and in response to both appliance positions.

*Results:* Twenty-three adults completed the study with four dropouts, two of whom were unable to tolerate the appliance. The advanced MAD reduced the participants' snores per hour (P=0.003), partners' sleep disturbance (P=0.001) and day time sleepiness (P=0.002) and increased the participants' oxygen saturation (P=0.01) significantly more than the non-advanced MAD.

The most common side-effect was a dry mouth and 64% of subjects considered the appliance bulky. Radiographic analysis revealed significant vertical opening associated with the appliance and small but significant post-lingual changes with protrusion.

*Conclusion:* This study suggests that the activated TheraSnore<sup>TM</sup> MAD is effective at treating snoring in two out of three non-apnoeic snorers and improves their sleeping partners' sleep.

*Implications:* This appliance may be useful to nonapnoeic snorers but dentists must monitor its long-term effects on occlusion as this may lead to other complications for the patients.

A randomized clinical trial to investigate bond failure rates using a self-etching primer *The European Journal of Orthodontics* 2006 Oct; 28(5): 444–9 Murfitt PG, Quick AN, Swain MV, Herbison GP.

*Objectives:* To compare bond failure rate of edgewise brackets bonded with either a self-etching primer (SEP) or conventional acid etch technique.

Design: Split-mouth randomized controlled trial.

*Setting:* Orthodontic clinic, University of Otago, Dunedin, New Zealand.

*Participants:* Thirty-nine adolescent patients (13 male, 26 female; aged 11–16 years) requiring one or two arch fixed appliance treatment. Patients with gross enamel defects were excluded.

*Interventions:* Participants were randomly assigned to receive treatment from one of two equivalently experienced orthodontic trainees. Participants were randomly allocated, in blocks of 10, to have diagonally opposite quadrants bonded with either Transbond Plus SEP (3M Unitek, Monrovia, Clalif) or conventional acid etch technique using 37% phosphoric acid and Transbond MIP Primer. All brackets were then bonded with Transbond XP adhesive and treatment observed for the following12 months.

*Outcome measures:* Bracket failure rate, bracket survival rate and adhesive remnant index (ARI) scores.

*Results:* 661 brackets, excluding molars, were bonded. Self-etching primer had a statistical significantly

(P=0.001) higher bracket failure rate (11.2%) and a 40% higher chance of failure (risk ratio=0.4, 95% CI 0.2, 0.8) than conventional etching (3.9%) over the 12 month observational period. The ARI index for 70% of failures with SEP was 0, indicating adhesive failure at the enamel/adhesive interface whereas conventional etching had more cohesive bond failures (36%) with more than half the composite remaining on the tooth.). No statistically significant differences were found for the failure rate with respect to the age of the patient, operator, tooth location, or the number of manipulations of the bracket prior to curing.

*Conclusion:* Brackets bonded using SEP had a significantly higher bond failure rate comparison with those bonded with conventional acid etch technique.

Implications: This study suggests that the increased bond failure rate of SEP may negate the potential time saving advantage of this technique. Further RCTs or a systematic review of existing trials are required to determine the validity of these findings.