



ROYAL COLLEGE OF
PHYSICIANS AND
SURGEONS OF GLASGOW



Intercollegiate Specialty Fellowship Examination

Part A

Orthodontics

Critical Appraisal

Note: Parts of the sections within the original article are not relevant to this examination and have been redacted.

Please note that the sample answer key provided has model answers and they are not exclusive. Other options could be considered as correct answers.

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Part A

Extract - 35 marks

Sonesson, M., Naraghi, S. and Bondemark, L., 2022. Cost analysis of two types of fixed maxillary retainers and a removable vacuum-formed maxillary retainer: a randomized controlled trial. *The European Journal of Orthodontics*, 197-202. Doi:10.1093/ejo/cjab080.

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1. What are the aims of the present study? **(3 marks)**

This investigation aimed to use RCT methodology **(1 mark)** to compare the costs of three retention methods **(1 mark)**, i.e., a bonded retainer to the maxillary four incisors, a bonded retainer to the maxillary four incisors and two canines, and a removable VFR in the maxilla. The costs of the three retention treatments were evaluated after 2 years of retention **(1 mark)**

2. What type of study design is the present study? **(2 marks)**

Any two from below:

- A single-center **(1 mark)**
- three parallel arms **(1 mark)**
- 1:1:1 allocation ratio **(1 mark)**

3. This study used block randomisation. What are the advantages (2 marks) and disadvantages (2 marks) of block randomisation?
(4 marks total)

• **Advantages**

- Each block has the same number of individuals in each treatment **(1 mark)**
- There are an equal number of individuals assigned to each treatment at any point in the experiment. This is especially valuable if the experiment were to end early because researchers would have the same amount of data for each treatment group **(1 mark)**

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- **Disadvantages**

- If the researchers know the block size then they may be able to know which treatment group a given individual will be assigned to late in the block **(1 mark)**
- Does not take into account co-variables - will have same number of individuals in each group but may not have similar baseline characteristics **(1 mark)**

4. What is an intention-to-treat analysis? **(1 mark)**

The intention-to-treat principle defines that every patient randomised to the clinical study should enter the primary analysis, even when the patient does not completely follow the treatment protocol **(1 mark)**

5. What is the advantage of the intention-to-treat analysis over per protocol analysis? **(2 marks)**

- The original randomisation and the number of patients in the treatment group remain unchanged **(1 mark)**, the analysis population is as complete as possible, and a potential bias due to exclusion of patients is avoided
- The ITT approach tends to under-estimate the outcome **(1 mark)** so is the more conservative approach in a clinical (superiority) trial

6. Comment on the appropriateness of the sample size and cost calculation. **(3 marks)**

- The power and statistical significance are appropriate **(1 mark)**
- A clinical difference of around €50 maybe appropriate, but no real reason given this amount was chosen **(1 mark)**
- The standard deviation of €50 is unfounded, there is no mention of how this figure was derived **(1 mark)**. The numerical value of the standard deviation will have a marked affect the final sample size

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7. Why in this study would an ANOVA with Tukey post hoc test have been used, and which groups were tested? **(2 marks)**

- The ANOVA test was run to avoid the problem of running numerous simultaneous tests and the probability of a significant result increasing with each test run, an increased risk of a type I error **(1 mark)**
- Analysis of variance with Tukey's post hoc test was used to compare the costs within and between the retention groups **(1 mark)**

8. How was the Chi-squared test used in this study? **(1 mark)**

The Chi-squared test was conducted between gender and type of retainer i.e., using categorical data. **(1 mark)**

9. What tasks should the "treatment time costs" for each type of retainer include? **(2 marks)**

- For DBRs - time to take impressions & fit DBRs **(1 mark)**
- For VFRs time to take imps & fit VFR **(1 mark)**

10. How much time was spent on the "treatment time costs"? (3 marks)
Comment on the appropriateness of this (1 mark). **(4 marks total)**

- At €333 per hour that would be
 - €633 for 3 to 3 = $€633 / €333 = 1.9$ hours **(1 mark)**
 - €600 for 2 to 2 = $€600 / €333 = 1.8$ hours **(1 mark)**
 - €579 for VFR = $€579 / €333 = 1.7$ hours **(1 mark)**
- This seems an excessive time to either fit and repair DBRs or replace VFRs with imps & fit **(1 mark)**

11. Describe five strengths of the study. **(5 marks)**

Any five from below:

- The randomization process was performed by a person not involved in the trial or treatment - blinded **(1 mark)**
- Randomization implies that selection bias is avoided, and any confounders were evenly distributed between the groups **(1 mark)**

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- Results were evaluated on an ITT basis **(1 mark)**
- Attrition bias was low since there was only one drop-out in the trial **(1 mark)**
- The patients who were included in the trial were diverse in terms of gender distribution, age, and treatment at a specialist clinic, and thus, were considered representative of orthodontic patients **(1 mark)**
- Hence, the design and performance of this trial allowed the results to be implemented in daily orthodontic practice **(1 mark)**

12. Describe four limitations of the study. **(4 marks)**

Any four from below:

- In the UK clinically meaningful and responsible retention often includes concurrent fixed AND removable retention, therefore may not be relevant to UK retention regime **(1 mark)**
- The decision regarding the type of retention method should be determined by clinical indication and not randomisation **(1 mark)**
- It is not clear from the study what the 'normal retention' strategy i.e. three months, nine months then every other year i.e. frequency of reviews is not known. The cost calculation would be different compared to a once a year review and should include retention review appointments **(1 mark)**
- Monetary variables are influenced by local factors such as insurance systems, staff salaries, rental costs, taxes, urban versus rural areas, etc., and consequently, the figures shown in this trial cannot be directly extrapolated to other locations. Thus, the generalizability of the findings to other settings may be limited as the study was carried out on a regional scale **(1 mark)**
- The trial did not include indirect costs, i.e. costs defined as loss of income (wages plus social security costs) incurred by the patients' parents' absence from work to accompany the patient to the orthodontic appointment, including waiting time at the clinic and the travelling duration **(1 mark)**

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13. Comment on the Conclusions of the study relating them back to the assumptions made in the sample size calculation i.e. the clinical significance. **(2 marks)**

- The clinical significance set at €50 to determine the sample size **(1 mark)**
- The study reported no statistically significant difference in cost between maxillary fixed and removable VFRs but there are clinical differences between retainer groups (see below) **(1 mark)**
 - For information
 - Between 2 to 2 DBR and 3 to 3 DBR there is €60 difference - clinically significant

Total Marks for Extract = 35 marks