

UNIVERSITI TEKNOLOGI MARA

**THE CLINICAL EFFECTIVENESS
AND COST ANALYSIS OF USING
TWO CLEAR ALIGNERS
MATERIALS:
A RANDOMIZED CLINICAL TRIAL**

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ABSTRACT

Introduction: No one aligner material is the same. This randomized clinical trial evaluated the clinical effectiveness and cost analysis between Erkodur and Zendura FLX including material, chair side time and the breakages in clear aligner treatment.

Methods: 19 adult participants were randomized (15 females and 4 males, 29.73 (SD8.44) years old) into two groups. Medit Design software (version 2.1) was used to measure the efficacy of orthodontic tooth movement by performing superimposition of predicted and achieved outcome. Data related to demographics, tooth movement accuracy and the related costs were recorded. The cost for each material was calculated by dissecting the costs involved in producing similar clinical outcome.

Results: The mean accuracy of tooth movement with Erkodur and Zendura FLX was comparable with no statistical differences in horizontal movement from T1 to T6 and vertical movement from T1 to T4 with $p < 0.05$. As the treatment advanced to T5 and T6, there was a statistically significant difference between Erkodur and Zendura FLX in vertical movement, with mean differences of 0.05mm in extrusion ($p = 0.036$). Total cost for raw material of each plastic sheet is RM9.03 for Erkodur and RM29.32 for Zendura FLX respectively. Erkodur chair side time duration was longer (131 minutes SD 53.4) than Zendura FLX's (105.6 minutes SD 21.9). Despite having longer chairside mean time score 25.4 min more than Zendura FLX, there was no significant difference in chairside time when both groups were compared ($p = 0.201$). Nevertheless, the average cost of treatment with Erkodur rises by RM95.97 because of the increase in chair side time ($p = 0.013$). Emergency visit for Erkodur was 1.3 times higher when compared to Zendura FLX since no emergency visits were documented during the first 6 months of therapy for Zendura FLX group ($p < 0.05$).

Conclusions: The accuracy of tooth movement is comparable between Erkodur and Zendura FLX. Cost incurred in providing clear aligner treatment with Zendura FLX is higher compared to Erkodur by half. Treatment duration rose in the Erkodur group because emergency visits were twice as often as in the Zendura FLX group, adding to the overall treatment cost.

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CHAPTER ONE

INTRODUCTION

1.1 Research Background

Clear aligners may be a great alternative for people looking for a more discrete orthodontic treatment. The use of thermoforming materials to move teeth is not news, and the simplicity of treatment flow for patients using clear aligners is one of the factors that is contributing to the rise in popularity of this appliance, in addition to its aesthetic advantage. The preliminary labour and effort required to produce a single pair of clear aligners are enormous, and the learning curve associated with doing so is rather steep (Hartshorne et al., 2022). They are different from the typical treatment flow for fixed appliances because they include patient management in addition to software and hardware components.

In 2012, Journal of Clinical Orthodontics nominated two major breakthroughs in orthodontics of the last 15 years: mini-implants and Invisalign (Robert G. Keim, 2012). Clear aligners are becoming a more accessible orthodontic treatment. This is due to advancements in clear thermoplastic materials, computer-aided design manufacturing (CAD/CAM), and software that mimics tooth movement becoming more user intuitive and highly accessible on the market than in the past. However, clear aligner therapy is case selective, and the most predictable mechanics of treatment entail non-extraction of mild to moderate malocclusion (Gu et al., 2017). By doing so, many a times the end resulted in flaring teeth especially of the anterior segment. A study by Hennessy et al (2016) on the other hand, found that there was no significant difference in the incisor proclination of patients using Invisalign and fixed appliance. This is one of the examples that shows efficacy of tooth movement in comparison to conventional fixed appliances. Though many researchers reported that the clinical findings were favourable, there have yet to be any study that investigates the amount of crowding, the magnitude of proclination and its resulting relationship with the supporting tooth structures at the time.

Invisalign are pioneers in the clear aligner industry and have successfully