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Comparative assessment of customized (insignia) and non-customized bracket systems (Damon Q) for clinical effectiveness and efficiency-A clinical study

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ABSTRACT

Objective: The study's goal was to compare and contrast the effectiveness and efficiency of customized and non-customized orthodontic brackets.

Materials and Methods: 10 patients (Group A) were treated with a Customized section System (Insignia™ USA) and 10 patients (Group B) were treated with a Non-customized Bracket system (Damon).Gathering this data, the clinical effectiveness and efficiency was measured by estimating Initial Peer Assessment Rating (PAR) and Final PAR scores, assessing the complete therapy time, number of scheduled appointments, number of examination visits, number of loose brackets and pain rating during the treatment which was recorded with a numerical rating scale.

Results: The Insignia group outperformed the Damon group in terms of clinical efficiency, but there was no difference in PAR score reduction so overall clinical effectiveness of the Insignia and Damon groups was identical.

Conclusion: Orthodontists would be able to give high-quality treatment in less time with fewer appointments and less chair time if they use the optimum bracket system.

1. Introduction

The Edgewise appliance, created by Edward Angle, improves the effectiveness and control of tooth movement in all three planes of space.[1] Lawrence Andrews' development of the Straight Wire Appliance (SWA) in the 1970s was the final step to enhance efficiency. By transferring frequent, adaptive wire bends to the bracket, this revolutionary technology was designed not only to meet defined treatment targets, but also to achieve great aesthetic and functional results reliably and consistently.[2]

Many bracket systems are available in the present phase of orthodontics in which Self Ligating Bracket (SLB) system is one.

2. Damon Technique (DT)

Damon proposed a hypothesis in which low friction and light forces equally distribute expansion forces, resulting in more biologically stable consequences. His orthodontic appliance system was inspired by his ideology.[3] Damon SLB reduced treatment time and patient visits by a statistically and clinically significant quantity.[4]

"It is illogical to expect that any straight wire appliance without specific adjustments will result in perfect teeth alignment." At the same time, they said that if the straight wire technique had to be employed, the bracket would have to be custom made.[5]

Orthodontists are constantly looking for more effective and efficient treatment methods. Patients demand quick, high-quality results with little effort on their side in today's fast-paced, high-tech, convenience-driven environment.[6]

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Customized orthodontic appliances for a specific tooth form of the individual patient have been developed thanks to advancements in computer-aided design and manufacturing technologies. As a result of this advancement, treatment times and chair time have decreased, making orthodontic situations more predictable, accurate, and efficient.[7,8]

A personalized appliance system simulates the best position of each tooth part and the perfect final occlusion using computerized models of the patient's arches.[8–11]

2.1. 'Insignia'

Patient-specific appliances based on an individual's anatomy would be required for a real SWA. The first real straight-wire appliance is Customized Insignia™.[12] Insignia technology transforms a clinician's treatment protocol into a digital 3-dimensional prototype of each patient's perfect occlusion and offer a comprehensive custom solution, computer-assisted bracket placement and individual wires, together with customized brackets, reduce time-consuming corrections during the treatment process.[11]

Apart from computerized techniques that just change the thickness of the bracket adhesive, the Insignia system reverse-engineers the brackets to the compliant mechanisms in one of two distinct ways, based on the sort of brackets the orthodontist selects. Customization is possible thanks to precision-cut slots on the milled-in faces of Insignia metal twin brackets. The thicknesses and angulations of the metallic bases are varied to create the Insignia SLB, a personalized version of the Damon Q* self-ligating model.[13]

The recommended setup (T2) is designed after the pre-treatment malocclusion (T1) is digitized out from impressions and turned into an accurate digital model of the patient. The configuration is uploaded to the Insignia online portal, where the clinician can simply adjust it using the Insignia Approver software based on clinical experience, functional and aesthetic choices, and intimate knowledge of the patient's individual orthodontic demands.[12]

Doctors can see how adjustments to the desired outcome in the Approver program affect the opposing occlusion in "real time." Once the doctor has confirmed the best configuration, the Insignia software engineers the customized brackets, wires, and precision bonding placement gauges.[12] Molds for bracket transfer are precision machined from a high-tech, high-plasticity material that matches the occlusion, enabling for precise and trustworthy bracket installation. Three-quarters of the bracket-pad edges are accessible during bonding, allowing extra composite material to be removed before polymerization.[13]

Insignia arch wires are not premade, but rather custom-made to keep the teeth as close to the trabecular bone as feasible. The form and shape of the dental arches are by far the most variable of all the criteria in patient-specific orthodontic treatment planning. Skeletal mapping is a solution to this issue.

2.2. 'Peer assessment rating index'

Numerous indices have already been established to evaluate orthodontic misaligned teeth and orthodontic treatment outcomes.[14,15] Occlusal indices are frequently used to assess clinical results after orthodontic treatment to determine the overall level of care. Dental parameters are calculated using study models collected pre and post therapy.[16]

In 1987, six sessions with a group of ten experienced orthodontists were held to establish the index. In addition, more than 200 dental casts representing developmental, before, and after phases were examined and discussed till a consensus was achieved on the specific aspects to be measured to produce an estimate of occlusion alignment.[17]

The Peer Assessment Rating (PAR) index uses eight graded variables to assess misaligned teeth in all three structural axes.[17]

The goal of this research is to compare the efficiency of custom (Insignia™ USA) and non-custom (Damon Q Brackets) bracket systems. By assessing Initial PAR and Final PAR scores, as well as efficiency in terms of evaluating total treatment time, number of scheduled appointments, number of check-up visits, number of loose brackets, and pain rating during the treatment.

3. Materials and Methods

The study included 20 patients who presented to the department of orthodontics with complaints of crowding and cosmetic concerns., 10 patients willing for orthodontic treatment with customized brackets (Figure 2) and 10 patients willing for orthodontic treatment with non-customized Damon Q brackets (Figure 5).

3.1. Method of collection of data

1. 20 individuals' treatment cast models were taken
2. Using a PAR grading form and a PAR scale, calculate the initial and final PAR index scores.

3.2. Inclusion criteria

1. Patients diagnosed with class 1 bimaxillary protrusion.
2. Patients who were willing for and Damon brackets.
3. Complete maxillary and mandibular fixed appliances were used.
4. Age group between 12 to 50 years.
5. Detailed data records, pre and post treatment casts, and panoramic images after therapy were all accessible.

3.3. Exclusion criteria

1. Cases where myofunctional appliances and developmental manipulation were used as part of the treatment.
2. Treatment included partial skeletal anchoring or surgical treatment.
3. Patients with Periodontally compromised dentition.

3.4. Materials used

1. Customized Brackets (Insignia^{TM}USA)
2. Non-customized Brackets (Damon Q Brackets system)
3. Pre-treatment and Post treatment casts.
4. PAR index Ruler.
5. Numerical pain rating scale.

3.5. Statistical analysis applied:

1. For data analysis, the information was gathered, categorized, and loaded into SPSS (IBM version 23).
2. Descriptive statistics included mean and Standard deviation.
3. Independent t 'tests and paired t 'tests were used as descriptive statistics.
4. At a 95% probability value, the statistical significance was established at <0.05.

3.6. Procedure

20 patients were assessed clinically if they had a malocclusion complaint such as crowding, proclination, retroclination, or spacing. Pre-treatment diagnostic castings were taken after an oral and stomatognathic assessment. The Pre-treatment diagnostic casts were analyzed using the PAR system (Figures 3 and 6).

10 patients taken in Group A and are treated with Customized bracket System (Figure 2) (Insignia^{TM}USA) and 10 patients taken in Group B are treated with Non-customized Bracket system (Figure 5) (Damon Q bracket system).

The Post-treatment diagnostic casts were analyzed using the PAR ruler and the scoring was given.

The effectiveness is measured by:

1. Comparing PAR gradings of Initial and Final treatment.

(Group A- treated with Customized bracket system and Group B- treated with Non-customized Bracket system)

The efficiency was measured in terms of:

1. Evaluate the total treatment time,
2. Number of Scheduled appointments,
3. Number of check-up visits,
4. Number of loose brackets,
5. Pain Rating during treatment.

A numerical rating system (NRS) is perhaps the most frequent approach for assessing pain, in which the individual is asked to describe his pain on a scale ranging from 0 to 10.

Pain levels varies from zero to ten, 0 representing negligible pain, 1–3 representing minor pain, 4–6 representing moderate pain, and 7–10 representing extreme pain.

4. Results

This prospective study has a sample size of 20 patients, with 10 patients in the customized bracket system (Figure 1) and 10 patients in the non-customized bracket system (Figure 2).

4.1. The following tables and graph illustrate the comparison of clinical effectiveness of customized and non-customized bracket system.

Table 1 shows the clinical effectiveness data for the customized and non-customized groups of patients, and a graph has been plotted for the same, as shown in Graphs 1 and 2 for the Insignia and Damon groups, respectively. Initial PAR scores of Insignia (mean 18.100) and Damon group (mean 22.9000) were not statistically significant (p> 0.05) when compared, with standard deviations (SD) of 4.3033 in Insignia and 7.964 in Damon group. The final PAR score of the Insignia (mean 0.9000) and Damon groups (mean 1.000) were not statistically significant (p> 0.05) with SD of 0.56765 for the Insignia group and 0.66667 for the Damon group.

When compared to the Insignia and Damon groups' Initial and Final PAR ratings. It was noted that both groups had highly significant PAR scores with p<0.05, as shown in Table 2.

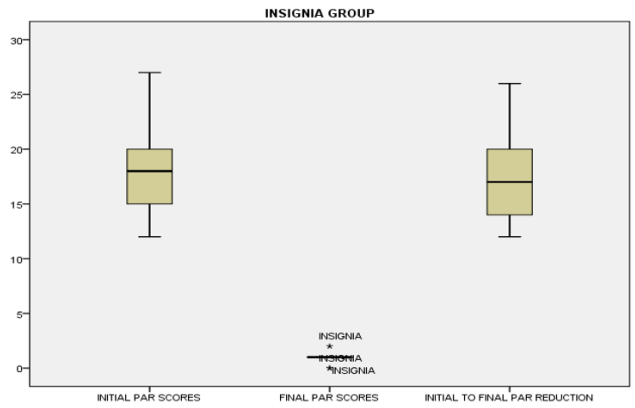
When the initial and final PAR scores of the Insignia (mean 17.2000) and Damon groups (mean 21.900) were compared, the difference was not significant (p>0.05). Table 3 and graph 1 for the Insignia group, and Graph 2 for the Damon group, show the reduction changes.

4.2. Insignia and damon group clinical effectiveness interpretation

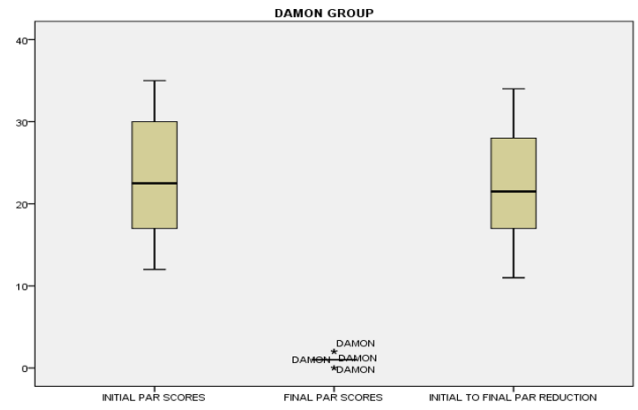
When comparing two groups, the results just weren't statistically significant because the p value was >0.05, implying that both groups have an equal influence on the reduction of initial to final PAR scores. When the impacts of these results were compared within the group, they were very significant, indicating that both groups are effective in lowering PAR scores. As a result, both bracket systems can be used to rectify malocclusion; They have the same effect on patients and are just as effective.

4.3. The following table and graph illustrate the comparison of clinical efficiency of customized and non-customized bracket system

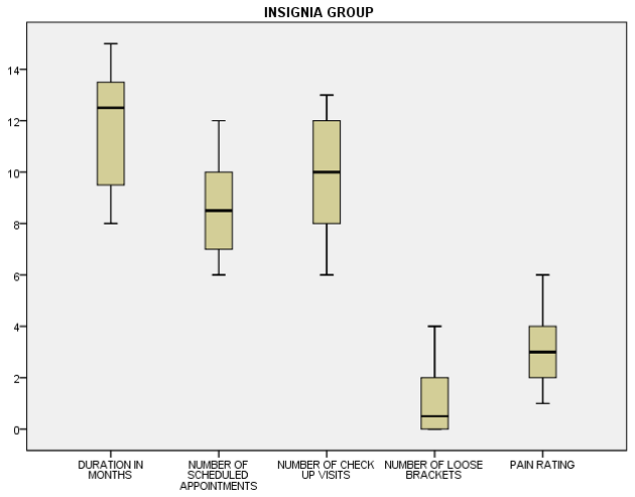
Table 4 shows the clinical efficiency data for the customized and non-customized groups of patients, and a graph has been generated for the same, which can be seen inGraphs 3 and 4. When compared to the Damon group, the average adjusted treatment time for the Insignia group was statistically significantly shorter ($p<0.05$). On average, they had 8 to 9 lesser visits ($p<0.05$). When it comes to the frequency of checkup appointments, the frequency of loose brackets, and the pain rating throughout treatment were examined, the Insignia group exhibited a very significant value ($p<0.05$) when compared to the Damon group, as shown in Table 4 and Graphs 3 and 4.



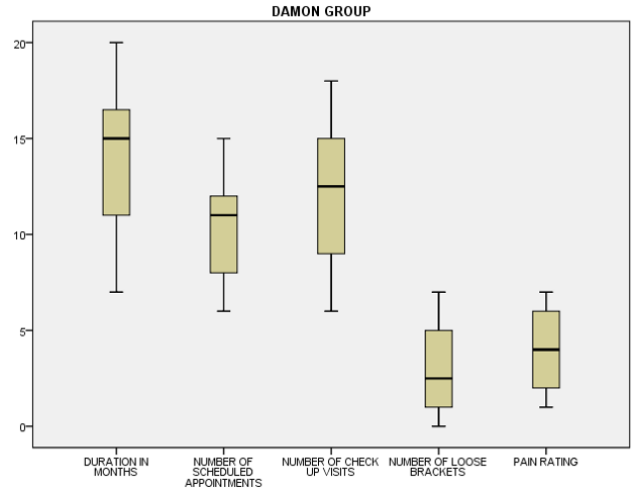
Graph 1: Comparison of Initial PAR scores, Final PAR scores and Reduction from initial to Final PAR scores of Insignia group using Box and Plot whiskers.



Graph 2: Comparison of Initial PAR scores, Final PAR scores and Reduction from initial to Final PAR scores of Damon group using Box and Plot whiskers.



Graph 3: Box and Plot graph showing the Clinical Efficiency of Insignia group (Customized).



Graph 4: Box and Plot graph showing the Clinical Efficiency of Damon group (non-Customized).

4.4. The Insignia and Damon groups' clinical efficacy was interpreted

The results were statistically significant ($p<0.05$). When compared with two group the Customized bracket system had an unrivalled treatment result, decreased treatment time, patients had experienced less pain during the treatment, need for bracket repositioning toward the finish of treatment was eliminated, number of loose brackets were also less, number of checkups visits due to any emergency was significantly low when compared to cases treated with a non-customized bracket system.

Nevertheless, it is important to note the small sample size of both groups, as well as the variability shown by the box plot whiskers, when interpreting these results.

Table 1: Clinical effectiveness of customized as well as non-customized groups

		Mean	Standard deviation	t	Sig.
Initial	Insignia	18.1000	4.3033	-1.676	0.111(NS)
	Damon	22.9000	7.96450		
Final	Insignia	0.9000	0.56765	-0.361	0.722(NS)
	Damon	1.000	0.66667		

Table 2: Comparison of Clinical effectiveness within the Customized and Non-Customized groups

		Mean	Standard deviation	t	Sig.
Insignia	Initial	18.1000	4.3033	12.522	**0.006(HS)**
	Final	0.9000	0.56765		
Damon	Initial	22.9000	7.96450	8.665	**0.001(HS)**
	Final	1.000	0.66667		

Table 3: Comparison of Clinical effectiveness by reduction factor between Customized and Non-Customized groups

Reduction	Mean	Standard deviation	t	Sig
Insignia	17.2000	4.21110	-1.725	0.092(NS)
Damon	21.9000	7.51960		

Table 4: Comparison of Clinical efficiency of Customized and Non-Customized groups

		Mean	Standard deviation	t	Sig.
Treatment duration (months)	Insignia	11.8000	2.33571	-1.441	**0.016(S)**
	Damon	13.9500	4.09912		
Number of scheduled appointments	Insignia	8.8000	1.93218	-1.227	**0.023(S)**
	Damon	10.2000	3.04777		
Number of checkup visits	Insignia	9.9000	2.18327	-1.434	**0.012(S)**
	Damon	12.1000	4.33205		
Number of loose brackets	Insignia	1.1000	1.44914	-1.961	**0.049(S)**
	Damon	2.9000	2.51440		
Pain rating during Rx	Insignia	3.2000	1.47573	-1.175	**0.029(S)**
	Damon	4.2000	2.25093		

5. Discussion

Malocclusion is among the most common malformations today. When the jaws are closed, it is characterized as an irregular occlusion in which teeth are not in a regular relationship to opposing teeth or adjoining teeth in the same jaw. Malocclusion is a morphological variation that can be related with or not relate to pathological disorders. The craniofacial structures are affected by this occlusal condition, which affects the temporomandibular articulation, neuromuscular systems, and other soft tissues. These issues cause the patient to experience unpleasant indications and symptoms, which affect facial aesthetics as well as stomatognathic system activities such as mastication, deglutition, breathing, and phonation.

Orthodontists would be able to give high-quality treatment in less time with fewer appointments and less chair time if they used the optimum bracket system. Andrews' Straight-Wire Appliance, which enhanced treatment efficiency by including 1st-, 2nd-, and 3rd-order compensations into the brackets, was the first attempt at creating such a system. However, because to variances in tooth-surface morphology, inaccuracies of direct bonding, and mechanical inadequacies of edgewise orthodontic equipment, clinicians have discovered that finishing with a straight wire is rarely achievable; detailed bends are frequently necessary.

In the Insignia* custom bracket system, the clinician uses computer-assisted technology to build a virtual design of the ultimate occlusion and alignment, then, to accomplish the required outcome, customized brackets and arch wires are used. The bracket grooves are modified to fit a straight wire which transfers every tooth to its optimum final position, as specified by the digital arrangement. Thus, the need for this study is to compare the effectiveness and efficiency, evaluate the total treatment time, scheduled appointments, number of check-up visits, number of loose brackets, pain rating during the treatment between the Customized (Insignia^{TM}USA) and Non-customized (Damon Q Brackets) bracket system.

Fig. 1: Customized group: Pre-treatment extra oral and intraoral photograph

Fig. 2: Customized group: Mid-treatment and PAR assessment photographs

The clinical outcome of 10 cases treated with the Customized Insignia bracket system were compared to the clinical outcome of 10 cases treated with the Non-customized Damon bracket system in this retrospective study. Full fixed appliances were used in all cases. In none of the cases, growth adjustment or surgical treatment were required. The clinical Investigation continued despite the modest sample size for the comparison between the two-bracket systems.

5.1. Insignia and damon group clinical effectiveness

It is critical to employ a reliable grading system to objectively measure treatment outcome. When evaluating the outcome of orthodontic treatment, the PAR index provides consistency and standardisation, according to Richmond et.al. [17]

The equivalent end PAR ratings for the customized (Fig 3) and non-customized groups (Fig 6) show that customized bracket systems can yield comparable clinical results to non-customized bracket systems (Table 1,2&3).

According to Weber et al., the American Board of Orthodontics scores were superior for the Insignia patients in nearly all aspect, including orientation, overjet, and root inclination since they focus more precisely on minutiae of tooth position. [6]

Based on the morphology of the linked crown, the software of the Insignia Bracket system develops virtual roots using the scanned impression and dental anatomy. This virtual root accounts for greater root parallelism, preventing bracket repositioning at the end of the orthodontic treatment. This bracket system also comes with customized arch wires, which will help keep the arch in coordination during the orthodontic treatment.

5.2. The insignia and damon groups' clinical efficacy

Because all components of tooth placements are constructed virtually, it is likely that the teeth will migrate in a more direct path to the final occlusion when using the Insignia approach.

In the current study, we discovered that employing the customized bracket system made aligning and finishing the treatment faster, and that there was no need to reposition

Fig. 3: Customized group: Post-treatmentextraoral and intraoral photograph

Fig. 4: Non-customized group: Pre-treatment extra oral and intraoral photographs

the brackets at the finishing stage. (Table 4). When using non-customized bracket systems, we discovered that the customized torque for each tooth had aligned the tooth in the precise position following the treatment, removing the need for extra torque.

According to Weber et.al one case in the conventional group and five in the Insignia group did not require bracket repositioning or wire bends.[6]

A real SWA, according to many writers, is both practically and clinically impossible. The most mentioned factors in the research are incorrect bracket positioning, variations in dental anatomy, skeletal discrepancies, tissue rebound, and mechanical flaws in edgewise orthodontic system.[18] Because of the virtual manufacturing and indirect bonding process, the Insignia appliance may have overcome the issue of variances in tooth morphology.

A basic bracket pad, which is practically placed just on tooth to ensure at least 3 contact points, holds the customized bracket in place. The transfer jig enables the clinician to transfer the virtual bracket location to the mouth and keep the bracket in place while the composite is applied to create a personalized bracket pad.[6]

The aftereffects of the present study showed that cases treated with a Customized bracket system (Insignia group) had an unrivalled treatment result, decreased treatment time, less pain experience during the treatment, need for bracket repositioning toward the finish of treatment was eliminated, clinical efficiency was predominant when compared with cases treated with a non-customized bracket system.

A numbered pain scoring system was offered to kids and adults (> 9 years old) in all healthcare settings who can use numerals to evaluate the severity of their pain.[19]

The more time spent establishing the virtual setup and paying attention to detail, the less time will be necessary for detailing later in treatment. The absence of integration of soft tissue drape and occlusal plane angulation with the virtual setup is another key flaw with virtual treatment planning.[6]

The Insignia software's SmileArc™ feature allows dentists to adjust the maxillary incisors vertically while the lower incisors invade or extrude to compensate. While this is a useful tool, clinical measurements are required to

Fig. 5: Non-customized group Mid-treatment and PAR assessment photograph

determine how much maxillary incisor intrusion/extrusion is required, as there is currently no way to overlay a photo or 3D image on the virtual setup.[12] The smile arc and incisor inclination shift as you move and rotate the dentition on the computer screen since there is no constant landmark. The lateral cephalogram might be used to estimate the occlusal plane angulation, but having the dentition orientated as it is in natural head position would be highly advantageous.[10]

Perhaps a combination of intraoral scanners and customized computer-assisted treatment planning integrating a 3-D extraoral image, cone beam CT radiograph, and a virtual occlusal setup will be the future of orthodontics. This combination would allow for real soft tissue paradigm treatment planning as well as a better understanding of the orthodontic procedure and outcome by the patient. The Insignia process might thus serve as a link between the virtual and actual worlds.[6]

The cost of treatment with a personalized appliance is higher, owing to higher laboratory expenditures.[20]

Weber et al findings are consistent with ours, who found that baseline PAR and end PAR scores just weren't significantly different between the two groups, who exhibited a comparable decline in PAR levels post operative.[6]

Fig. 6: Non-customized group post-treatment extra oral and intra oral photograph

Our findings contradict those of E W Penning et al, who discovered the personalized orthodontic system did not result in a substantial reduction in treatment time when compared to the non-customized system, and the treatment outcomes were comparable. The orthodontist and the severity of malocclusion at the commencement of treatment had a greater impact on treatment time and quality than the orthodontic method utilized. Treatment with something like a personalized appliance, like the ones shown in this research, took significantly longer for the orthodontist to arrange and was correlated with a greater frequency of visits due to detached brackets.[20]

In this study, the PAR index was used to detect clinical effectiveness, and clinical efficiency was measured by total treatment time, number of scheduled appointments, number of check-up visits, number of loose brackets, and pain rating during treatment. However, due to the limited sample size, our study has a few shortcomings.

There is significant doubt about how well the virtual configuration was examined and changed prior to appliance manufacture, which could result in greater repositioning and wire bends in the Insignia group. The clinical efficacy of the treatment may be erroneous since the patient may have provided a false reading of pain, or he may have missed a visit and broken the brackets, as it is dependent on individual upkeep, orthodontist skill, and the severity of malocclusion at the commencement of treatment had a greater impact on treatment time and quality than the orthodontic method utilized.

Insignia's effectiveness and efficiency should be further investigated in future studies. Clinical studies with a bigger sample size and subsequently treated patients should be carried out. More research on the accuracy of bracket positioning, tooth movement in the alveolar bone, and bonding jigs in transmitting virtual bracket position to the tooth may also be beneficial.

6. Conclusion

Results of the current clinical study showed the treatment impacts delivered in the wake of treating with Customized bracket system and non-customized bracket system. The records of 20 patients separated into two equivalent gatherings of 10 each were taken as pre-treatment and post treatment casts, photos and numerical pain rating during the treatment was recorded by requesting the patient to rate the seriousness of pain on a size of 0 to 10.

The following are the study's principal findings: When compared cases treated with a non-customized bracket system (Damon Q group), the results of the current study showed that cases treated with a Customized bracket system (Insignia group) had an unrivalled treatment result.

1. The Customized group had a shorter treatment period.
2. The patient has less pain during therapy by the customized group.
3. The requirement for bracket repositioning towards the finish of treatment was dispensed for customized bracket systems as the bracket positioning is detailed by the computer-based technology.
4. The Insignia group outperformed the Damon group in terms of clinical efficiency.
5. Because there was no difference in the lowering of PAR score between the Insignia and Damon groups, the clinical effectiveness of both groups was similar.

Taking into the considerations of above findings I hereby conclude my study by saying that Orthodontists would be able to give high-quality treatment in less time with fewer appointments and less chair time if they used the customized bracket system.

7. Conflict of Interest

The authors declare no relevant conflicts of interest.

8. Source of Funding

None.

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