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The Rationale for Choosing Modern Adhesives for Bracket Attachment in Orthodontic Practice

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INTRODUCTION

Relevance of the research topic

The success of orthodontic treatment with brackets depends on the strength of the bond between the bracket and the tooth surface [65, 69, 74, 142].

Occasional bracket debonding can significantly increase treatment time, cost and patient discomfort. One of the reasons for bracket debonding may be the insufficient bonding strength of the adhesive used with enamel and/or with the orthodontic bracket structure (its base) [51, 91].

The perfect bracket bonding technique involves creating a bond that is strong enough to withstand the force loads of orthodontic treatment and chewing [156]. At the same time, the bracket bonding procedure should be safe enough to avoid damage to the enamel surface both during orthodontic treatment and also at the final stage of treatment when the appliances are removed [31, 36, 63, 99].

Compliance with the manufacturer's instructions and the basic principles of adhesive preparation in most cases guarantees long-term success of orthodontic appliances fixation and avoids complications [5, 14, 139].

The range of traditional foreign adhesive systems for brackets bonding on the Russian Federation market has decreased and new solutions for the use of alternative adhesives are required. A new Russian adhesive «Compofix-ortho» (Vladmiva, Russia) has appeared. This situation requires practicing orthodontists to become familiar with the new adhesive from a Russian manufacturer, to conduct a comparative analysis of the chemical, physical, and mechanical properties of adhesives, as well as to analyze the use of adhesives in conjunction with the chosen bracket system, and to study the potential changes in the properties of modern adhesive systems under the influence of the oral environment.

There is currently a lack of research on the clinical and clinical-economic effectiveness of the use of the «Compofix-ortho» adhesive for bracket fixation in the scientific literature.

Extent of research topic development

A large number of studies have been devoted to bonding in dentistry, but most of them cover the field of restorative and prosthetic dentistry [8, 30, 32].

Orthodontic treatment with brackets is impossible without the use of reliable adhesive materials with proven effectiveness [1, 10].

The range of available adhesives for bracket fixation is limited [137]. Currently, the export of most of them is complicated, and the information about the comparative effectiveness of the materials remaining on the market of the Russian Federation is poorly described. There is no unified protocol for the study of adhesive bond strength in orthodontics in the National Standards of the Russian Federation, and recommendations for determining adhesive bond strength from expert organizations are contradictory. There is insufficient information about the new Russian adhesive «Compofix-ortho», presented on the market in 2023, its physical properties and efficiency of use. The clinical and clinical-economical effectiveness of the use of foreign and Russian adhesives for bracket fixation in a comparative aspect is poorly studied. These factors indicate the relevance of the study.

The aim of this study: To improve the clinical effectiveness of orthodontic treatment with modern adhesive systems.

Research objectives:

1 Characterize the adhesives used in orthodontic practice based on the literature review.

2 Determine the ultimate shear bond strength of orthodontic adhesives «Compofixortho», «Enlight» with the most widely used in clinical practice base structures of modern brackets «Damon Q», «Orthos» and the influence of adhesive bond strength on enamel structure at debonding in experiment and clinic. 3 Study the characteristics of domestic adhesive «Compofix-ortho» and foreign adhesive «Enlight» for brackets fixation in comparative aspect with the subsequent evaluation of debonding frequency during the first 26 weeks of orthodontic treatment.

4 Determine the relative viscosity of «Compofix-ortho» adhesive in comparative aspect with foreign adhesive «Enlight», its influence on the performance characteristics of these adhesives.

5 Determine the comparative clinical and clinical-economical effectiveness of «Compofix-ortho» and «Enlight» adhesives for bracket fixation.

6 Develop clinical recommendations for the selection of orthodontic adhesive, taking into account its physical and chemical properties and working characteristics.

Scientific novelty

For the first time the shear bond strength of the adhesive bond of the Russian adhesive material «Compofix-ortho» was determined in a comparative aspect with the foreign orthodontic adhesive «Enlight» in combination with the use of different bracket designs: self-ligating «Damon Q» and ligature «Orthos». First time the influence of adhesive bond strength using domestic adhesive «Compofix-ortho» on the structure of enamel at debonding was evaluated. The first time in a comparative aspect the frequency of debonding with the use of domestic adhesive «Compofix-ortho» and foreign adhesive «Enlight» observed during the clinical study during the first 26 weeks of orthodontic determined. The relative viscosity and consistency-dependent treatment was manipulation characteristics of the domestic adhesive «Compofix-ortho» in a comparative aspect with the imported adhesive «Enlight» were studied for the first time. For the first time the clinical and clinical-economical efficiency of the use of adhesives «Compofix-ortho», «Enlight» for bracket fixation is indicated. For the first time a comparative analysis of the working characteristics of orthodontic adhesives «Compofixortho» and «Enlight» has been performed.

Practical significance

Based on the data obtained in the experiment and in the clinic, the Russian adhesive «Compofix-ortho» is recommended for wide application in the practice of an orthodontist for bonding both self-ligating and ligature braces. It can be a full-fledged substitute for its foreign analog adhesive «Enlight». Having a strength limit in the safe range, low viscosity and improved performance characteristics, the adhesive can be used both on teeth with healthy enamel as well as with atypical enamel. Comparative clinical and clinical - economical evaluation of the results of using two adhesives for brackets fixation determines the universal and economically feasible to use the adhesive material «Compofix-ortho».

The following are submitted for defense

1 As a result of the experimental study, the shear strength of adhesive materials «Compofix-ortho» and «Enlight» was determined; in the clinical study, the frequency of debonding of these materials during the first 26 weeks of orthodontic treatment was determined. The average shear strength of the adhesive material «Compofix-ortho» was 11.98-12.17 MPa and «Enlight» was 22.51-22.79 MPa. The average debonding rate was almost the same: «Compofix-ortho» - 2.188%, «Enlight» - 2.143%.

2 The relative viscosity and consistency-dependent manipulation characteristics of the Russian adhesive «Compofix-ortho» were determined in comparison with the imported adhesive «Enlight». Low viscosity of these adhesives determined the convenience and speed of work for the orthodontist, as well as the ease of penetration into the mesh base of the bracket and good adaptation to the enamel surface.

3 The effect of adhesive bond strength on enamel structure during debonding in experiment and clinic for both adhesives was evaluated. In the clinical study, after debonding occurred, adhesive residues were detected on the bracket, while they were practically absent on the enamel surface. In the experimental conditions, the situation was the opposite. After debonding with the test machine indenter, adhesive residues were detected to a greater extent on the enamel surface.

4 The values of clinical effectiveness of the Russian adhesive «Compofix-ortho» are lower than those of the imported adhesive «Enlight» by 0.045%, which is insignificant. The greatest clinical and economical efficiency according to the CER and ICER criteria has the adhesive «Compofix-ortho». The use of «Enlight» adhesive requires high inexpedient economic costs with practically similar clinical efficacy.

Approbation of the results of the dissertation and implementation in practice

The research results have been implemented in the work of the Dentistry Department of the Federal State Budgetary Educational Institution "The Saint-Petersburg State University" and "OMEGADENTAL" Ltd. dental clinic.

Publications

Four scientific papers have been published on the subject of the dissertation: three in the journals indexed by VAK, one in the proceedings of the scientific-practical conference.

Personal author's contribution

The author analysed scientific literature sources on the subject of the study, prepared the programme of the dissertation work, selected the study group of patients and bracket bonding for the study group of patients with subsequent dynamic observation during the first 26 weeks of orthodontic treatment, selected extracted teeth to perform the tasks of the experimental study, prepared samples for testing in the laboratory, carried out studies in the clinic, clinical and economic calculations, statistical processing and analysis of collected information. The thesis work is summarized with conclusions and practical recommendations.

Scope and structure of the work

The dissertation consists of 3 chapters, contains 152 pages, accompanied by 31 figures and 23 explanatory tables, supplemented with 4 appendices.

Main scientific results

1 «History of the development of adhesive techniques in orthodontics Part I: from the advent of Bowen resin to the concept of photopolymerisation» [26]. A study of the evolution of adhesive materials in the field of orthodontics was carried out, taking into account the transformation and emergence of new orthodontic structures used for tooth movement. The author selected 90% of scientific publications from printed editions and electronic scientific information databases PubMed, eLibrary, ScienceDirect, Springer, Wiley Library; studied the available knowledge and summarised in chronological order; carried out a comparative analysis of theories and practices (90%); noted the interconnectedness of the emergence of new medical techniques and technologies and the development of the chemical-pharmaceutical industry; formulated conclusions, identified the feasibility of research work in the chosen scientific field (85%).

2 «History of development of adhesive techniques in orthodontics. Part II. Emergence of improved adhesives, current status of adhesive systems» [27]. Knowledge about new adhesive techniques and their modifications, about the influence of adhesion forces on tooth enamel, about fixation of orthodontic structures to atypical enamel and restorative surfaces is integrated, the need of orthodontic practitioners to reduce the stages of adhesive techniques while maintaining its effectiveness and quality of treatment results is assessed. The author searched for existing research in the subject area, selected 85% of scientific publications from printed editions and electronic scientific information databases PubMed, eLibrary, ScienceDirect, Springer, Wiley Library; synthesised, analysed, compared and summarised the results of scientific research, graphically presented an updated chronology of the development of adhesive techniques in orthodontics, formulated conclusions and recommendations, and confirmed the relevance of the research topic (85%).

«Indirect method of bracket bonding using a new Russian adhesive» [4]. The 3 study in the context of the actual problem of medical activity of a practicing orthodontist in the choice of new domestic materials, methods and technologies that provide simultaneously with optimal expenditure of time and economic resources high quality of orthodontic care that meets modern standards of its provision in the current conditions of limiting imports of high-tech products and reducing its availability. The author conducted a clinical study (previously unpublished) of the application of a new Russian adhesive with indirect bracket bonding for orthodontic treatment of 20 patients in compliance with the clinical protocols of diagnosis and treatment in order to master the new Russian adhesive and inform the professional community about its functional properties observed in the clinic. The author developed the study design (85%); defined the criteria for selection of patients participating in the study (70%); carried out the laboratory stage of bracket bonding on working models, manufactured mouth guards, bonded brackets by the indirect method, monitored patients during the first 26 weeks of orthodontic treatment (100%); cases of bracket debonding were documented and the frequency of debonding was quantified (95%), debonded brackets were examined and the modified Adhesive Remnant Index was assessed (95%), the results were analysed and summarised (80%); conclusions were drawn (80%).

Additional results provided by the author on a poster presentation «History of development of adhesive techniques in orthodontics» at the All-Russian Scientific and Practical Conference «Theoretical and practical issues of clinical dentistry» [25]. A systematic review of the evolution of adhesive techniques and materials for fixation of orthodontic appliances has been prepared with the aim of transferring the world scientific and practical knowledge presented in numerous publications. A large amount of synthesised and analysed scientific information on the subject is briefly, meaningfully and clearly reflected, summarised and concluded. This poster presentation is significant not only for orthodontists, but also for researchers-chemists, physicists, domestic

manufacturers, working together on scientific problems in the interdisciplinary space to create innovative domestic products in the field of medicine, so necessary in the objective conditions of limited imports.

CHAPTER 1. LITERATURE REVIEW

1.1 Adhesion in orthodontics

Adhesion is the bonding of two dissimilar substances in liquid and/or solid phase, which is caused by intermolecular interaction in the surface layer. The intermolecular interaction can be mechanical, chemical or diffusive [13, 84].

The substrate in orthodontics is the surface of the tooth enamel/restorative material to which the bracket base with pre-applied adhesive is bonded.

Adhesive system when working with fixed orthodontic appliances (brackets) a set of complex materials (etching agent, primer, adhesive) in various combinations, which is able to achieve micromechanical and chemical bonding of the bracket with the hard tissues of the tooth.

Adhesive technique when working with fixed orthodontic appliances (brackets) is the process of modifying the tooth enamel/restorative surface in the planned area of bracket/attachment fixation in order to ensure a strong bond between the bracket/attachment and the tooth enamel/restorative surface. As a common practice, the sequential steps include etching, priming, bonding of the bracket/attachment to the prepared surface with an adhesive.

A total-etch adhesive system is a type of adhesive system in which the tooth enamel or restorative surface is treated with 37% orthophosphoric acid gel to create a micromechanical bond to the composite material. The etchant is washed off after the substrate surface treatment.

A self-etching adhesive system is a type of adhesive system that does not require the etching agent to be washed off the tooth enamel or restorative surface.

Etching agent - orthophosphoric acid in liquid state at a concentration of 37%, which is necessary for the formation of microroughness on the tooth enamel/restorative surface, which facilitates the penetration of adhesive components into the tooth enamel/restorative surface.

Hybrid layer is an artificial structure that is formed on the enamel/restorative surface after treatment with an etching agent and infiltration with the following adhesive system components [17].

Primer is a component of an adhesive system designed to impregnate the structures of the etched tooth enamel/restorative surface and form a hybrid layer, which enables the bond between the brackets with the adhesive applied on their base and the tooth enamel/restorative surface. It is a complex chemical complex with hydrophilic monomers and a solvent as its main components.

Hydrophilic monomers are low molecular weight methacrylates (4-META; HEMA; BPDM; PENTA; GPDM; PMDM; PMGDM), which are polar organic molecules with low aqueous pH and pronounced hydrophilic properties. These properties in combination with the solvent promote the formation of ionic bonds with hydroxyapatites.

The solvent is a complex chemical substance that is capable of providing a liquid homogeneous consistency to the primer. The liquid/semigel form of the primer facilitates the penetration of the adhesive system components into the tooth tissue. Acetone, alcohol or water, or combinations thereof, may be used as a solvent for primers. The solvent is volatile, and upon evaporation of the solvent, the components of the adhesive system are converted from a liquid phase to a viscous semigel phase. The volatility of the solvent requires that the primer container be tightly sealed immediately after use.

Adhesive is a component of an adhesive system designed to impregnate the structures of etched enamel and form a hybrid layer in it. Hydrophobic monomers, fillers, initiators, polymerization stabilizers are the key ingredients of the adhesive. Serves for adhesion of the bracket to the pre-treated tooth enamel.

The hydrophobic monomer is high molecular weight high viscosity methacrylates (Bis-GMA; UDMA; TEGDMA; PEG-DMA). During polymerization, these molecules cross-link to form an organic matrix.

Filler - in the adhesive system consists of inorganic particles of inhomogeneous size (silicon dioxide, acrosil), which give strength and stability to the hybrid layer.

An initiator is a chemical substance which, under certain conditions, causes the formation of free radicals. Free radicals, in turn, promote the formation of bonds between

low- and high-molecular-weight methacrylates, which leads to the formation of a single organic matrix. Camphorquinone, lusterin, phenylpropanedione are used in light-activated materials, while tertiary amines and benzoyl peroxide are used in chemoactivated materials.

Stabilizer is a chemical substance that prevents spontaneous interaction of monomers in adhesive system components and their premature polymerization. The stabilizer determines the shelf life of the material [3, 20, 28, 52].

Bracket debonding is the breakdown of the adhesive bond between the bracket and the tooth enamel/restorative tooth surface, causing the bracket to come off.

Bracket debonding rate for unknown cause is the ratio of the number of brackets debonded for an unknown reason during a given time period to the total number of brackets fixed, expressed as a percentage.

The known and unknown debonding rate is the ratio of the number of brackets coming off for known (e.g., hard food) and unknown reasons during a given time period to the total number of brackets fixed, expressed as a percentage.

1.2 Requirements for adhesives in orthodontics

Prior the launch of a new adhesive on the market and its entry into widespread use by orthodontists in the clinic, researchers conduct both preclinical and clinical trials. Each phase of testing evaluates the properties of the adhesive to ensure that it meets accepted standards. At the preclinical stage, cytotoxicity, teratogenicity, allergenic effects are assessed in experiments on cell cultures and animals, tests are conducted to determine the ultimate strength characteristics, tensile strength, solubility and other tests [68, 71, 134, 159].

Provided the adhesive successfully passes preclinical trials, researchers have the opportunity to start clinical trials in various expert organizations, where the following science-based requirements are imposed on adhesives used in orthodontic practice:

- be versatile and compatible with most bracket designs on the market;

- provide an immediate, load-resistant, strong bond in the bracket-adhesiveprimer-enamel system;

- compensate for stresses resulting from polymerization shrinkage of the adhesive;

- withstand the stresses developed by brackets and archwires during orthodontic treatment;

- to provide an optimal strength level of fixation. Braces are fixed to the tooth enamel for an average of 1,5-2 years, unlike a filling material, which is designed for a longer period of time. After completion of orthodontic treatment, the brackets should be removed together with the adhesive without damaging the tooth enamel;

- should have a more fluid consistency than restorative materials. The adhesive for bracket retention should be easily and evenly distributed between the base of the bracket and the tooth enamel, while flowing into the subcavities of the metal mesh of the bracket base;

- prevent the development of enamel demineralization around the base of the bracket;

- be biocompatible;
- be insoluble in contact with oral fluid;
- be comfortable and easy to use;
- have a long shelf life;
- be non-sensitizing to the patient and clinician [17, 19, 97].

1.3 History of the development of adhesive techniques in orthodontics

Since the advent of fixed orthodontic appliances, braces have traditionally been soldered to gold or steel rings. The band ring encompassed the tooth, which required the creation of an interproximal space. Initially, metal wire ligatures were used for separation, which were replaced by elastomeric ligatures. Separation required additional visits to the orthodontist. This procedure was uncomfortable for the patient, as the banding rings often caused trauma to the gums during placement and decalcification of the enamel underneath them during the long period of orthodontic treatment. At the end of treatment, the interproximal spaces had to be closed. The obvious solution to these problems was to bond the brackets directly to the tooth.

In 1955, Buonocore M. demonstrated increased adhesion of attachments to enamel when its surface was exposed to 85% phosphoric acid solution for 30 seconds. He suggested that the increased adhesion to enamel may be due to an increased surface area amenable to mechanical adhesion, as well as increased wettability of the adhesive surface, which allows for closer contact with the adhesive. This is how the technique of acid etching of enamel was substantiated [59].

In 1962, Dr. Bowen R. patented a new type of composite filling material that contained aromatic Bis-GMA dimethacrylates and an inorganic filler. This material became known as Bowen resin and initiated the development of the wide range of composite restorative materials used in dentistry today [56].

In the early 1970s, based on Bowen's research, the composite restorative systems «Concise» (3M Unitek) and «Adaptic» (Johnson & Johnson) with interlocking adhesives with minimal polymerisation shrinkage were developed and became popular. Both systems required acid etching of the enamel with a 40% phosphoric acid solution. Unfilled resin was then applied to the enamel as a wetting agent, and metal brackets were fixed to the conditioned enamel with a chemically curing paste.

Dr Newman G., an orthodontist from Orange, New York, Jersey and Professor Miura F. Head of the Department of Orthodontics at Tokyo Medical and Dental University, Japan, were the first to fix brackets to tooth enamel [169]. In the mid-1960s they began their experiments to develop an adhesive to bond plastic brackets to tooth enamel. In their opinion, the orthodontic adhesive had to: resist the forces of occlusion and arch tension during orthodontic treatment; allow the removal of brackets without damaging the enamel; be hydrophilic, taking into account the fact that the fixation process is performed in a humid environment; and be stable during a long period of orthodontic treatment, while maintaining the necessary bond strength. Newman G. published «Epoxy adhesives for orthodontic attachments: progress report» (1965), where he described an epoxy resin adhesive for fixing plastic brackets to enamel [169].

Among the advantages of epoxy resins Newman G. attributed insignificant polymerization shrinkage during curing, the same coefficient of thermal expansion with enamel, minimal water absorption. These properties provided the necessary bond strength when fixing the plastic bracket to the enamel, made it possible to resist the occlusal forces and stress of the orthodontic arch arising during chewing and tooth movement. He used a 40% phosphoric acid solution to etch the enamel. His article has been characterized as innovative and the concept of bracket bonding as more aesthetic and hygienic. In 1980, Newman G. introduced an epoxy resin-based adhesive in the form of a paste called «Contacto», the feature of which was that it did not polymerize until the paste was in contact with the primer on the bracket and tooth [121].

Miura F. developed a technique for bonding polycarbonate plastic brackets to enamel pre-etched with phosphoric acid using «Orthomite» adhesive, which was developed by Masuhura E. at the Medical and Dental University of Tokyo. The «Orthomite» adhesive consisted of methyl methacrylate and polymethyl methacrylate. The role of chemical reaction gas pedal was played by tri-n-butylborane. Miura F. found that the bond strength of the bracket to enamel decreased over time as a result of exposure to oral fluids. In addition, chewing and the use of metal arches caused the ligature wings of plastic brackets to break, deforming their slot [117]. However, at the time, the system became quite popular as an alternative to banded rings. The disadvantages of this bonding technique stimulated research on the development of adhesives resistant to oral fluid, the selection of a more durable polycarbonate for plastic brackets, and the introduction of metal brackets into orthodontic practice. New methyl and polymethyl methacrylate adhesive systems such as GAC International and TP Orthodontics, which had the same properties, appeared on the market.

In the mid-1970s, a new polycarbonate called Lexan (General Electric, Fairfield, Conn) began to be used for plastic braces. This improved polycarbonate was harder, less prone to wear and fracture of the wings; however, it was not as strong and reliable as stainless steel. Continued patient demand for improved aesthetics led to the development of ceramic materials for clear braces. Ceramics withstands stress, does not break, does not discolor, and is still the material of choice for aesthetic braces.

In 1974, Dentsply/Caulk introduced the first ultraviolet (UV) light-curable adhesive for braces in the form of a single Nuva Tach paste. This system utilized a UV unfilled bonding resin (Nuva Seal) per enamel and a single UV-curable paste (Nuva Tach). The paste and unfilled resin were cured with light-emitting energy in the 280 nm range. These UV-light curable composites, like their chemically curable predecessors, were initially introduced as restorative materials from restorative dentistry with little change in paste viscosity. However, unlike chemically curing systems, UV-light-cured systems had no working time limitations. This characteristic gave the clinician unlimited working time to place the bracket, clean the peripheral area around the bracket of excess material, and, if necessary, reposition the bracket prior to photopolymerization. However, the use of these UV-curing systems was discontinued when it was discovered that they were harmful to exposed skin and eyes and sometimes even caused soft tissue burns.

In 1975, Lee Pharmaceuticals (South El Monte, CA) developed a chemically curing system for direct brackets bonding that required the orthodontist to apply a liquid activator to the etched enamel and to the metal (or plastic) base of the brackets. A single paste was applied to the activator-treated bracket base. The bracket base was then placed on the tooth and the bracket was fixed in position. Liquid enamel activator and paste applied to the bracket were mixed, resulting polymerization reaction to start.

In 1983, Reliance Orthodontic Products developed «Excel» adhesive in the form of a strong liquid paste for fixation of large acrylic expansion appliances, proposed in the very early 1980s by McNamara JA. for the treatment of mesial bite [116].

The «Excel» material adhered well to the plastic, would not wash out of the appliance, and was successfully removed with no signs of decalcification after treatment.

In 1979, Ormco developed and patented a method of soldering the mesh to the metal foil base of the bracket. This design allowed the adhesive to penetrate between the mesh and the foil base of the bracket, thereby increasing mechanical retention.

In the first half of the eighties, Tavas J. and Watts M. introduced the concept of light-cured composites. By bonding brackets using photopolymerization, they proved that the bond strength of brackets to enamel when activated by light is comparable to the bond strength achieved with two chemically curing adhesives [151]. Unlike adhesives cured by UV light, the catalyst in this case is camphorquinone. The material is cured under the influence of rays of the visible part of the spectrum of halogen polymerizer in the range from 400 to 500 nm, which makes them safe for eyes and skin. When the adhesive is exposed to visible light, the photoinitiator camphorquinone enters an activated state. In this state, it is able to react with amines to form free radicals. The free radicals interact with the monomer molecules, attaching them to themselves. This results in the formation of chains of monomer links that increase in length. As the chains grow further, they activate the interaction, which triggers the formation of a cross-linked mesh. The described reaction generates a modification of the physical properties of the adhesive - its curing. To start and continue polymerization, a sufficient intensity of light flux is required, which provides excitation of photoinitiator [151].

In 1985, Suh E. produced the adhesive «Enhance» (Reliance Orthodontic Products), which was designed for teeth with fluorosis and atypical enamel surfaces and use with any chemical or light-curing system. «Enhance» was applied to the etched enamel prior to the application of unfilled resin. The monomer in «Enhance» (biphenyl dimethacrylate) chemically bonded to the composite and metal. From this point on, clinicians were able to bond to any metal surface without using a metal primer or to a composite restoration without a plastic conditioner.

The «Crypsis» adhesive, which changes color after polymerization, was introduced in 1986 by Orec (Beaverton, Oregon). This adhesive consisted of two pastes, was yellow after mixing and during the gelation period, and after polymerization acquired the color of the tooth. This color characteristic allowed the orthodontist to see excess composite around the bracket and remove it before polymerization. The mechanism of color change was a function of the photocuring catalyst.

In 2004, Reliance Orthodontic Products, 3M Unitek and Ormco introduced several light-curing adhesives that changed color during polymerization. The color change

mechanism in the adhesive from Ormco was caused by temperature. In order to identify the adhesive residue left after debonding the bracket, it was necessary to moisten the tooth in with cold water.

In 1995, Silverman B. and other researchers developed a technique for fixation of metal brackets to wet enamel without acid etching using «Fuji Ortho LC» (GC, Japan), a dual-curing glass ionomer cement. This two-component system consists of a powder (fluoroaluminosilicate glass) and a liquid (polyacrylic acid, water, hydroxyethyl methacrylate, and camphorquinone light activator). The patient's enamel is cleansed, rinsed and dried. The powder and liquid are mixed together and applied to the metal base of the bracket, then the bracket is fixed to the enamel. The paste under the base of the bracket is cured by light for 20 seconds with a polymerization lamp, 5 minutes after polymerization, the clinician can set the active archwire [144].

In 1996, 3M Unitek introduced a metal bracket system with a light-curing adhesive pre-applied to the base of the bracket. The orthodontist would etch the tooth enamel, treat with a primer, and place the bracket. The advantage of this system was that there was no need to pre-apply material to the base of the brackets [49].

In 1998, several hydrophilic primers were introduced such as «Ortho Solo» (Ormco, USA), «Assure» (Reliance Orthodontic Products, USA) and «Transbond MIP» (3M Unitek, USA). These primers adhere well to both wet and dry enamel. Due to the biphenyl dimethacrylate content in the «Assure» primer, bracket bonding was possible on teeth with fluorosis, hypoplasia, atypical enamel surface, as well as on various surfaces (gold, amalgam, zirconia, ceramic, stainless steel and composite) without the use of special metal, ceramic or plastic primers.

In the early 1990s, microetching (sandblasting) became a mechanical preparation for fixation of fixed orthodontic appliances in the area of teeth with restorations [175]. Aluminum oxide, an abrasive powder for intraoral microetching, created a fine roughness and significantly increased mechanical retention to the artificial surfaces. This mechanical preparation prior to bracket fixation showed an increase in adhesion of almost 100%. After microetching, the surface of the ceramic crown was chemically etched with 8% hydrofluoric acid to further increase the adhesion strength.

In 2000, self-etching primers «Transbond Plus» (3M Unitek, USA) and "SEP" (Reliance Orthodontic Product, USA) became effective in conditioning enamel in orthodontic treatment. These primers are two-liquid systems of water and methacrylic ester of phosphoric or nitric acid. The advantage of self-etching primers is that there are no rinse and drying steps after application, which are necessary with traditional phosphoric acid etchings. Self-etching primers are hydrophilic, which means they can be applied to a slightly moisture surface. However, as with any bonding procedure, there is a sensitivity to the primer application technique that determines success or failure. Enamel is first cleaned with a prophylactic pumice stone and then rinsed and dried. The two liquids must be mixed. Next, the enamel is coated with the active solution, which is rubbed in for 5 seconds. The self-etching primer works similarly to the phosphoric acid calcium is released from the hydroxyapatite. The difference is that there is no rinsing after application of the self-etching primer, the released calcium is not removed but forms a bond with the phosphate group during polymerization. The self-etching primer penetrates to the full depth of the etchant and, due to this process, achieves its adhesive strength with the enamel [48].

Studies of a new organically modified ceramic restorative material ormoker «Admira» as an adhesive for brackets fixation showed its high biocompatibility and wear resistance [38].

Moving away from the use of band rings and bonding the brackets directly to the enamel meant that less enamel surface would be protected during treatment and a more responsible patient attitude to oral hygiene would be required. Unfortunately, disciplined patient cooperation is not always found. As a result, 23% of all orthodontic patients have enamel decalcification at the end of treatment [89]. Orthodontic adhesive manufacturing firms have begun to offer solutions to reduce decalcification during treatment. In 2003, «Pro Seal» (Reliance Orthodontics, USA) was introduced in the market as a light-curing, fluoride filled sealant that remains intact on exposed enamel for 2-3 years with regular brushing. This sealant was more durable and more effective than its predecessors due to the modification of the catalyst trimethylbenzoyldiphenylphosphinoxide (TPO), whereby the resin was fully cured. Complete curing of the resin eliminated the dispersion layer and

the resulting porosity. Acids, bacteria from oral fluid could not penetrate the sealant structure without porosity and damage it.

In 2010, «Select Defense» (ClassOne Orthodontics, California) was introduced as a selenium-containing enamel sealant. Tran P. et al. reported that organoselenium compounds covalently attach to various biomaterials, thus inhibiting bacterial biofilms.

In 2013, 3M introduced Flash-Free technology to protect tooth enamel during orthodontic treatment by allowing a new clear adhesive to spread out while the bracket is attached, adhering perfectly to the tooth surface. The orthodontist does not need to remove excess material around the contour when the braces are fixed on the teeth. Braces bonded with this technology fit over the surface of the teeth without gaps or cavities, creating a rim of «armor» around the perimeter that prevents the entry of food and saliva. Flash-Free technology is available on 3M Clarity Advanced, Clarity SL and Smart Clip braces [82].

In 2014, universal hydrophilic primers containing biphenyl dimethacrylate were introduced. These primers allowed orthodontists to bond brackets to gold, ceramic and steel crowns, composite and amalgam restorations without the need for special primers for ceramic, metal or plastics.

Between 2017 and 2022, the development of nanobiotechnology has led to the creation of several novel antimicrobial nanomaterials for dental applications. Various studies have evaluated the antimicrobial and mechanical properties of orthodontic adhesives containing nanoparticles [129].

Thus, the addition of divalent copper oxide nanoparticles to the «Transbond XT» composite at concentrations of 0,01; 0,50 and 1,00% showed a significant antimicrobial effect compared to the control group. The antimicrobial effect tended to increase with increasing concentration of nanoparticles. The shear strength was not affected by the addition of nanoparticles compared to the control group [155].

Studies on including silver nanoparticles in the adhesive also showed a good antibacterial effect and did not affect the shear strength compared to the control group [39].

Experiments in the laboratory on adding zirconium dioxide and titanium nanoparticles to orthodontic adhesive increased compressive, tensile, and shear strength [80].

There was an improvement in the mechanical properties of «Heliosit» adhesive when calcium hydroxyapatite nanoparticles were incorporated at a concentration of 2% [92].

A chronicle of events in the field of materials science and new technologies for orthodontics for the period 1955-2022 is presented in Appendix A [25–27].

1.4 Classification of adhesive systems in orthodontics

Adhesive systems in orthodontics are categorized according to the following criteria [124].

According to the polymerization method of the adhesive system:

- chemical polymerization (self-curing);
- light polymerization (photopolymerizable, light-cured);
- hybrid;
- thermo-cured.

Based on operating principle:

- self-etching systems;
- systems with total etching of tooth tissues.

By fluoride content:

- fluoride-containing;
- fluoride-free.

In relation to the presence of moisture during polymerization:

- moisture-resistant;
- moisture-active.

Classification according to the method of polymerization of the adhesive system and according to the presence of moisture during polymerization is presented in Table 1.

Adhesive	Polymerization initiation	Operating Characteristics	Properties	Supplement
Chemical	Mixing liquid and	Labor-intensive,	Increased contact time of	First on the market.
polymerization,	paste components	time-consuming	components with air causes	Representative: «Concise» (3M
two-phase			oxygen inhibition. During the	Unitek, USA)
			mixing process voids are formed	
			due to oxygen entrapment, which	
			reduces strength, increases	
			microleakage	
Chemical	Application of the	Efficient	Limited data on cure level and	The development of these
polymerization,	liquid component	application,	bond strength. Inhomogeneous	materials has replaced biphasic
single phase	to the tooth enamel	limited time	polymerization pattern due to the	systems. Not recommended in
	and the base of the	required	«sandwich» method of diffusion	cases where the thickness of
	bracket. No mixing		of the liquid component into the	the adhesive is increased, such
	is required		paste during application. The	as cheek tube bonding of
			adhesive sides of the enamel and	molars.
			bracket are more polymerized	Representatives:
			compared to the middle zones	«System 1» (Ormco, USA);
				«Rely-a-bond» (Reliance
				Orthodontics, USA); «Unite»
				(3M Unitek, USA).

Table 1 Adhesive classification in orthodontics

Light-cured	Exposure to light source	Extended working time to allow for optimal brace positioning. Ideal for the learning process. Labor intensive curing process	High tensile properties, hydrophobic, optimum viscosity	Available since the 1980s. More time-consuming than single- phase chemical curing systems. Most manufacturers on the market offer photo-curable adhesives: «Enlight» (Ormco, USA), «Grengloo» (Ormco, USA), «Blugloo» (Ormco, USA), «Compofix-ortho» (Vladmiva, Russia), «High-Q-Bond Bracket Adhesive» (BJM Lab, Israel)
Hybrid	Initiation is achieved by exposure to light. The reaction is a chemical curing reaction	Combines the performance disadvantages of both light-cured and chemically cured materials. The most labor-intensive	Adhesive bond strength is lower than that of light-curing adhesives. Hydrophilic. Release, replenishment of fluoride ions. Chemical adhesion to enamel and bracket base	Introduced into the profession from prosthetic dentistry. Ideal material for bonding cheek tubes to molars and partially erupted teeth. Representative of: Fuji «Ortho LC» (GC, Japan), «Ortho Glass LC» (DFL, Brazil)

Continuation of Table 1

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Heat-cured	Initiation occurs when heat is applied	Not designed for direct fixation	Excellent properties	The polymerization initiator limits their use for direct bonding. Representative: «Therma-Cure» (Reliance Orthodontics, USA)
Moisture-active	Cyanoacrylates. No liquid in the composition. Consists only of a paste. Polymerization is initiated by exposure to water	One-step procedure. The enamel surface must be intentionally wet	Some studies have shown acceptable bond strength	Representative: «SmartBond» (Gestenco, Sweden)
Moisture- resistant	Primer compatible with use of adhesives	Application of primer on wet enamel surface	Provides acceptable adhesive bond strength in case of moisture contamination of enamel surface	Suitable for bonding brackets in areas where there is a high risk of contamination of the enamel surface. Representatives: «Compofix- ortho» (Vladmiva, Russia), «Ortho Solo Universal Bond Enhancer» (Ormco, USA), «Transbond MIP» (3M Unitek, USA), «Assure» (Reliance Orthodontics, USA)

Chemical polymerization adhesives

These adhesive systems have been used since the advent of bonding in the modern history of orthodontics, since the 1970s [169].

Chemical polymerization adhesives are available in two-phase and single-phase. The polymerization initiator is benzoyl peroxide, which is activated by a tertiary amine (dimethyl-p-toluidine, dihydroxyethyl-p-toluidine). Initiation occurs as a result of mixing of the two components of the adhesive system, resulting in the formation of free radicals, which ensure polymerization.

Two-phase adhesive systems are a type of adhesive system that require mixing of a paste and a liquid component. This is a labor-intensive manipulation that can lead to surface porosity and air voids due to trapped air bubbles (Figure 1). Due to these disadvantages, biphasic adhesive systems have been gradually eliminated from orthodontic practice.

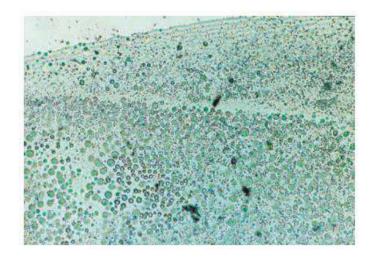


Figure 1 Porosity of biphasic chemically cured orthodontic resin (initial magnification x150) [76]

Single-phase adhesive systems

Single-phase adhesive systems are a type of adhesive system that do not require mixing of two components. They were developed to eliminate a major disadvantage of two-phase systems, such as air bubble formation and porosity. In single-phase systems, the catalyst diffuses from the tooth enamel surface to the brackets, resulting in the formation of a hybrid layer. The thickness of the adhesive layer varies from 120 to 230 μ m and depends on several factors, including tooth enamel morphology, bracket base design, and adhesive viscosity.

Light-curing adhesive systems

In these monomer systems, light source is used to initiate polymerization. The degree of polymerization depends on several factors: exposure time; photoinitiator concentration; light intensity emitted by the photopolymerization lamp; and filler volume fraction [123].

The spectral distribution of the light source significantly affects the polymerization of the material [34].

The light intensity at the maximum absorption wavelength of the photoinitiator (λ) as well as the duration of light exposure have a great influence on the degree of polymerization of the adhesive. Light scattering on the surface of the filled composite can reduce the intensity of incident light reaching the bulk material, resulting in a significant decrease in the degree of polymerization in the thickness of the sample. The filler size is a crucial factor for the degree of scattering, and the optimum particle size is $\sqrt{\lambda/2}$.

The light emission frequency of the photopolymerization lamp is also relevant. In dental lamps, the wavelength of the light source varies from 400 to 500 nm. Under steady-state or pulsed polymerization conditions with high light source flash rates, the concentration of free radicals is proportional to the square root of the light intensity in the

range of the maximum absorption wavelength. At lower light source emission frequencies, the concentration of free radicals decreases by a factor of $(\sqrt{2})$ [64].

Under clinical conditions, light-cured composites provide superior mechanical properties and better peripheral sealing of brackets compared to chemically cured systems. This is due to the fact that increased polymerization time and light intensity leads to increased composite strength and that the rapid curing reaction of relatively thin adhesive layers significantly reduces the time required for oxygen diffusion into the composite volume and deactivation of free radicals [45, 166].

Light-cured adhesives have excellent surface curing characteristics because the adhesive layer has a very high surface-to-volume ratio. This means that per unit volume of adhesive there is more surface area that can be cured by light [42].

Hybrid adhesive materials

This group of materials combines the advantages of rapid initiation of photopolymerization of the adhesive and high rate of conversion of chemically curing resins into bulk material [150]. In these systems, polymerization activation occurs by exposing the surface of the material to a visible light source, and polymerization in the thickness of the material occurs as a result of the chemical curing process and the initiation of the terminal methacrylate groups of polycarboxylic acids by the catalyst. In addition to chemically bonding to the enamel surface, the composite resin monomers penetrate the irregularities in the enamel surface, creating a micromechanical bond after polymerization. Light-activated polymerization proceeds much faster than the acid-base cross-linking reaction of polyacid macromolecules with metal ions, resulting in improved early physical properties, especially fracture resistance. Photocuring allows the orthodontist to utilize as much time as required for precision bracket positioning [79]. Sustained release and replenishment of fluoride ions, caries inhibition, and the ability to perform bonding in the presence of moisture are similar to classical glass ionomer cements [33].

In the orthodontic market, the hybrid adhesive material for bracket retention is marketed as «Fuji Ortho LC» [165].

«Fuji Ortho LC» hybrid adhesive consists of a powder (aluminofluorosilicate glass, pigments, catalyst system) and a liquid (acrylic and maleic acid copolymers, hydroxyethyl methacrylate, water, camphorquinone, sodium toluene sulfate).

When fixing braces with «Fuji Ortho LC» there is no need to etch/dry the tooth enamel surface. «Fuji Ortho LC» is mixed in a ratio of three quarters of a scoop of powder to two drops of liquid. The base portion of the material is applied to the base of the bracket without creating voids. After positioning the bracket, excess material is removed from the enamel surface around the periphery of the bracket. The material is illuminated with a dental photopolymerization lamp for 30-60 seconds.

Wide variations in the adhesive bond shear strength of hybrid materials, ranging from 5,4 to 18,9 MPa, have been reported in the orthodontic literature.

A study by Fricker J. (1998) comparing the shear adhesive bond strength between hybrid and composite material showed that the incidence of bracket debonding was 5% for hybrid and 8,3% for composite adhesives [85].

In a randomized controlled clinical trial conducted by Gorthon J., Featherstone D. (2003), a qualitative tooth microhardness test showed that tooth enamel to which braces were fixed with «Fuji Ortho LC» hybrid adhesive had significantly less mineral loss compared to tooth enamel to which braces were bonded with «Transbond XT» light-cured composite adhesive [89].

Hybrid adhesives are the preferred materials for fixation of orthodontic components in situations of extreme wetness, such as in the area of second molars.

Koyal S., Valiathan A. (2003) compared the frequency of adhesive bond breakage in clinic between «Fuji Ortho LC» and «Transbond XT» using oral segmentation technique over a period of 6 months. The study showed that «Transbond XT» and «Fuji Ortho LC» had comparable incidence of adhesive bond disruption. The study reported no significant differences in plaque index as well as periodontal condition in both groups. The authors concluded that «Fuji Ortho LC» is an alternative material to composite adhesive for brackets in orthodontics [107]. Pithon M. et al. (2006) evaluated the shear bond strength of metal brackets using hybrid adhesives «Fuji Ortho LC» and «Ortho Glass LC». The researchers fixed the brackets to the enamel without etching, with enamel etching with 37% phosphoric acid gel, and by pretreating the enamel with a self-etching primer called «Transbond Plus». The authors concluded that «Fuji Ortho LC» provided higher shear bond strengths than «Ortho Glass LC» regardless of enamel treatment [128].

Hegarty D. and Macfarlane T. (2002) in a randomized clinical trial determined the incidence of adhesive bond failure between brackets fixed with hybrid adhesive and composite adhesive and compared their clinical effectiveness over 12 months in 61 patients. The incidence of bracket debonding was 10% for hybrid adhesive and 4% for composite adhesive. Compared to the composite adhesive, the hybrid adhesive demonstrated no loss of enamel surface during debonding, less enamel demineralization, and easy removal of adhesive residue from the enamel surface. However, the hybrid adhesive had a 2,6 times higher rate of bracket debonding than the composite adhesive [93].

Ali H. and Marali S. (2012) concluded that «Fuji Ortho LC» can be used as an orthodontic adhesive under the condition of enamel etching. Composite adhesives are superior to hybrid adhesives in terms of adhesive bond shear strength. The advantages of hybrid adhesives are fluoride release, adhesion to both enamel and the metal base of the bracket. The presence of these qualities of hybrid adhesives determines their use in the clinical practice of orthodontists [41].

Moisture-resistant adhesive systems

Bracket fixation to etched enamel with composite adhesives is technique sensitive. Moisturization of enamel is the most common cause of adhesive bond failure [86]. When the etched enamel is moistened, most of the pores on the enamel surface become clogged and the penetration of the composite resin is impaired. Hormati A. et al. in their study found that the shear strength of the adhesive bond is reduced by 50% in the presence of moisture [96]. Saliva drying is not enough to increase the strength of the adhesive bond. In scanning electron micrographs, the researchers demonstrated an etched enamel pattern with moisture-filled pores. The depth of the composite tubules was insufficient for adequate retention of the adhesive material. Composite adhesives have hydrophobic properties and require dry etched enamel to realize mechanical adhesion to the enamel surface. To avoid the difficulties associated with the sensitivity of this technique, moisture resistant primers have been developed. This primer is available on the market as «Compofix-ortho» (Vladmiva, Russia), «Ortho Solo Universal Bond Enhancer» (Ormco, USA), «Transbond MIP» (3M Unitek, USA), «Assure» (Reliance Orthodontics, USA). Manufacturers recommend using moisture-resistant primer on dry or wet enamel in combination with chemically and photo-cured composite adhesive. The moisture resistant primer is identical in chemical composition to the ethanol-containing dentin primer. A copolymer of polyalkenoic acid with methacrylate functional groups is an important reactive component of the moisture resistant primer [124].

Littlewood S. et al. (2001) conducted a study of the adhesive bond strength of braces under experimental conditions. Using the standard technique of bracket fixation, the adhesive bond strength of brackets fixed with a hydrophilic primer was compared to the adhesive bond strength of brackets fixed with a traditional hydrophobic primer. The experiment was conducted under dry field conditions. The average adhesive bond strength with the hydrophilic primer was 6.43 MPa and was significantly lower than that of the conventional primer (8.71 MPa) [114].

Grandhi R. et al. (2001) conducted a pilot study on bull enamel to evaluate the shear adhesive bond strength of stainless steel brackets fixed in a dry and wet working field using the moisture resistant primer «Transbond MIP», and to evaluate the effectiveness of «Transbond MIP» in combination with the chemically curable adhesive «Concise» and the photo-curable composite adhesive «Transbond XT». The results of this study showed that «Transbond MIP» should only be used with light-curing adhesives, as this combination provides higher adhesive bond strength. The researchers suggested that «Transbond MIP» should be used in clinical situations where moisture control is difficult to achieve [90].

Rajagopal R. (2004) compared the adhesive bond strength using three adhesive primers: traditional «Transbond XT», moisture resistant «Transbond MIP» and self-etching «Transbond plus». The adhesive bond strength was determined in laboratory conditions on brackets fixed both on dry enamel and on enamel contaminated with natural saliva. The self-etching primer showed maximum adhesive bond strength under both dry and wet conditions. The conventional primer was comparable to the moisture resistant primer in dry conditions, but did not provide clinically adequate adhesive bond strength when contaminated with moisture. Both the self-etching primer «Transbond plus» and the moisture-resistant primer «Transbond MIP» showed adequate adhesive bond strength, superior to that of the traditional primer «Transbond XT» in the case of moisture contamination [130].

Valiathan A. and Ashil A. (2006) studied the efficacy of moisture resistant primer «Transbond MIP» under experimental conditions in wet and dry field and also compared the adhesive bond strength of brackets fixed with «Transbond MIP» primer with traditional «Transbond XT». It was found that in the presence of saliva contamination, brackets fixed with «Transbond MIP» had a significantly higher shear bond strength (14,53 MPa) compared to brackets fixed with traditional «Transbond XT» primer (9,36 MPa) [108].

Madhu S. et al. (2014) concluded that «Transbond MIP» showed acceptable average adhesive bond strength values on dry, wet and blood-contaminated enamel surfaces, therefore it is suitable for bracket fixation in settings where there is a high risk of enamel surface contamination [75].

Moisture-active adhesives

Unlike moisture resistant primers, these require the presence of moisture for proper curing [62]. These adhesives are available as pastes, have a characteristic chemical cyanoacrylate composition and polymerization mode, do not require etching of enamel and subsequent coating of the enamel surface with primer.

A unique property of cyanoacrylates is the ability to polymerize at room temperature without the addition of a catalyst when the cyanoacrylate paste is pressed into a thin film between two surfaces to be bonded. The adhesion between the two surfaces to be bonded is the result of anionic polymerization. Small submicroscopic amounts of water or alcohol initiate the polymerization reaction, whereas acidic substances render the adhesive inactive. Adhesion occurs partly due to mechanical adhesion between the polymer and the surface and partly due to strong secondary bonding forces. The isocyanate group of cyanoacrylate reacts with water to form an unstable carbamic acid component. This unstable component further dissociates into carbon dioxide and amine. The amine then reacts with the residual isocyanate groups to crosslink the adhesive through substituted urea groups.

Munajed M. et al (2000) evaluated the tensile adhesive bond strength of cyanoacrylate orthodontic adhesive and the site of adhesive bond failure in comparison to composite orthodontic adhesive for fixation of metal and ceramic brackets. The mean shear bond strength of the adhesive bond of cyanoacrylate adhesive was significantly lower than that of brackets fixed with composite adhesive. This study showed that cyanoacrylate adhesives are unsuitable for use as an adhesive material in the practice of an orthodontist [43].

Bishara S. et al. (2001) conducted a comparative study of the shear strength of adhesive bond for cyanoacrylate «SmartBond» and composite «Transbond XT» adhesives and determined the nature of adhesive bond failure in the «enamel-adhesive-bracket» system in both groups of adhesives. In the experimental study, brackets were fixed to extracted human teeth using one of two protocols. In the first group, the teeth were etched with 37% phosphoric acid, and after primer application, the brackets were fixed with «Transbond XT» and cured with light for 20 seconds. In the second group, the teeth were etched with 35% phosphoric acid, after which the brackets were fixed with «SmartBond». The shear adhesive bond strength results obtained showed that the use of cyanoacrylate adhesive to fix the brackets to the enamel surface did not significantly change the shear adhesive bond strength (mean 5,8+2,4 MPa) compared to the first group (mean 5,2+2,9 MPa). After debonding was performed, comparison of the Adhesive

Remnant Index scores showed that significantly less adhesive residue remained on the teeth with the cyanoacrylate adhesive compared to the teeth where the composite adhesive was used. In conclusion, it was noted that the new adhesive «SmartBond» can be used for bracket fixation, while reducing the overall bonding time of brackets [55].

Karamouzos A. et al. (2002) compared the incidence of debonding in the clinic between braces fixed with cyanoacrylate adhesive and braces fixed with composite adhesive over a 9-month period. Cyanoacrylate adhesive showed a high rate of bracket debonding (22,4%) compared to composite adhesive (5,1%). Bracket debonding was reported less frequently in incisors and canines than in premolars. The researchers concluded that further studies aimed at improving the physical and mechanical properties of cyanoacrylate adhesive are needed [101].

Sunny J., Valiathan A. (2003) conducted a comparative experimental study of the shear bond strength of brackets bonded with «SmartBond» cyanoacrylate adhesive and Right-On composite adhesive. Shear adhesive bond strength measurements were performed after one hour in a dry working field, 24 hours and 48 hours in artificial saliva. The composite adhesive showed higher shear bond strength than the cyanoacrylate material in all time intervals. «SmartBond» achieved a maximum adhesive bond strength of 5,07 MPa after 24 hours, which then decreased after 48 hours. The authors concluded that «SmartBond» was inferior in strength characteristics to the traditional composite orthodontic adhesive «Right-On» [157].

Le P. et al. (2003) in a comparative clinical study determined the incidence of adhesive bond failure and the incidence of enamel decalcification for the cyanoacrylate adhesive «SmartBond» and the composite adhesive «Light Bond». A total of 327 teeth were examined between 12 and 14 months from the start of orthodontic treatment: brackets on 163 experimental teeth were bonded with cyanoacrylate adhesive, and brackets on 164 control teeth were bonded with light-cured composite adhesive. The cyanoacrylate adhesive showed a high rate of bracket debonding (55,6%) compared to the composite adhesive (11,3%). The enamel of all maxillary incisors was evaluated for decalcification using a step scale. The frequency of enamel decalcification between the two adhesives after one year of orthodontic treatment was similar. The frequency of

debonding of the cyanoacrylate adhesive was reported in the researchers studies to be 4 times more frequent than the frequency of debonding of the composite adhesive. The rate of enamel decalcification for the «SmartBond» cyanoacrylate adhesive was the same as for the traditional «Light Bond» composite adhesive. The authors concluded that «SmartBond» cyanoacrylate adhesive is not a suitable material for use as a retention material for brackets [110].

1.5 Adhesive preparation of enamel. Hybrid layer

Enamel is the hard, wear-resistant mineralized tissue of the human body [2].

The thickness of tooth enamel is not uniform: it reaches 2,3-3,5 mm on the chewing cusps of permanent teeth, 1,1-1,3 mm on the lateral surfaces, and only 0,01 mm on the tooth neck [9]. The main structural and functional units of enamel are enamel prisms (Figure 2), which run in bundles through its entire thickness radially and are somewhat curved in the form of the letter «S». Enamel prisms are absent in the area of dentin-enamel border, as well as in the outermost layer of enamel [15]. The chemical composition of tooth enamel includes mineral substances (95%), organic substances (1,2%) and water (3,8%). Mineral compounds are represented mainly by hydroxyapatite, carbonatapatite, fluorapatite and others. The organic substances of tooth enamel contain proteins, lipids and carbohydrates. Water is bound to crystals and organic components, and is also found in a free state. The chemical composition of the enamel, the thickness of the enamel layer, and the course of the enamel prisms should be taken into account when implementing the adhesive protocol [29].



Figure 2 Enamel prisms stroke [153]

1.5.1 Total enamel etching technique

The enamel preparation in this technique begins with treating the enamel surface with a concentrated solution of orthophosphoric acid. Dissolution of inorganic substances in the surface layer of the enamel leads to the formation of micro-roughness including pores, grooves and furrows and, as a consequence, to an increase in the contact area of adhesion of the enamel with the adhesive [11, 12].

Scientific studies have established that the most effective for etching enamel is 37% orthophosphoric acid gel with pH 0,5-0,8 units. The concentration of etching agent more than 40% leads to complete dissolution of the surface layer of enamel without formation of micro-roughness, and the concentration less than 20% is insufficient to create micro-roughness of enamel. In both cases, the contact area and bonding strength of the adhesive system to the enamel will be much smaller, which can affect the strength of the brackets-enamel bond. To obtain micro-roughness of the enamel, the enamel must be etched for 15-30 seconds. After washing off the etching agent, the enamel is dried, it should be matte [18].

The hydrophobic monomers of the adhesive readily penetrate into the microspaces of the enamel. Subsequent polymerization of the adhesive leads to the formation of a hybrid layer on the enamel surface (Figure 3).

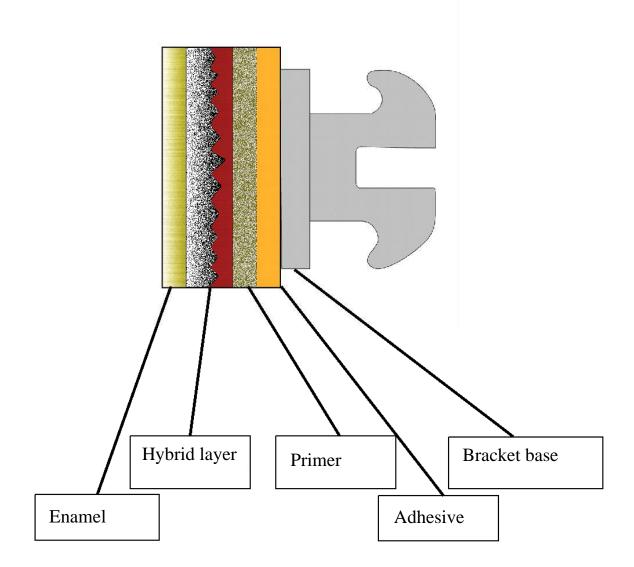


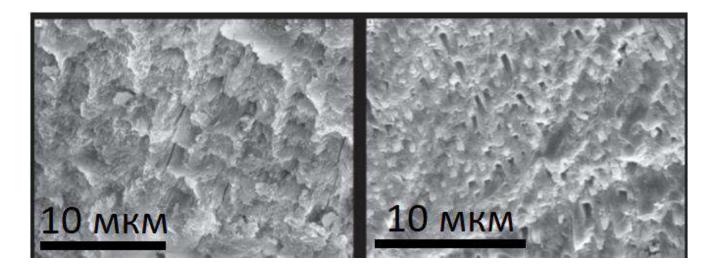
Figure 3 Hybrid layer formation in enamel

1.5.2 Self-etching enamel technique

When using a self-etching primer, demineralization of the enamel takes place without the step of washing off the etching gel and subsequent drying of the enamel. The acidic monomers in their composition serve to create micro-roughness of the enamel. The key factor for adhesion is the pH value of the etchant component, which determines the degree of demineralization of the enamel surface layer. A hydrogen value of less than 1,5 units is favorable for the performance of the self-etching adhesive. The required curing time of self-etching adhesive systems is 15-30 seconds [24].

In the adhesive system, the neutralization reaction occurs between the molecules of the acidic component of the primer and calcium ions released from the enamel hydroxyapatite crystals [70].

Using a scanning electron microscope (SEM), the researchers found that enamel surfaces treated with the total-etch system had a clearer etch pattern than enamel surfaces treated with the self-etch system. Figure 4 presents SEM micrographs of the enamel surface taken at 2000x magnification after application of the total-etch adhesive system and the self-etch system.



b Figure 4 Enamel surface after application a - adhesive system of total etching, b - self-etching adhesive system [127]

a

A unique characteristic of self-etch bonding systems in operative dentistry is that they combine conditioning and priming agents in a single product. The combination of conditioning and priming saves the clinician time and is more comfortable for the patient [120].

In addition to saving time, fewer steps in the adhesive bonding process can lead to fewer procedural errors, minimizing the sensitivity of the method.

Representatives of self-etching primers: «Ex-First Step» (Reliance Orthodontics, USA), «Transbond Plus» (3M Unitek, USA), «Ideal 1» (GAC Orthodontic products, USA), «Prompt L-Pop» (3M ESPE, Germany).

The active ingredient of self-etching primers is a methacrylate ester of phosphoric or nitric acid, which releases calcium from hydroxyapatite. The released calcium ions are not rinsed away after application of the self-etching primer, but are incorporated into the monomer mesh during polymerization. Etching and primer penetration occur simultaneously, resulting in identical etching and primer penetration depths [163].

Three mechanisms stop the etching process in this technique:

1 Acid groups attached to the monomer are neutralized by forming a complex with calcium from hydroxyapatite.

2 As the solvent is displaced from the primer during the air-blowing step, the viscosity is reduced, slowing the transport of acid groups to the enamel interface.

3 As the primer cures with light and the primer monomers polymerize, the transport of acidic groups to the interface stops.

Clinical sequence of actions when using the self-etching primer «Transbond Plus» [58].

1 Dry the tooth surface.

2 Apply «Transbond Plus», which consists of three compartments:

The first compartment contains methacrylate esters of phosphoric acid, photosensitizers and stabilizers.

The second compartment contains water and soluble fluoride.

The third compartment contains the microbrush applicator.

Compressing and folding the ingredients of the first compartment into the second compartment activates the system.

The mixed ingredient is then ejected into the third compartment to wet the tip of the applicator.

3 Bond the bracket with «Transbond XT» adhesive and light cure.

The main ingredients of «Transbond Plus» are:

- water;
- methacrylate esters of phosphoric acid;
- phosphine oxide;
- stabilizer;
- fluoride complex;
- parabens.

The chemical composition of «Transbond Plus» self-etching primer is similar to the chemical composition of phosphoric acid with two primer chains that form a solid matrix when cured. The liquid begins etching the enamel immediately after application, but turns into a primer when the two hydroxide chains are converted and hydrogen is released. Since no etching agent remains on the enamel, there is no need to rinse it off.

The reactive components of self-etching primers are formed by polymerizable acid monomers containing an acid with a mono- or bi-ester as a functional group. Thus, one of the two hydrogen atoms of the phosphoric acid is substituted with at least one methacrylate group.

When the self-etching primer is activated and the monomer is rubbed into the tooth, hydrogen cations are released from the phosphate group of the monomer and etch the tooth structure. In response, calcium hydroxide ions are released from the hydroxyapatite crystals, which react with the monomer, which enters into a polymerization reaction. This monomer further reacts with the composite resin used for bracket retention to form a complex.

Due to its own acidity, the self-etching primer dissolves the enamel surface and thereby creates a three-dimensional micro-retention pattern on the surface, while at the same time facilitating the penetration of the monomer. Thus, the depth of demineralization of the enamel and the depth of penetration of the bonding agent are identical, as both processes run in parallel. As a result, the light-curing of these interpenetrating monomers and copolymerization with the coating binder and composite resin form a continuous bond to the enamel surface [66].

Since the etch-inducing monomers are also responsible for binding, the penetration depth of the polymerizable monomers is exactly the same as the demineralization depth, resulting in a complete hybrid layer.

1.6 Orthodontic adhesive viscosity

The concept of viscosity in the medical literature is interpreted as the resistance to sliding of liquid layers due to intermolecular interaction forces. The weaker the interaction forces between molecules, the higher the fluidity and lower the viscosity [16].

For composite orthodontic adhesives, the overall viscosity of the unpolymerized paste depends on the viscosity of the dimethacrylate and the amount of filler. The viscosity of the composite increases with increasing filler concentration. Parameters such as level of cure and manipulation properties depend on the viscosity of the unpolymerized composite. In addition, the viscosity of the dimethacrylate component will affect the amount of filler that is added to the composite. There is an upper limit to the unpolymerized viscosity, so the dimethacrylate component will affect the amount of filler that can be included in the composite formulation. In the polymer matrix of the composite, Bis-GMA produces a strong and rigid polymer mesh, has a high viscosity and when fillers are added can result in a paste that is impossible to manipulate in the clinical setting. TEGDMA monomer is used to achieve optimal composite viscosity [40, 168, 173].

The viscosity of composite orthodontic adhesive is one of the most important properties that directly affects the expression of such factors as polymerization stress, monomer conversion rate during polymerization, material hardness, and elastic modulus. The viscosity of the adhesive also determines the manipulation characteristics of the material during the clinical appointment of the orthodontist. Stickiness of the material, the possibility of qualitative adaptation to the surface of the mesh base of the bracket, adaptation of the material at the time of fixation directly to the enamel of the tooth indirectly affects the working time of the adhesive [170]. Orthodontic adhesive with optimal viscosity is able to prevent marginal adhesion failure in the system «enamel-adhesive-bracket», which serves as a prevention of microleakage, reducing the risk of bacterial invasion, thereby preventing postoperative enamel sensitivity, caries formation and its complications [7, 50, 174].

1.7 Adhesive bond strength. Determination methods

Since the advent of direct fixation of brackets, the reliability of bonding to tooth enamel has been the subject of close attention of researchers. This is due to the fact that the stable position of the bracket on the tooth enamel surface is important in orthodontic treatment, which usually lasts several years. The emergence of new adhesives has stimulated the development of research in this area, which has led to an increased number of publications in the scientific literature [141, 143].

Although research on adhesive bond strength has been conducted since the 1970s, there is still no consensus on its clinical significance. A uniform protocol for the experimental determination of adhesive bond strength in orthodontics has not been developed.

In most case studies, adhesive bond strength is understood as a physical quantity that characterizes the force required to break the adhesive bond that causes the adhesive bond to fail at or near the interface of two surfaces.

All existing studies on adhesive bond strength in orthodontics can be classified according to:

A) on the testing environment:

1 Laboratory tests are studies that determine the adhesive bond strength by mechanical impact with a testing machine or by simulating a bracket removal procedure. The type of adhesive bond failure is visualized using a microscope.

2 Determining the incidence of bracket debonding in the clinic. These studies focus on the type of bracket and the group affiliation of the tooth in which debonding occurred. 3 Studies using finite element analysis allow the modeling of stress distribution in the «enamel-adhesive-bracket» system.

B) from the load application method:

- shear bond strength of the adhesive bond;
- shear tensile strength of the adhesive bond;
- torsional strength of the adhesive bond.

Determination of adhesive bond shear strength is popular because of the relative simplicity of the experiment and fairly high reliability in modeling the debonding process that occurs during orthodontic treatment. Tensile and torsional adhesive bond strengths are of much less interest to researchers due to the difficulty of reproduction and therefore become less relevant.

C) from the surface to which the bracket is bonded:

- enamel;
- composite fillings;
- ceramic fillings;
- amalgam fillings.

These studies are becoming increasingly relevant due to the growing need for orthodontic treatment in adult patients and the necessity to fix braces to restorative surfaces.

Main steps in determining the adhesive bond strength in orthodontics in an experiment

1 Tooth selection

The use of different teeth (incisors, premolars) in adhesive bond strength tests made it impossible to correctly compare the results of tests performed in different laboratories. When orthodontic treatment is indicated, premolars may be extracted, and in such cases the collection of teeth from this accessory group for testing is easier. However, it has been observed that the variability of the surface contour of the crown surface of premolars can create difficulties in standardizing the procedure of fixation of brackets to these teeth [152].

The upper and lower incisors are mainly removed in patients with periodontal disease. Generally, this is a group of elderly patients. The use of teeth from this group is not suitable for the experiment. Studies have shown that with age, changes occur in the tooth enamel that lead to a decrease in its permeability. These changes are that the enamel crystal lattice becomes more dense and the microspaces between crystals decrease. As a result, the amount of water between the crystals decreases. The concentration of calcium, phosphorus, zinc and fluorine in enamel increases with aging [146, 160].

In addition, various factors such as adsorption of inorganic or proteinaceous saliva particles, the effects of various therapeutic procedures and the pharmaceuticals used, may alter the reactivity of the surface layers of enamel, which may affect the strength of the adhesive bond [161].

2 Samples storage

In tests on adhesive bond strength, the effect of storage time of specimens from 24 hours to five years in different storage solutions: thymol, physiological solution, aqueous chloramine and formalin was studied [162].

The combinations of different solutions and exposure times of specimens in them do not allow for objective conclusions to be drawn, and the results obtained for adhesive bond strength in orthodontics cannot be compared.

The differences in adhesive bond strength results prompted researchers to conduct tests determining the effect of specimen storage time and storage medium on adhesive bond strength within a laboratory setting [57, 158].

When the samples were stored for more than 20 minutes, no significant effect on the adhesive bond strength was observed [148].

Another study reported that the adhesive bond strength values of teeth stored in formalin were twice as high as those of similar specimens stored in physiologic solution [104].

In an article entitled « Storage medium and enamel hardness» Muhlemann H. found that enamel specimens stored in physiological solution were softer than corresponding specimens stored in water [119].

Linden L. when examining the enamel structure of extracted teeth, observing different storage conditions, found only slight differences in coloration [113].

Silverstone L. in his study recommends avoiding formaldehyde as a sample storage medium due to its strong acidity and subsequent oxidation to formic acid can change the pH of the storage medium [145].

A study of the adhesive bond strength between enamel and glass ionomer cement showed that the bond strength values in laboratory conditions are twice as high as in clinical conditions, all other conditions being equal [100].

Recent studies on adhesion in dental practice have primarily focused on the strength of the adhesive bond to dentin. This bond is crucial for ensuring the longevity of dental restorations and preventing long-term adverse effects. It is important to note that the bond strength between adhesive and dentin cannot be extrapolated to enamel due to the differences in the chemical composition of these tissues. Ionic and enzymatic storage environments can damage dentin, which contains a high amount of organic matter. Enamel, however, is more resistant to such effects due to its high inorganic content [132].

Thus, it is likely that storage time and environment have little or no effect on the adhesive strength of the bond to enamel.

Some researchers believe that a six-month storage period for specimens can be used to standardize various experimental protocols [132].

Often the preparation of tooth samples requires smoothing the enamel surface through grinding [77]. This is to standardize the surface topography because the vestibular enamel surface of teeth, especially premolars, may have different contours and convexity. The different contour and convexity of the vestibular surface of teeth can lead

to uneven adaptation of the adhesive to the tooth surface and cause variation in adhesive thickness during bracket bonding.

Obviously, this procedure cannot be applied in the clinic, as its main disadvantage is that it significantly alters the substrate. The outer surface of the enamel is more abundantly saturated with fluoride, which distinguishes it from the deeper layers of enamel. Grinding tooth enamel with grinding stones and diamond disks is a subjective manipulation because the degree of roughness of the enamel surface is determined visually [136]. The change in the structure of the tooth enamel surface after this manipulation makes it difficult to compare the results of different laboratory tests.

Rueggeberg F. in his article drew attention to an interesting aspect of storing samples in alcohol, formalin and other disinfectants [109]. He found that sample storage solutions can contain pathogens (Staphylococci, Pseudomonas, Shigella, Enterobacter, Klebsiella, Proteus) that can spread as aerosol and colonize the laboratory environment [133]. The bacterial colonies obtained from the dental specimens varied considerably in species composition. This resulted in cross-contamination of the specimens when they were stored in solution. Since the extracted teeth contained pathogenic bacteria, they needed to be autoclaved to destroy them.

The use of autoclaving to prepare teeth for testing necessitated a study of the effect of sterilization on adhesive bond strength and enamel structure. Autoclaving teeth at 127°C for 20 minutes followed by storage in 1% sodium hypochlorite solution was found to have an effect on adhesive bond strength but did not alter enamel structure [140].

3 Bonding

Bracket bonding to tooth enamel includes:

 penetration of the liquid material into the etched enamel and formation of resin loops after polymerization;

- formation of firmly bound surface precipitates that serve as the substance for mechanical and chemical bonding of the adhesive [60];

– chemical binding of the adhesive to calcium ions of enamel hydroxyapatite [147].

The process of applying adhesive to the bracket base and applying force to bracket bonding to tooth enamel raises two questions for researchers: how much adhesive is needed to securely bond the bracket and how much force is required to ensure strong adhesion.

One study suggests two approaches to quantifying adhesive application. The first approach is to apply a standard amount of adhesive and the second approach is to use an arbitrary amount of adhesive. The standard amount of adhesive makes the application process more predictable. This allows the properties of the material under investigation such as the degree of conversion and leaching of the monomer to be evaluated. However, it is practically impossible to simulate this situation at a clinical appointment, so it is proposed to standardize the basic amount of adhesive.

The research proposes to overcome the shortcomings of current methods by standardizing the application of a basic amount of adhesive to the bracket base. This may be achievable by conducting trials in which the adhesive is applied by a specially trained orthodontist.

In most trials, the bracket bonding force was not controlled, which could lead to subjective assessment of adhesive bond strength. A fixed force applied during bracket bonding can result in stable adhesion, but too much force can result in thin layers of adhesive that can reduce its retention properties [73].

Simulation of the clinical environment in laboratory studies cannot fully recreate oral conditions. In particular, it is not possible to recreate the stresses caused by an activated arch in combination with occlusal loads, extreme fluctuations in pH and temperature, and the presence of oral microflora. Microbial flora can significantly alter the structure and properties of adhesive materials, arches and brackets [125].

Matasa C., who investigated debonded brackets, found that microbial colonization during orthodontic treatment can lead to poor adhesion [115].

4 Trials

The load application method and the use of a universal testing machine to perform adhesive bond strength tests were investigated by Katona T. and colleagues [103].

Finite element analysis found that the stress distribution within the adhesive layer and the resulting stresses in the brackets and enamel during testing were not uniform, contradicting the uniform stress assumption that prevailed in most experimental studies [102]. Studies have shown that the maximum stresses produced by tensile strain loading in the «enamel-adhesive-bracket» system can be up to five times greater than the average stress values obtained in studies using other loading methods (shear, torsion). This suggests that the results of studies using different loading methods are not directly comparable. Conventional adhesive bond strength studies do not take into account the maximum stresses generated by the tensile loading of the «enamel-adhesive-bracket» system, which is the reason for the significant underestimation of the probability of brackets debonding.

Analyzing the causes of bracket debonding based on the assumption of uniform stress distribution may lead to misleading conclusions about the strength of individual adhesive components. This is due to the fact that localized adhesive bond failure may be caused by higher stresses in certain areas.

Fox N. found that the experimental test configuration can affect the results of adhesive bond strength studies [83]. This is due to the fact that the applied force may produce force moments of varying magnitude depending on the distance from the point of force application to the brace base surface. This can make it difficult to extrapolate conclusions about the probability of debonding.

Thus, the results of adhesive bond strength tests in orthodontics may be influenced by the following factors:

1 The standard load plate traverse speed for shear testing is 0,5 mm/min, but this is not clinically appropriate [77]. Under clinical conditions, the adhesive bond can break at much higher loading rates. In this case, the viscoelastic properties of the adhesive, which may be important at low speeds, are practically unimportant.

2 When the brace is removed with a wire loop, the loop may deform and cause friction, which can make interpretation of the results difficult. Katona T., Chen J. suggested using a long and thin wire in order to reduce these effects [103].

3 Bracket design can lead to uneven load distribution, which can lead to failure of the «enamel-adhesive-bracket» system. The variability of bracket design with the same prescription from different manufacturers makes it difficult to compare adhesive bond strength studies [102].

Fatigue failure is another factor affecting the strength of the adhesive bond. It occurs in the «enamel-bracket» adhesive component and involves five main stages [149]:

- 1 microstructural changes that initiate the nucleation of irreversible damage;
- 2 microscopic cracks formation;
- 3 growth of defects with the formation of macroscopic cracks;
- 4 stable propagation of macrocracks;
- 5 structural instability leading to adhesive bond breakage.

The rate of crack propagation and progression of adhesive bond failure depends on a number of variables including environmental conditions, mechanical properties and structural configuration of the adhesive. Research in this area utilizes two basic approaches to the study of fatigue [149]:

1 The whole lifespan approach determines the range of cyclic stresses or strains required to propagate a crack in an initially uncracked specimen before the adhesive bond breaks.

2 The sustainable defect approach, which assumes that all engineering components inherently contain defects. In this approach, fatigue life is determined by the number of fatigue cycles or the time for a crack to propagate from its original size to a critical size.

To understand the fatigue of orthodontic adhesive systems, post-mortem analysis is necessary to provide evidence of complex interactions between system components. The lack of such evidence can be attributed to the diversity of materials, complex mechanical behavior, and microscopic nature of fatigue.

Fatigue failure of adhesive systems depends on the testing environment, the molecular structure of the polymers, the nature of cycling, loading conditions and the type of deformation (elastic, linear or nonlinear viscoelastic). Because detailed fatigue stages are difficult to detect in the laboratory, localization and characterization of defects may be limited to the site of final failure.

The clinical implications of fatigue failure of adhesives in orthodontics are unknown, and sensitive methods to investigate them are not expected to be developed in the near future.

1.8 Systematic review of studies on the ultimate shear strength of adhesive systems under experimental conditions

Experimental studies allow the use of standardized procedures to test a particular fixation system. However, the different test conditions that are used make it difficult to compare their results [72, 83, 98].

Some of the main test conditions affecting adhesive bond strength are the origin of enamel (bovine, human), substrate storage (physiologic solution or water), and pretreatment of the enamel surface (grinding, use of cleaning agents) [95, 112, 126, 154]. Therefore, the varying results of adhesive bond strength studies can be attributed to the fact that bond strength cannot be isolated. The combination of mechanical properties and test-related factors can distort the actual estimate of the adhesive bond strength value. Currently, there is no standardized protocol for determining adhesive bond strength in orthodontics, which makes it difficult to draw general conclusions. The increasing number of published experimental studies can only be evaluated individually due to the lack of standardization.

In this regard, an attempt was made by Finnema K. to draw the attention of researchers to the test conditions that can significantly affect the resulting values of ultimate adhesive bond strengths.

A total of 121 studies were selected to evaluate the conditions of adhesive bond strength tests in detail. A list of 27 (Table 2) items was selected that reflected the conditions affecting the results of adhesive bond strength tests in the experiment [81].

The 121 studies reported using an average of about 20 test conditions in experiments, with a minimum of 12 conditions [138] and a maximum of 26 conditions [61, 173]. The condition of the magnitude of force application during brace placement was the worst covered, being reported in 18 of the 121 studies. The most common experimental adhesive bond strength determination test conditions were reported in the following order: adhesive type -98%, traverse speed -97% [105], enamel cleaning method -93% [112], etchant type -92% [67], etchant time -90% [87], sample storage time -90% [164], tooth storage solution before bonding -89% [154], bracket type -78% [54], total polymerization time -69%, bracket force application -69% [105], photopolymerization lamp type -62% [122], tip design -60% [118].

Experimental condition	Number (%) of studies that reported on the experimental conditions		
Substrate origin	121 (100)		
Tooth type	121 (100)		
Storage time before bonding	38 (31)		
Storage temperature before bonding	38 (31)		
Storage solution before bonding	108 (89)		
Sample purification	113 (93)		
Brace material	121 (100)		
Brace type	94 (78)		
Type of processing, dressing	111 (92)		
Etching time	109 (90)		
Adhesive type	119 (98)		
The amount of force when a brace is placed	18 (15)		

Table 2 Experimental conditions described in 121 studies

Continuation of Table 2

Curing lamp type	75 (62)		
Photopolymerization time	84 (69)		
Light direction	65 (54)		
Sample storage time	109 (90)		
Sample storage solution	103 (85)		
Sample storage temperature	97(80)		
Thermal cycling	26 (22)		
Testing machine	119 (98)		
Shear strength test	121 (100)		
Crosshead speed	117 (97)		
Force applied to the bracket	83 (69)		
Indenter (tip) design	73 (60)		
Adhesive Remnant Index (ARI)	93 (77)		
Magnification used in determining the ARI	70 (58)		
Adhesive strength in megapascals, MPa	121 (100)		

The results of the meta-analysis showed that the experimental conditions of sample storage, photopolymerization time, and traverse speed had a significant effect on the shear bond adhesive strength values in the experiment [111].

The ability of the samples to accumulate water decreased the shear adhesive bond strength by an average of 10,7 MPa. This observation was influenced by the large sample size for which artificial saliva was used as a storage medium [61]. Distilled water was used for sample storage in the majority of experimental studies on adhesive bond strength. However, in 11% of the studies, the sample storage medium was not reported.

The second experimental condition that significantly affected the adhesive bond strength was the photopolymerization time. An increase of 0,077 MPa in adhesive bond strength was observed for each additional second of photopolymerization. The meta-analysis revealed significant variation in photopolymerization time, ranging from 2 to 50 seconds. Additionally, 31% of the studies did not report polymerization times. In the

majority of studies, adhesive polymerization was completed within 40 seconds, which aligns with the typical clinical standard.

The traverse speed of the testing machine was identified as the third experimental condition that significantly impacted adhesive bond strength. An increase in traverse speed of 1 mm per minute led to a rise in average bond strength of 1,3 MPa. Two experimental studies demonstrated the opposite effect when the traverse speed was increased from 0,5 to 5,0 mm per minute and from 1 to 200 mm per minute, respectively, resulting in a significant decrease in adhesive bond strength [53].

It was hypothesized that the impact of the test machine crosshead causes induction of the rigid body response and elimination of the viscoelastic characteristics of the adhesive. In another study, no effect on adhesive bond strength was observed when the speed of the test machine traverse was varied from 0,1 to 5 mm per minute.

The adhesive bond strength values reported in the studies in this meta-analysis ranged from 3,5 to 27,8 MPa.

There is controversy in the orthodontic literature as to what minimum adhesive bond strength is required to ensure successful orthodontic treatment. Most studies refer to the article by Reynolds I. (1975) in which he suggested a value of 6-8 MPa based on the stresses occurring during the adaptation of the archwire in the bracket slot [131].

This value has been taken as a reference and has been cited in the literature more than 150 times.

The adhesive bond strength value proposed by Reynolds I. (6-8 MPa) is outdated and does not take into account many factors that affect adhesive strength in clinical practice (stresses developed during mastication and associated loads, cyclic fatigue of adhesive materials in the oral cavity, extreme fluctuations in pH, temperature, and microbial colonization of the oral cavity).

This value is based on mechanics and materials of relevance more than 30 years ago, as well as on uncertain assumptions about loads occurring during orthodontic treatment. In addition, adhesives are subject to aging, which can lead to a decrease in bond strength. The Reynolds I. study lacks data on the comparability of loads in the clinic and experiment.

A systematic review and meta-analysis by Finnema K. provides a summary of factors that may affect adhesive bond strength in an experiment [81]. The conditions outlined in Table 2 can be considered mandatory to standardize the conditions of adhesive bond strength studies in an experiment.

CHAPTER 2. MATERIALS AND METHODS

2.1 Study design and stages of research

The study has eight phases and the design is shown in Figure 5.

The study contains of two parts. The first part of the study consisted in the experimental study of relative viscosity and shear strength of the adhesive bond in the laboratory on the basis of the Science Park of St. Petersburg State University; the Centre of Functional Materials for Medicine, for Diagnostics Pharmacology and Nanoelectronics; the Centre for Extreme States of Materials and Structures; the Centre for Microscopy and Microanalysis; the Institute of Chemistry of St. Petersburg State University. The second part of the study consisted in studying the strength of adhesive bonding in the clinic, was conducted at the educational and clinical base of the Faculty of Dentistry and Medical Technologies of the Federal State Budgetary Institution of Higher Education «St. Petersburg State University» Omegadental LLC (St. Petersburg).

For a systemic approach to the research problem at the initial stage, a lot of work with sources of information on the studied area was carried out, the problem was considered in historical development, the scientific experience of domestic and foreign scientists was analysed and presented in publications, the state of the problem of adhesive bond strength during orthodontic treatment with brackets was assessed, unsolved issues were identified and the relevance of the research topic was confirmed.

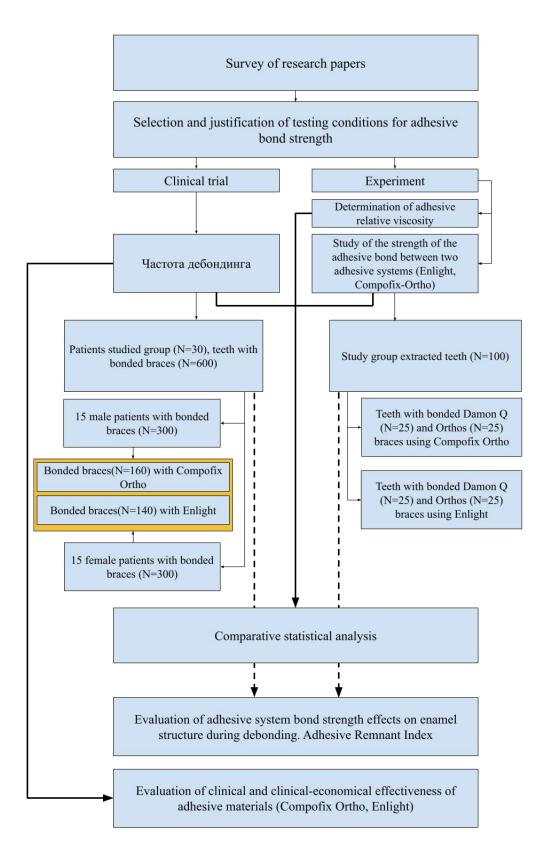


Figure 5 Research design

The second stage of the study involved the selection of experimental conditions for determining the relative viscosity of the compared adhesives and the shear strength of the adhesive bond on the basis of the world experience in conducting studies on this subject, as well as in accordance with the available protocols in dentistry. The relative viscosity of adhesives was determined in accordance with the American Dental Association recommendation for assessing the fluidity of endodontic restorative materials. The ultimate shear strength of the adhesive bond was determined taking into account the requirements of GOST R 59423 - 2021 (ISO 29022 : 2013). National Standard of the Russian Federation. Stomatology. Restorative materials. Shear test methods for determining the strength of adhesive bonds. M., 2021. The conditions outlined in the recommendations, protocols and standardization normative document were recorded. The laboratory test to determine the ultimate shear strength of the adhesive bond was guided by the 25 experimental conditions shown in Table 3.

Table 3 List of experimental conditions for laboratory tests of the ultimate shear strength
of adhesive bonding

Experimental condition	Justification
Substrate origin	Extracted intact human teeth
Type of tooth	Vestibular surface of third permanent molar
Storage time before bonding	3 months
Storage temperature before bonding	$4 \pm 4^{\circ}C$
Storage solution before bonding	Distilled water
Sample purification	After extraction, teeth are thoroughly rinsed under running water, all blood residues and adhering tissues are removed. Before bonding, the teeth are cleaned with a rubber cup using a fluoride-free preventive paste «Polident No. 2»
Orthos, Damon Q braces material	Stainless steel
Orthos, Damon Q bracket type	Ligature, self-ligating

Continuation of Table 3

Experimental condition	Justification		
Type of processing, etching	Travex-37 Gel (OmegaDent, Russia)		
Etching time	25–30 seconds		
Type of adhesive	Composite		
Type of curing lamp	LED lamp (wavelength 440-480 nm, luminous flux power 1000–1200 mW/cm ²)		
Photopolymerisation time of Enlight, Compofix-ortho adhesive	30 seconds		
Light direction	Directional polymerisation on medial, distal, occlusal, gingival sides		
Samples storage time	24 hours		
Sample storage solution	Distilled water		
Sample storage temperature	37°C		
Thermal cycling of samples	500 cycles in water at 5°C and 55°C with a time exposure at each temperature of at least 20 seconds and a transfer time from one temperature to the other of 5–10 seconds		
Testing machine	Schimadzu AG-50kNXD		
Traverse speed	0,1 mm/min		
Force applied to the bracket	Directly perpendicular, occlusal side		
Indenter (tip) design	In the form of a sickle knife		
ARI	It was determined using a Leica M205 stereomicroscope with image display on a personal computer and evaluation of the Adhesive Remnant Index on the bracket and tooth using the LAS v4.10 programme.		
Magnification used in determining the ARI	10x magnification		

Continuation of table 3

Experimental condition	Justification
Shear strength of the adhesive bond, MPa	Determined according to the formula: $\sigma a dg = \frac{F}{S},$ where F is the maximum force at which the sample fracture occurs, H; S – surface area of the fracture surface, mm ²

During the clinical study, the same orthodontist applied a standard amount of adhesive using a consistent technique in carefully selected groups of patients and observed them over a period of time.

We measured the relative viscosity in the third step by placing a portion of adhesive on a slide and covering it with three more slides. The area of composite discs made of two adhesives was evaluated using FIJI software.

The ultimate shear strength of the adhesive bond was directly investigated in the fourth step.

For the experimental study, 100 extracted third permanent molars with healthy enamel and no signs of carious or non-carious damage were thoroughly washed under running water, and all blood residues and adhering tissues were removed from their surface. Prior to bracket bonding, the teeth were cleaned using a rubber polishing cup with fluoride-free paste called «Polident No. 2» (Vladmiva, Russia). The teeth were then randomly divided into four groups, each containing 25 teeth. Group 1 utilized a direct bracket bonding technique with the light-curing orthodontic adhesive «Enlight» and the light-curing adhesive primer «Orthosolo». A traditional ligature bracket for the upper right second premolar, «Orthos», was used in this group. Group 2 used a direct bonding technique with «Enlight» light-curing orthodontic adhesive and «Orthosolo» light-curing adhesive primer, along with a «Damon Q» self-ligating bracket for the upper right second premolar. Group 3 used the direct fixation technique with «Compofix-ortho» light-curing orthodontic adhesive primer, along with a

traditional «Orthos» ligature bracket for the upper right second premolar. Group 4 utilised a direct fixation technique, using light-curing orthodontic adhesive «Compofix-ortho» in conjunction with a light-curing adhesive primer of the same name. They employed a «Damon Q» self-ligating bracket for the upper right second premolar (Table 4, 5).

Tooth group	group Number of Brace designed teeth	
1 Orthosolo, Enlight	25	Orthos
2 Orthosolo, Enlight	25	Damon Q
3 Compofix-ortho	25	Orthos
4 Compofix-ortho	25	Damon Q

Table 4 Groups of selected teeth for the pilot study

Table 5 Adhesives and primers used in the research

Material	Manufa cturer	Curing method	Mechanism of adhesion	Fluoride release	Expiry date and lot number	Average market value, RUB
Adhesive Enlight	Ormco, Orange, Calif	light curing, 30 seconds	mechanical	No	09.06.2025 № 9101122	6500
Primer Orthosolo		no light curing required		No	09.06.2025 № 9101122	8660
Compofix -ortho Adhesive	Vladmiva Belgorod, Russia	Ũ	mechanical	Yes	01.09.2024 № 9633	1540
Compofix -ortho primer	Vladmiva Belgorod, Russia	-	_	Yes	01.09.2024 № 9633	1320

After bracket bonding, extracted teeth were mounted in blocks made of EpoxiCure 2 (Buehler), a viscous and slow-curing polymer (Figure 6, Figure 7).



Figure 6 The slow curing dental mounting polymer used in the trial

The tooth to be mounted in the block was placed in 23°C water as early as possible to allow the plastic to cure under water. Under this condition, absorption of the polymer by the tooth tissue and overheating of the tooth by the heat of polymerisation can be avoided.



Figure 7 Extracted teeth placed in plastic blocks and prepared for testing

Prior to direct testing, the teeth were immersed in distilled water and incubated at 37°C for 24 hours, then thermocycled. After removing the specimens from the water,

moisture was removed using filter paper. The specimens were levelled using grips and metal frame and fixed in the clamps of Shimadzu testing machine for ultimate shear adhesive bond strength tests (Figure 8, Figure 9).



Figure 8 Shimadzu testing machine



Figure 9 Extracted tooth with bonded bracket placed in an acrylic block mounted in the clamps of the testing machine

The experiment was conducted at a temperature of 24°C and a relative humidity of 30%.

In the fifth stage of the study, 30 adolescent patients aged between 14 and 18 years, who required orthodontic treatment, participated [4]. The patients were divided equally by gender, with 15 female and 15 male patients in each group. All patients had their «Damon Q» brackets (Ormco, USA) bonded using «Compofix-ortho» (Vladmiva, Russia) and «Enlight» (Ormco, USA) orthodontic adhesives (Figure 10, Figure 11).



Figure 10 Primer and adhesive «Compofix-ortho» (Vladmiva, Belgorod) used in the

research



Figure 11 «Orthosolo» primer (Ormco, USA) and «Enlight» adhesive (Ormco, CA) used in the study

In Group A, seven female patients included in the study had their braces bonded with «Enlight» light-curing orthodontic adhesive together with «Orthosolo» light-curing adhesive primer using the direct bonding technique. In Group B, seven male patients included in the study had their braces bonded with «Enlight» light-cured orthodontic adhesive in conjunction with «Orthosolo» light-cured adhesive primer using the direct bonding technique. In Group B, eight female patients included in the study had their braces bonded with «Compofix-ortho» light-curing orthodontic adhesive, together with «Compofix-ortho» light-curing adhesive primer, using the direct bonding technique. In Group D, eight male patients included in the study had their braces bonded with «Compofix-ortho» light-curing orthodontic adhesive, together with «Compofix-ortho» light-curing adhesive primer, using the direct bonding technique (Table 6).

Study group of patients	Number of patients	Number of teeth	Primer and adhesive used	Brace design
Group A	7	140	Orthosolo, Enlight	
Group B	7	140	Orthosolo, Enlight	Domon ()
Group C	8	160	Compofix-ortho	Damon Q
Group D	8	160	Compofix-ortho	

Table 6 Group of patients who participated in the clinical trial

Eight female and eight male patients had their «Damon Q» braces bonded with «Compofix-ortho» adhesive (Vladmiva, Russia), seven female and seven male patients had their «Damon Q» braces bonded with «Enlight» adhesive (Ormco, USA). Before starting the clinical trial, the conditions of the study were explained to the participating patients, after which they provided voluntary informed consents for the processing of personal data (Appendix B) and voluntary consents for orthodontic treatment (Appendix C). Patients were selected for participation in the study according to the following criteria: adolescents aged 14 to 18 years who needed orthodontic treatment with the 1st and 2nd degree of complexity of orthodontic treatment, informed consent of the patient. The orthodontic treatment complexity degree was determined according to the method of assessing the degree of severity of dentofacial anomalies (DFA) by L.S. Persin [22]. Patients with inflammatory periodontal diseases; severe somatic pathologies; hereditary and acquired malformations of hard tissues of teeth; anomalies of tooth shape; restorations on the vestibular surface of teeth; occlusal interference; clinical cases of orthodontic correction, in which extraction of individual teeth is required to normalise occlusal contacts; 3rd and 4th degree of complexity of orthodontic treatment, if the patient refused to participate in the study, were not included in the study process To fulfil the objectives of the study, patients were monitored for the first 26 weeks of orthodontic treatment. Upper and lower jaw braces were placed in one visit. All patients were informed about the rules of eating behaviour during orthodontic treatment with brackets, and instructions were given on the peculiarities of individual oral hygiene. The frequency

of check-ups for activation of the «Damon Q» brackets was every seven weeks, and patients had unscheduled appointments when the brackets came off. The anamnesis, data on unfastened brackets were described in the patient's orthodontic outpatient record (Appendix D).

The obtained data on the adhesive bond strength of the materials «Compofix-ortho» (Vladmiva, Russia), «Enlight» (Ormco, USA) in clinical and experimental studies were subjected to statistical analysis using application programmes at the sixth stage of work.

After removal of brackets, each tooth and bracket (in the experimental study), each bracket (in the clinical study) were viewed using an optical stereomicroscope with an external light source to study the structure of enamel at debonding (in the experimental study), determination of the index of residual adhesive (in the experimental and clinical studies) at the seventh stage of work.

At the eighth stage of work the clinical and cost-effective effectiveness of the use of adhesives «Compofix-ortho», «Enlight» for bracket bonding was evaluated.

2.2 Research methods

Direct bracket bonding method of «Orthos», «Damon Q» brackets using «Enlight» adhesive (Ormco, USA) under experimental conditions

Before bracket bonding, the extracted teeth were cleaned with a rubber polishing cup with fluoride-free paste «Polydent No. 2» (Vladmiva, Russia). Then rinsed and dried with air-water tip for 5–10 seconds. For etching, 37% phosphoric acid gel «Travex-37» (OmegaDent, Russia) was applied for 20 seconds, then washed thoroughly for 20 seconds. The teeth were dried with an air/water handpiece for 20 seconds and inspected to see if the enamel was characteristically matte. A thin layer of «Orthosolo» primer (Ormco, USA) was applied to each tooth using an applicator and slightly dried. Then «Enlight» adhesive was applied to the surface of the «Orthos», «Damon Q» bracket base, after which the bracket with the applied adhesive was positioned on the tooth in the centre of the crown. After alignment of the bracket, excess adhesive was removed with a

scaler and the «Orthos», «Damon Q» bracket was photopolymerised on the mesial and distal surfaces.

Direct bracket bonding method of «Orthos», «Damon Q» brackets using «Compofix-ortho» adhesive (Vladmiva, Russia) under experimental conditions

Before bracket bonding, the extracted teeth were cleaned with a rubber polishing cup with fluoride-free paste «Polydent No. 2» (Vladmiva, Russia). Then rinsed and dried with air-water tip for 5–10 seconds. For etching, 37% phosphoric acid gel «Travex-37» (OmegaDent, Russia) was applied for 20 seconds, then washed thoroughly for 20 seconds. The teeth were dried with an air/water handpiece for 20 seconds and inspected to see if the enamel was characteristically matte. A thin layer of primer «Compofix-ortho» (Vladmiva, Russia) was applied to each tooth using an applicator and slightly dried. Then «Compofix-ortho» adhesive was applied to the surface of the «Orthos», «Damon Q» bracket base, after which the bracket with the applied adhesive was positioned on the tooth in the centre of the crown. After alignment of the bracket, excess adhesive was removed with a scaler, the «Orthos», «Damon Q» bracket was photopolymerised on the mesial and distal surfaces of the bracket.

Preparation of test specimens. Method for recreating the oral cavity environment

Thermocycling included 500 cycles in 5°C and 55°C water with a exposure time at each temperature of at least 20 seconds and a transfer time from one temperature vessel to the other of 5–10 seconds (Figure 12) [88].



Figure 12 LOIP LF-60/350-VS2 laboratory drying oven used in the thermal cycling test

Method for determining the relative viscosity of composites

Two syringes of adhesives were selected for the measurements of relative viscosity characteristics: «Enlight» (Ormco, USA), lot number 9101122, and «Compofix-ortho» (Vladmiva, Russia), lot number 9633. Measurements were carried out 15 times for each group of materials. The relative viscosity was determined in accordance with the American Dental Association recommendation for assessing the fluidity of endodontic restorative materials [78].

The weight of the «Enlight» syringe on a scale (PIONEER OHAUS with an accuracy of 0,1 mg) 12,342 g and «Compofix-ortho» 13,382 g was measured before applying the adhesive to the slide (Figure 13).

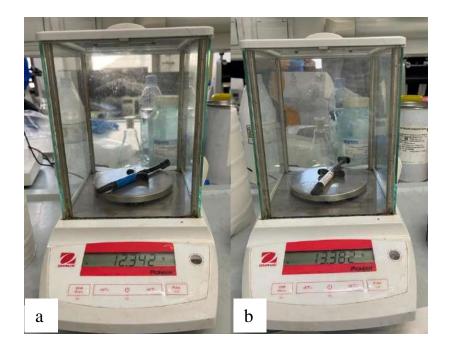


Figure 13 Weighing of the initial weight of adhesive syringes before testing:a -«Enlight» adhesive, b - «Compofix-ortho» adhesive

The adhesive was then applied to a «MiniMed» microdissection slide (26x76x1 mm) and then immediately covered with three slides to form a disc of unpolymerised adhesive (mass of each slide about 5 g). After 30 seconds, the adhesive was illuminated with a polymerisation lamp («GMG» LED WL-070 Dentmate) for 20 seconds. After application of the adhesive, the syringe was reweighed. The portion of adhesive applied to the slide was controlled in this sequence. The experiment was performed under the following climatic conditions - temperature was 24°C and relative humidity was 30%. In order to avoid inaccuracy in the results of the study, all tests were performed by one researcher.

After photopolymerisation of the adhesive, photofixation of the discs on a sheet with 8 bit markers was performed. A reference ruler was placed next to the slide. Spherical aberrations were removed in Photoshop CC 2018 software, also the perspective corrections of the photo were corrected relative to the markers (Figure 14).

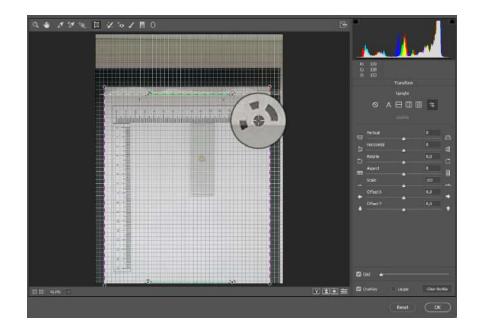


Figure 14 Correcting perspective and removing spherical aberrations in Photoshop CC 2018 using 8-bit markers

An algorithm based on FIJI software has been developed to ensure productive operation [171]. The purpose of the algorithm was to automate and simplify the process of linear measurements of adhesive disc dimensions. The following actions were included in the macro: opening a file of photographs, calibrating each photograph by the selected line length of 10 mm, cropping the area of interest of the photograph, creating a mask, calculating the area and saving the data.

To measure the area of the adhesive disc, a photograph of the composite disc image was loaded into the software, a line was drawn on a reference ruler, the length of which was used to calibrate the image. An area of interest that included the adhesive disc was then selected and cropped around its perimeter. The outline of the adhesive disc was created manually. The area of the disc was measured three times and the average value was used.

The results of measurements of the photographed adhesive discs «Compofixortho» and «Enlight» were automatically recorded into one xlsx file and processed in Excel computer program in order to determine statistical indicators (arithmetic mean, standard deviation, dispersion, minimum and maximum values). To confirm the statistical hypothesis about the homogeneity of adhesives «Compofix-ortho» and «Enlight» by their relative viscosity, the two-sample t-criterion was used to test the null hypothesis (H0) about the equality of the mean values of the general populations of «Compofix-ortho» and «Enlight» on the basis of sample values of the area of the discs of the two adhesives photographed in the experiment.

Sample analysis with a Leica M205 C stereomicroscope

Samples after debonding were examined using a Leica M205 C stereomicroscope. Image display on a personal computer and evaluation of the Adhesive Remnant Index on the bracket and extracted tooth were performed using the LAS v4.10 software. The Leica M205 C stereomicroscope allows easy implementation of repeatability of the experiment parameters when taking and analysing images, obtaining photographs with a large depth of focus (Figure 15).



Figure 15 Leica M205 C Stereomicroscope

The Adhesive Remnant Index (ARI) was used to assess the adhesive residue on all samples (tooth enamel and bracket base after debonding) involved in the experiment. To determine the Adhesive Remnant Index, brackets that underwent debonding for an unknown reason were counted during the clinical trial. Debonding of brackets for an unknown reason could be related to the strength properties of the adhesive used [135, 167, 172].

Assessment of adhesive residues on tooth enamel and bracket base after debonding was performed according to the Artun and Bergland index score (Table 7).

Index score	Value	Image
0	No adhesive left on the tooth, all the adhesive remained on the base of the bracket	
1	Less than half of the adhesive remained on the tooth, more than half of the adhesive remained on the base of the bracket	
2	More than half of the adhesive remained on the tooth, less than half of the adhesive remained on the base of the bracket	
3	All the adhesive remained on the tooth with the relief of the mesh base of the bracket, no adhesive remained on the base of the bracket	

Table 7 Adhesive Remnant Index (Artun, Bergland, 1984)

Methodology for assessing the severity of dento-mandibular-facial anomalies

The method of assessing the degree of severity of dentofacial anomalies (DFA) was developed by the faculty of the Department of Orthodontics of the Moscow State

Medical and Dental University named after A.I. Evdokimov, Ministry of Health of Russia.

Persin L.C. in 1997 proposed a point estimate of 4 degrees of complexity of orthodontic treatment depending on the point estimate of the degree of severity of signs of dento-mandibular-facial anomalies. The classification of DFA signs is based on the criterion of considering occlusion disorders in 3 directions (sagittal, vertical and transversal) with their further differentiation according to the following features: dependence on the size of the gap between the teeth; anomaly of teeth interlocking and participation of the upper or lower dentition in the formation of occlusion.

Depending on the size of the gap between the teeth, four groups of anomalies are distinguished: the first group – anomalies of one tooth row; the second group – the size of the gap between the teeth up to 3 mm (Figure 16); the third group – the size of the gap between the teeth 3,0–6,0 mm; the fourth group – the size of the gap between the teeth more than 6 mm (Figure 17). In each of these groups, the anomalies of tooth closure in three directions (right, front, left) are analysed and the involvement of the teeth of the upper and lower rows is taken into account.

The degree of severity of each feature of the DFA with the depth of consideration «direction of occlusal disturbance – size of the gap between the teeth – anomalies of tooth alignment – involvement of the upper or lower dentition» is evaluated as 1 point. The severity degree of the DFA for each patient is determined by summing up the scores for all the signs inherent to each patient individually, in the context of the groups characterising the size of the gap between the teeth, and can be evaluated to a maximum of 18 points.

Depending on the evaluation of the severity of the DFA and the anomaly group characterising the gap between the teeth, the degree of complexity of orthodontic treatment is determined from the first to the fourth.

Using the subcategories of the degree of difficulty, it is possible to further develop, for example, criteria for assessing the cost of orthodontic treatment (Table 8) [21].



Figure 16 Patient M., included in the study, second degree of DFA severity, second degree of complexity of orthodontic treatment

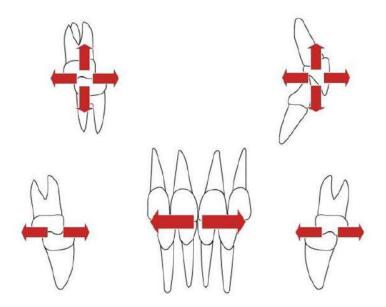


Figure 17 Scheme for determining the severity of the FMA

	A single			Up to 3 mm	3 mm					3–6 mm	mm		2			Over 6 mm	mm		
Direction	tooth	right	t	front	It	left		right	ht	front	nt	left	L	right	ht	front	nt	left	ſť
	row	B	H	B	H	B	H	B	H	в	H	B	H	в	H	B	Ŧ	B	H
Sagittal	1	-	-								-	-			-			-	-
Vertical	1		-								-				-	-			-
Transversal	1		-		-										-			-	-
Score		-	-	-															
Category of complexity	1			2						3						4			
Subcategory	Ι	1		2		3		-		2		З		-		2	•	3	
(points)	(1–3)	(1–6)		(7–11)	(1	(12–18)	18)	(1–6)	(9	(7–1	(7–11)	(12–18)	18)	(1–6)	(9)	(7–	(7–11)	(12–18)	-18)
* - colur	* - columns in the "Scores" line are used for filling in when estimating the degree of the patient's DFA severity	Scores	' line	are u	sed fo	or filli	ing in	when	estin	nating	the d	legree	of the	e patie	nt's D	FA se	sverity		

Table 8 Determining the degree of orthodontic treatment complexity

Hygienic status of patients participating in a clinical trial. Simplified OHI-S (J. C. Greene, J. R. Vermillion, 1964)

The hygiene status of patients is assessed using the simplified oral hygiene index (OHI-S), which consists of two components, the plaque index (DI) and the calculus index (CI), and is calculated as the sum of their average values based on the number of teeth examined [106]. In order to determine the hygienic status of the patients, the surfaces of six teeth (four molars and two central teeth) were examined as part of the clinical study: buccal surfaces of upper first molars, lingual surfaces of lower first molars, vestibular surfaces of upper and lower incisors using a probe that was moved from the incisal/occlusal margin to the gingival margin (Figure 18).

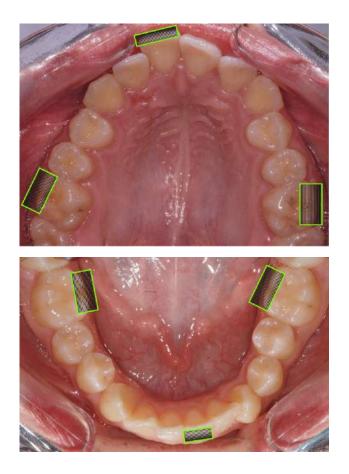


Figure 18 Teeth surfaces indexes for the OHI-S scoring

Determination of the debris index (DI)

The plaque detection technique is shown in Figure 19.

Figure 19 Determination of the debris index (DI)

Criteria for assessing the plaque index:

0 – no plaque;

1 -soft plaque covering not more than one third of the examined tooth surface;

2 -soft plaque covering more than one third but not more than two thirds of the tooth surface;

3 -soft plaque covering more than two thirds of the tooth surface.

Determination of the calculus index (CI)

Determination method of the calculus index is shown in Figure 20.

Criteria for assessing the calculus index:

0 – no calculus.

1 – supra-gingival calculus covering not more than one third of the examined tooth surface.

2 - supra-gingival tartar covering more than one third but not more than two thirds of the tooth surface and/or the presence of individual conglomerates of subgingival tartar around the vestibular part of the tooth.

3 – supra-gingival calculus covering more than two-thirds of the tooth surface or a continuous thick band of subgingival calculus around the cusp of the tooth.

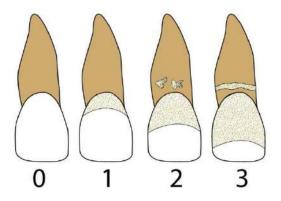


Figure 20 Methodology for determining the calculus index (CI)

The hygiene status of a patient according to the simplified oral hygiene index (OHI-S) is determined on the basis of the following correspondence between the calculated OHI-S index and the qualitative assessment given to it [23]:

up to 0,6 - good oral hygiene;

0,7 to 1,6 – satisfactory oral hygiene;

1,7 to 2,5 – unsatisfactory oral hygiene;

2,6 and above – poor oral hygiene.

Use of the colourant «Color-test No. 1» (Vladmiva, Russia) for detection of inflammatory periodontal diseases

Characteristics of the gingiva according to the degree of inflammation after staining the gingiva with «Color-test $N_{2}1$ »: a) straw-yellow colour – no inflammation of periodontal tissues; b) light brown colour – weakly expressed inflammation of periodontal tissues; c) dark brown colour - expressed inflammation of periodontal tissues (Figure 21) [35].

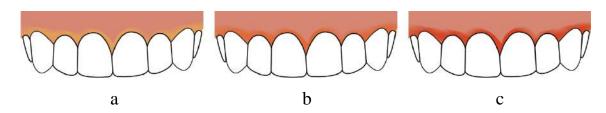


Figure 21 Characterisation of gingival staining with colouring agent

In all patients included in the study, the gingiva stained straw yellow, confirming the absence of inflammation in the periodontal tissues (Figure 22).



Figure 22 Absence of inflammation in the periodontal tissues of patient C., included in the study

Direct method of bracket bonding with «Compofix-ortho» adhesive

Before direct bracket bonding on the enamel of the teeth, the enamel surface of the teeth was cleaned using «Polident No. 2» paste without fluoride (Vladmiva, Russia). Using a retractor with saliva ejector "Nola Dry Field System" and dry tips, the tooth surface was isolated from saliva. Travex-37 etching gel (OmegaDent, Russia) was applied with a syringe to the part of the vestibular surface of the tooth enamel where the bracket was planned to be placed. After 30 seconds, the etching gel was removed with a hoover and thoroughly washed off with an air-water flow for 5–7 seconds per tooth, the vestibular surface of the tooth enamel white in colour. Next, the enamel was coated with «Compofix-ortho» primer and slightly dried. The primer-treated tooth enamel surface had a characteristic glossy lustre [44].

Adhesive paste was applied to the base of the bracket, the bracket was positioned on the tooth, adjusted, then pressed firmly against the tooth, excess adhesive paste was removed with a scaler. Directional polymerisation of the adhesive was carried out with a dental lamp for 20 seconds. Immediately after bracket placement, weak archwires were used.

Direct bracket bonding method with «Enlight» adhesive

Before direct bracket bonding on teeth enamel, the surface of teeth enamel was cleaned with «Polident № 2» paste without fluoride (Vladmiva, Russia). Using a retractor with saliva ejector "Nola Dry Field System" and dry tips, the tooth surface was isolated from saliva. Travex-37 etching gel (OmegaDent, Russia) was applied with a syringe to the part of the vestibular surface of the tooth enamel where the bracket was planned to be placed. After 30 seconds, the etching gel was removed with a hoover and thoroughly washed off with an air-water flow for 5–7 seconds per tooth, the vestibular surface of the tooth enamel were chalky white in colour. Then the enamel was coated with «Orthosolo» primer and slightly dried The tooth enamel surface treated with primer had a characteristic glossy lustre [44].

Adhesive paste was applied to the base of the bracket, the bracket was positioned on the tooth, adjusted, then pressed firmly against the tooth, excess adhesive paste was removed with a scaler. Directional polymerisation of the adhesive was carried out with a dental lamp for 20 seconds. Immediately after bracket placement, weak archwires were used.

Methodology for determining the frequency of bracket debonding

Outpatient orthodontic records recorded the number of brackets that debonded for an unspecified reason during the first 26 weeks of orthodontic treatment. In order to determine the relationship between adhesive strength properties and debonding rate, data on bracket debonding for an unknown reason were included in the field of interest of the study.

The frequency of bracket debonding due to unknown cause was defined as the ratio of the number of brackets adhered for unknown reason to the total number of bonded brackets, expressed as a percentage [37].

Methodology for calculating the clinical effectiveness of bracket bonding with orthodontic adhesives

To assess the clinical effectiveness of orthodontic adhesive for bracket bonding (CEB), the ratio of the number of teeth with no bracket debonding during the first 26 weeks of follow-up (unless the cause of debonding is the patient's failure to comply with the orthodontist's recommendations, such as eating hard food) to the total number of teeth with bonded brackets, expressed as a percentage, is taken as follows [47].

The clinical effectiveness of orthodontic bracket bonding adhesive (CEB) can be calculated as the difference between the total number of teeth with bonded brackets, expressed as 100%, and the incidence of debonding for an unknown reason.

Methodology for calculating the clinical and economic efficiency of bracket bonding with orthodontic adhesives

The clinical and economic effectiveness of bracket bonding with «Compofixortho», «Enlight» adhesive was determined using the Cost-Effectiveness Ratio (CER), and Incremental Cost-Effectiveness Ratio (ICER) [46, 94].

The CER criterion is based on the cost of adhesive for a unit of teeth with bonded braces that have not been debonded for an unknown reason. The CER criterion, rubles, was calculated using the formula (1):

$$CER = A / CEB, \tag{1}$$

where A is the cost of adhesive material for bracket bonding at the start of treatment, rubles;

CEB – clinical efficacy of bracket bonding using adhesive, expressed in units of teeth with bonded brackets that were not debonded for unknown reasons.

The cost of adhesive material used for bracket bonding at the start of treatment, A, rubles, was calculated as the product of the cost of adhesive material for bracket bonding of one bracket C1B, rubles, and the number of bonded brackets at the start of treatment.

The average cost of an adhesive material package used for bracket bonding was calculated according to the price lists of companies selling this material. The required amount of adhesive for bracket bonding was determined by experiment. The procedure consisted of weighing a syringe of adhesive paste before and after bracket bonding on the extracted tooth and calculating the weight difference of the tube. Weighing was performed on a PIONEER OHAUS precision scale with an accuracy of 0,1 mg. The procedure was carried out three times, thus determining the average amount of adhesive required for bonding per bracket.

The cost of adhesive material for bonding of one bracket C1B, rubles, was calculated according to the following formula (2):

$$C1B = (C / K) \times B, \qquad (2)$$

where C is the average cost of the package, rubles;

K – amount of adhesive material in the package, g;

B – weight of adhesive material for bracket bonding, set in the experiment, g.

ICER is a measure of incremental cost per unit of clinical effectiveness. The ICER criterion shows what additional costs per unit of clinical efficacy should be incurred in favour of an adhesive with greater clinical efficacy [6]. The ICER criterion, rubles, was calculated by formula (3):

ICER =
$$(A2 - A1) / (CEB2 - CEB1),$$
 (3)

where (A2 - A1) – difference in the cost of two compared adhesives for bracket bonding, rubles;

(CEB2 - CEB1) – difference in the clinical effectiveness of bracket bonding using the compared adhesives, expressed in units of teeth with bonded brackets that were not debonded for an unknown reason.

Statistical research methods

The experimental data obtained in the study were subjected to statistical analysis with calculation of descriptive statistics (mean value, standard deviation, coefficient of variation, range of variation, minimum and maximum values). Statistical significance of differences in adhesive bond strength between groups was assessed using ANOVA and Tukey's test. For each ARI value in all compared groups of teeth, the frequency of its detection was analysed and the proportion of teeth with an established ARI value was calculated. Using the chi-square test, the statistical significance of the differences between the proportions in the compared groups of teeth was tested. The determination of the statistical significance of the results was based on standard significance levels of 0,05 and 0,01. A comparison of debonding occurrence frequencies for unknown cause was made using Sign test for paired data. For the statistical hypothesis verification of adhesives "Compofix-Orto" and "Enlight" homogeneity by their relative viscosity, the Kolmogorov-Smirnov and Shapiro-Wilk criteria, Livigne's criterion, and Student's two-sample t-test were used. Statistical calculations and analysis were performed using a special application program Excel and SPSS version 26.

CHAPTER 3. RESEARCH RESULTS

3.1 Determination of relative viscosity

In order to test the statistical hypothesis of homogeneity "Compofix-Orto" and "Enlight" adhesives by their relative viscosity, a two-sample t-test was used with testing the null hypothesis (H₀) of equality of mean values of «Compofix-Orto» and «Enlight» sets based on samples of disc surface area values of the two adhesives that had been photographed during the experiment (Table 9).

Descriptive statistics of the samples (arithmetic mean, standard deviation, variance, minimum and maximum values) were determined. Both adhesives composite discs surface area had almost the same value: the arithmetic mean value of the surface area of the adhesive disc for the «Compofix-ortho» sample was 39,330 mm², for the «Enlight» sample it was 39,399 mm².

The choice of t-criterion is conditioned by the results of testing the distribution of sample values for conformity to normal distribution using Kolmogorov-Smirnov criterion (p with Liljefors correction is 0,165) and Shapiro-Wilk (p = 0,172), that is, the sample data can be considered as a sample from a normally distributed population at the significance level of 0,05. The hypothesis of variance equality was tested using Livigne's criterion (F = 2,591, p = 0,119), at the significance level of 0,05 the hypothesis of variance equality cannot be rejected.

According to the t-criterion calculation results, the hypothesis about the average area equality of the photographed composite discs in two samples cannot be rejected at the significance level of 0,05 (t = 1,652, p = 0,109), i.e. the hypothesis H₀ about adhesives «Compofix-Orto» and «Enlight» homogeneity by their relative viscosity cannot be rejected at the significance level of 0,05.

N⁰ sample	Compofix-ortho, mean value, mm ²	Enlight, mean value, mm ²
1	39,421	39,593
2	39,309	39,250
3	39,259	39,217
4	39,272	39,485
5	39,313	39,553
6	39,359	39,278
7	39,420	39,395
8	39,455	39,431
9	39,441	39,510
10	39,258	39,356
11	39,247	39,179
12	39,486	39,324
13	39,253	39,534
14	39,259	39,523
15	39,196	39,354
Mean - arithmetic mean of the sample	39,330	39,399
SD - standard deviation	0,092	0,132
S2- sampling dispersion	0,009	0,017
Minimum sampling value	39,196	39,179
Maximum sampling value	39,486	39,593

Table 9 Area of composite disc for relative viscosity determination

3.2 The ultimate shear strength of the adhesive bond in an experiment research

3.2.1 Results of analysing the shear bond strength of the adhesive bond by groups

The obtained experimental data were subjected to statistical analysis with calculation of descriptive statistics (mean value, standard deviation, coefficient of variation, range of variation, minimum and maximum values). Using analysis of variance (ANOVA) and Tukey's test, the statistical significance of differences in ultimate adhesive shear bond strength between groups was assessed. For each ARI value in all the compared tooth groups, the frequencies of its detection were analysed and the proportion of teeth with an established ARI value was calculated. Using the chi-square test, the statistical significance of the differences between the proportions in the compared groups of teeth was tested. The judgement of the statistical significance of the results was based on standard significance levels of 0,05 and 0,01. Statistical calculations were performed using the special application programme SPSS version 26.

Table 10 shows the calculated values of descriptive statistics of the ultimate shear strength of the adhesive bond by tooth group. In group 1, the mean value is 22,8 MPa ($\pm 6,6$), with values ranging from 14,4 to 30,5 MPa, in group 2 – 21,5 MPa ($\pm 0,6$), ranging from 20,9 to 22,4 MPa, in group 3 – 11,98 MPa ($\pm 4,5$), ranging from 8,9 to 18,3 MPa, and in group 4 – 12,2 MPa ($\pm 0,95$), ranging from 11,2 to 13,4 MPa. The lowest coefficient of variation was observed in group 2 and was less than 3,0%, while the highest was observed in group 3 (37,6%). In all groups the coefficient of variation does not exceed 50,0 per cent, therefore no additional tests are required.

Table 10 Descriptive statistics of shear bond strength of adhesive bond by groups, MPa

Group of	Number of	Mean	Standard	Variation	Variation	Variation Minimum Maximum	Maximum	p*
teeth	teeth, n	value	deviation	coefficient, %	range			
1 Enlight,	25	22,79	6,58	28,85	16,07	14,41	30,48	p ₁₋₂ =0,676
Orhos								p ₁₋₃ <0,001
								p ₁₋₄ <0,001
2 Enlight,	25	21,51	0,63	2,93	1,49	20,89	22,38	p ₂₋₁ =0,676
Damon Q								p ₂₋₃ <0,001
								p ₂₋₄ <0,001
3 Compofix-	25	11,98	4,50	37,60	10,39	7,89	18,29	p ₃₋₁ <0,001
ortho,								p ₃₋₂ <0,001
Orhos								p ₃₋₄ =0,998
4 Compofix-	25	12,17	0,95	7,77	2,26	11,19	13,45	p4-1<0,001
ortho,								p4-2<0,001
Damon Q								$p_{4-3}=0.998$

According to the results of the analysis of variance (Table 10), the average shear strength of the adhesive bond in group 1 and group 2 differed statistically insignificantly (p > 0,05). The average ultimate shear strength of the adhesive bond in groups 3 and 4 is also insignificantly different (p > 0,05). At the same time, group 1 and group 2 differ statistically significantly (p < 0,001) from group 3 and group 4 in terms of the average ultimate shear strength of the adhesive bond. Thus, it can be concluded that group 3 and group 4 have statistically significantly lower average ultimate shear strength of adhesive bond than groups 1 and 2.

Figures 23– 26 show the Weibull distribution curves characterizing the shear strength of the adhesive bond in each group.

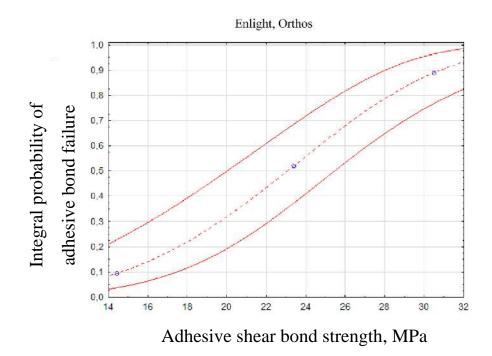


Figure 23 Weibull distribution curve characterising the shear bond strength of the adhesive in group 1

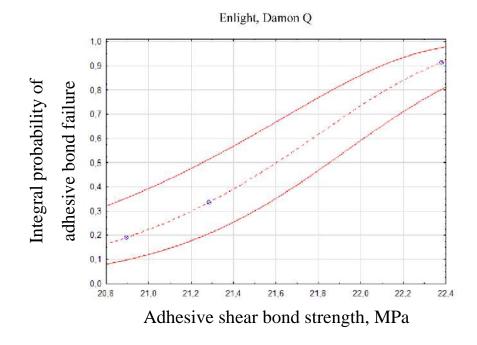


Figure 24 Weibull distribution curve characterising the shear bond strength of the adhesive in group 2

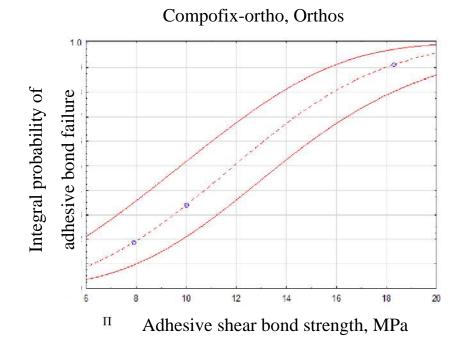
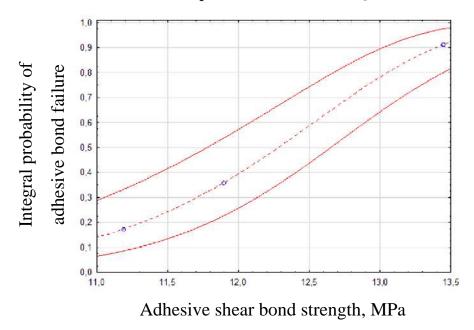


Figure 25 Weibull distribution curve characterising the shear bond strength of the adhesive in group 3

91



Compofix-ortho, Damon Q

Figure 26 Weibull distribution curve characterising the shear bond strength of the adhesive in group 4

3.2.2 Distribution of adhesive remnant index values by tooth groups

Table 11 shows the distribution of ARI values for the groups of teeth treated with the compared adhesives. As can be seen, in all groups the ARI value for the majority of tooth samples (88,0 to 96,0%) is equal to 3.

Using the chi-square test, the hypothesis that the proportions of tooth samples in the groups are evenly distributed according to the index values was rejected (p < 0,05). Consequently, it can be stated that the high proportions of the compared tooth samples with a Adhesive Remnant Index value of 3 are statistically significant.

It can be concluded that all groups have a high ARI value, with the ultimate shear bond strength of the adhesive being statistically significantly higher in groups 1 and 2 compared to groups 3 and 4.

Group of teeth		A	RI		Criterion χ ²
	0	1	2	3	
Enlight, Orthos	0	0	2	23	$\chi^2 = 14,63 \ (p = 0,03)$
	(0%)	(0%)	(8,0%)	(92,0%)	
Enlight, Damon Q	1	0	2	22	
	(4,0%)	(0%)	(8,0%)	(88,0%)	
Compofix-ortho,	0	1	2	22	
Orthos	(0%)	(4,0%)	(8,0%)	(88,0%)	
Compofix-ortho,	0	0	1	24	
Damon Q	(0%)	(0%)	(4,0%)	(96,0%)	

Table 11 Distribution of ARI values by tooth groups

Figure 27 shows a microscope photo image of a tooth with a residual adhesive remaining index score of 3. The tooth shows the remaining adhesive with imprints of the mesh base of the Optimesh bracket.

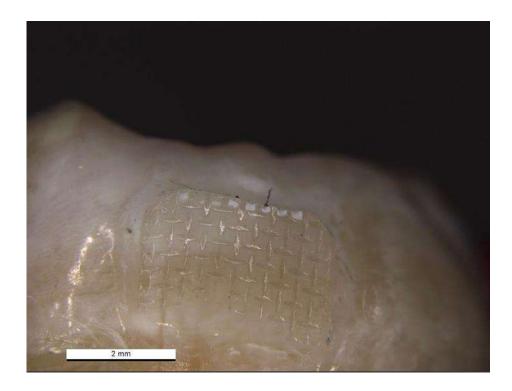


Figure 27 Microphotograph of the extracted tooth with residual adhesive remaining index score of 3

3.2.3 Determination of clinical and economic efficiency of bracket bonding with the studied orthodontic adhesives

A syringe of «Compofix-ortho» adhesive before and after bracket bonding on the extracted tooth was weighed three times and the difference of the weights was determined. This difference of measurements is equal to the weight of adhesive required for bracket bonding of one bracket. The results of the first measurement were 0,007 g, the second measurement was 0,006 g, and the third measurement was 0,006 g. The average mass of «Compofix-ortho» adhesive required for bracket bonding was 0,0063 g based on three measurements. A syringe of «Enlight» adhesive was weighed according to the same scheme described above. The results of the first measurement were 0,007 g, the second measurement was 0,007 g, the third measurement was 0,006 g. The average weight of «Enlight» adhesive required for bracket bonding based on three measurement was 0,007 g, the third measurement was 0,006 g. The average weight of «Enlight» adhesive required for bracket bonding based on three measurement was 0,007 g, the third measurement was 0,006 g. The average weight of «Enlight» adhesive required for bracket bonding based on three measurements was 0,0066 g. The results of determining the weight of adhesive required for bracket bonding are presented in Table 12.

Adhesive	M	easurement nur	nber	Mean value
	1	2	3	
Compofix-ortho	0,007	0,006	0,006	0,0063
Enlight	0,007	0,007	0,006	0,0066

Table 12 Weight of adhesive required for single bracket bonding, grams

One syringe of «Compofix-ortho» adhesive weighs 4 grams. It was determined that one syringe should be sufficient for bracket bonding to 634,9 eeth, i.e. for bracket bonding to 31,7 atients, assuming that bracket bonding is performed on 20 teeth for each patient.

One syringe of «Enlight» adhesive weighs 4 grams. It was determined that one syringe should be sufficient for bracket bonding to 606 teeth, i.e. for bracket bonding to 30,3 patients, based on the assumption that bracket bonding will be performed on 20 teeth for each patient.

One syringe of adhesive «Compofix-ortho» costs 1540 rubles. It was determined that the cost of this adhesive for bracket bonding to one tooth is 2,42 rubles, for bracket bonding to 20 teeth -48,51 rubles.

One syringe of «Enlight» adhesive costs 6500 rubles. It was determined that the cost of this adhesive for bracket bonding to one tooth is 10,72 rubles, for bracket bonding for 20 teeth – 214,52 rubles.

Thus, the cost of bracket bonding using «Enlight» adhesive is 4,43 times higher than the cost of bracket bonding compared to «Compofix-ortho» adhesive.

In order to determine the clinical and economic efficiency of using «Compofixortho» and «Enlight» adhesives for bracket bonding, as well as for statistical analysis, we recalculated the cost of «Compofix-ortho» and «Enlight» adhesives per bracket bonding to 1000 teeth. The cost of «Compofix-ortho» adhesive for 1000 teeth was 2420 rubles, the cost of «Enlight» adhesive was 10720 rubles. The clinical and economic efficiency of «Compofix-ortho» and «Enlight» adhesive according to the CER criterion for bracket bonding was determined, which was 2,47 and 10,95 rubles, respectively (Table 13).

Table 13 Evaluation of clinical and economic effectiveness of adhesive for bracket bonding according to the CER criterion

Adhesive	Cost of adhesive system (C) per 1000 teeth, rubles.	Clinical efficacy of adhesive for bracket bonding (CEB), teeth	Clinical and economic efficiency (CER), rub.
Compofix-ortho	2420	978,12	2,47
Enlight	10720	978,57	10,95

The increment in clinical effectiveness of the adhesive «Enlight» compared to the adhesive «Compofix-ortho» was 0,45 bonded brackets per tooth. According to the ICER criterion, in order to increase the clinical and economic efficiency of using adhesive for bracket bonding per tooth, an additional cost of 18444,44 rubles would be required (Table 14).

Adhesive	Cost of	Clinical	Increase	Increase in	ICER,
	adhesive	efficacy of	in value	clinical	rubles
	system (C)	adhesive for	rubles	efficiency, teeth	
	per	bracket			
	1000 teeth,	bonding (CEB),			
	rubles	teeth			
Compofix-	2420	978,12	_	_	_
ortho	2420	970,12			
Enlight	10720	978,57	8300	0,45	18444,44

Table 14 ICER values for the studied adhesives

3.3 Clinical trial of adhesive bond strength

3.3.1 Determining the frequency of braces debonding

Of the 320 brackets bonded (on 160 teeth in male patients and 160 teeth in female patients) with «Compofix-ortho» adhesive, debonding was recorded on 12 teeth (seven teeth in male patients and five teeth in female patients), of which debonding for unknown reason was bonded on seven teeth (four teeth in male patients and three teeth in female patients). In the first 26 weeks of orthodontic treatment, the rate of bracket debonding for known and unknown reasons bonded with «Compofix-ortho» adhesive was 3,750% (4,375% in male patients and 3,125% in female patients). In the first 26 weeks of orthodontic treatment, the first 26 weeks of orthodontic treatment, the first 26 weeks of orthodontic treatment, the first 26 weeks of unknown reason bonded with «Compofix-ortho» adhesive was 3,750% (4,375% in male patients and 3,125% in female patients). In the first 26 weeks of unknown reason bonded with «Compofix-ortho» adhesive was 2,188% (male patients – 2,500%, female patients – 1,875%) (Table 15, Table 16), (Figure 28). The frequency of debonding for unknown cause was statistically significantly dependent on the period of examination ($\chi 2 = 9,26$, df = 2, p = 0,01). With increasing treatment time, the frequency of debonding for unknown cause increased and decreased for hard food.

Table 15 Results of brace debonding cases bonded with «Compofix-ortho» for male patients

Patient №	unschedu	ncy of exam led visits, ind ber where th occurred		Debonding reason
	Up to 7 weeks	7 to 14 weeks	14 to 26 weeks included	
1	_	_	—	_
2	35	_	-	unknown
3	-	_	-	_
4	-	_	23	unknown
5	_	11,12	-	hard food
6	-	hard food		
7	-	unknown		
8	-	_	15	unknown
Number of teeth with debonded braces			7	
Number of teeth with debonded braces for unknown reasons			4	
Debonding frequency for unknown reason, %			2,500%	
Total number of teeth			160	

Table 16 Results of bracket debonding cases bonded with «Compofix-ortho» for female patients

Patient №	unschedu	ncy of exami led visits, ind oer where th occurred		Debonding reason	
	Up to 7 weeks	7 to 14 weeks	14 to 26 weeks included		
1	—	_	-	_	
2	21; 22			hard food	
3	_	_	_	_	
4	_	_	25	unknown	
5	_	_	_	_	
6	14 unknow				
7	– – 33 unknov				
8	_	_	_	_	
Number of teeth with debonded braces			5		
Number of teeth with debonded braces for unknown reasons			3		
Debonding frequency for unknown reason, %			1,875%		
Total number of teeth			160		

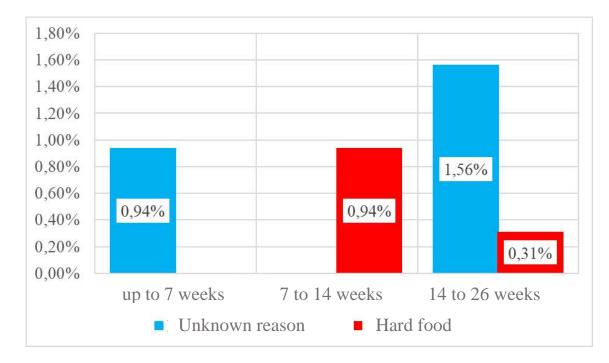


Figure 28 Frequency of debonding with «Compofix-ortho» adhesive on 320 teeth over a follow-up period of 26 weeks

Of the 280 brackets bonded (on 140 teeth in male patients and 140 teeth in female patients) with «Enlight» adhesive, debonding was recorded on eight teeth (four teeth in male patients and four teeth in female patients), of which debonding for unknown reason was bonded on six teeth (three teeth in male patients and three teeth in female patients). During the first 26 weeks of orthodontic treatment, the rate of bracket debonding for known and unknown reasons bonded with «Enlight» adhesive was 2,857% (2,857% in male patients and 2,857% in female patients). In the first 26 weeks of orthodontic treatment, the incidence of bracket debonding for unknown reason bonded with «Enlight» adhesive was 2,143% (male patients – 2,143%, female patients – 2,143%) (Table 17, Table 18), (Figure 29). The increase in the incidence of debonding for unknown cause with increasing treatment duration increased statistically insignificant ($\chi 2 = 0,89$, df = 1, p = 0,346).

Patient №	unschedu	ncy of exami led visits, ind ber where th occurred		Debonding reason	
	Up to 7 weeks	7 to 14 weeks	14 to 26 weeks included		
1	_	_	33	unknown	
2	—	_	_	_	
3	22			unknown	
4	_	_	14	unknown	
5	45 hard f				
6	_	_			
7	_	_	-	_	
Number of teeth with debonded braces			4		
Number of teeth with debonded braces for unknown reasons			3		
Debonding frequency for unknown reason, %			2,143%		
Total number of teeth			140		

Table 17 Results of bracket debonding cases bonded with Enlight for male patients

Patient №	unschedu	ncy of exami led visits, ind ber where th occurred		Debonding reason	
	Up to 7 weeks	7 to 14 weeks	14 to 26 weeks included		
1	12	_	_	hard food	
2	-	_	-	_	
3	_	_	-	_	
4	_	_	23	unknown	
5					
6	– – 25 unkno				
7	_	_	33	unknown	
Number of teeth with debonded braces			4		
Number of teeth with debonded braces for unknown reasons			3		
Debonding frequency for unknown reason, %			2,143%		
Total number of teeth			140		

Table 18 Results of brace debonding cases bonded with Enlight for female patients

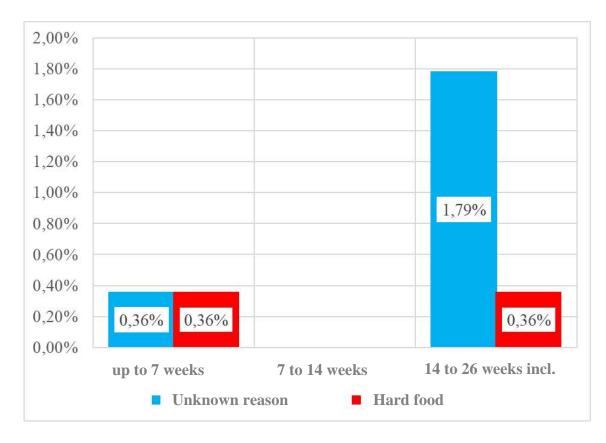


Figure 29 Frequency of debonding when using «Enlight» adhesive on 280 teeth over a follow-up period of 26 weeks

Figure 30 shows the frequency of debonding for the two orthodontic adhesives over a 26-week follow-up period in a comparative aspect.

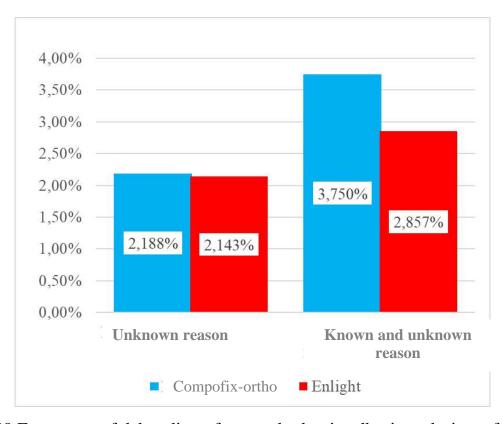


Figure 30 Frequency of debonding of two orthodontic adhesions during a follow-up period of 26 weeks

The frequency of debonding for an unknown reason was independent of the gender of the study patients when «Enlight» adhesive was used ($\chi^2 = 0,00$, df = 1, p > 0,99). The incidence of debonding for unknown reason when using «Compofix-ortho» adhesive in male patients was higher than in female patients by 0,625%, which could indicate a more careful and informed attitude of the female gender towards orthodontic treatment in this group of patients. However, this difference is statistically insignificant ($\chi^2 = 0,146$, df = 1, p = 0,702).

Debonding due to unknown reason in the group of patients with bonded braces using «Compofix-ortho» adhesive was higher for premolars (57,143%) than for canines (42,857%). The difference was statistically significant ($\chi^2 = 8,7$, df = 2, p = 0,013) (Table 19). Debonding due to unknown reason in the group of patients with bonded braces using «Enlight» adhesive was higher for canines (50,0%) than for premolars (33,333%) and incisors (16,667%). However, these differences are statistically insignificant ($\chi^2 = 1,78$, df = 2, p = 0,411) (Table 20). Table 19 During the 26-week follow-up period, a group of patients with bonded braces using «Compofix-ortho» adhesive experienced debonding of teeth in a tooth grouping. The cause of this debonding is unknown

Tooth grouping		of teeth with debonded for unknown reasons	Debonding for an unknown reason, %		
Premolars	7	4	57,143		
Canines	,	3	42,857		

Table 20 During the 26-week follow-up period, a group of patients with bonded braces using «Enlight» adhesive experienced debonding of teeth in a tooth grouping. The cause of this debonding is unknown

Tooth grouping		of teeth with debonded for unknown reasons	Debonding for an unknown reason		
Premolars		2	33,333		
Canines	6	3	50,000		
Incisors		1	16,667		

Most cases of debonding for unknown reason in both groups were recorded between week 14 and week 26 inclusive: the value of cases of debonding for unknown reason was 85,714% for «Compofix-ortho» adhesive and 83,333% for «Enlight» adhesive. Presumably, this may be the result of biodegradation of composite material occurring inside the oral cavity, occurrence of excessive stresses inside the adhesive due to the transition to stiffer arches at the stages of orthodontic treatment. Statistical analysis confirmed that there were no significant differences in the incidence of debonding due to unknown cause between both adhesives ($\chi^2 = 0,01$, df = 1, p = 0,97) (Table 21).

Adhesive name	Number of teeth with debonded brackets for unknown reason during follow-up of 26 weeks	Number of teeth with debonded brackets for unknown reason between week 14 and week 26 inclusive	Debonding for unknown reason, %	
Compofix-ortho	7	6	85,714	
Enlight	6	5	83,333	

Table 21 Debonding for an unknown reason between the 14th and 26th week inclusive

3.3.2 Evaluation of the adhesive remnant index of debonded braces

Of the 320 brackets bonded with «Compofix-ortho» adhesive, debonding for an unknown reason was recorded on seven teeth (four teeth in male patients and three teeth in female patients). In male patients across all debonded brackets, the Adhesive Remnant Index for «Compofix-ortho» (ARIC) was 1. In female patients, on the one bracket that was debonded, the ARIC was 0, on the remaining two brackets that were debonded, the ARIC was 1. The distribution of ARIC in the groups of patients combined by gender was statistically significant ($\chi^2 = 5$, df = 1, p = 0,015) (Table 22).

Table 22 Distribution of ARIC values by patient groups

Patient	Number of teeth withARIC				р	
group	debonded brackets for unknown reason	0	1	2	3	
Male patients	4	-	4	_	_	0,015
Female patients	3	1	2	_	_	

Of the 280 brackets fixed with «Enlight» adhesive, debonding for unknown reasons was recorded on six teeth (three teeth in male patients and three teeth in female patients).

In male patients, on one bracket that underwent debonding, the Index of Adhesive Remnant Index for «Enlight» (ARIE) was 0. On the remaining two brackets that underwent debonding, the ARIE was 1. In female patients, on all debonded brackets, the ARIE was 1. The distribution of ARIE in the groups of patients combined by gender was statistically significant ($\chi^2 = 3,3$, df = 1, p = 0,04) (Table 23).

Table 23 Distribution of ARIE values	by patient groups
--------------------------------------	-------------------

Patient	Number of teeth with	ARIE				р
group	debonded brackets for unknown reason	0	1	2	3	
Male	3	1	2	_	_	0,04
patients						
Female	3	_	3	_	_	
patients						

The adhesive remnant index values in the clinic for most brackets (83,333% for «Enlight», 85,714% for «Compofix-ortho») were 1 ($\chi 2 = 3,34$, df = <1, p = 0,006). More than half of the adhesive remained on the base of the brackets after debonding occurred (Figure 31).

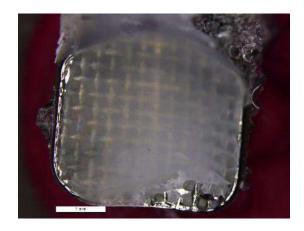


Figure 31 Microphotography of a bracket with a Adhesive Remnant Index score of 1

3.3.3 Determination of clinical effectiveness of orthodontic adhesive application

The frequency of bracket debonding for unknown reason bonded with «Compofix -ortho» adhesive was 2,188% (2,500% in male patients and 1,875% in female patients) during the first 26 weeks of orthodontic treatment. In 97,812% of teeth in male and female patients, there was no bracket debonding for unknown reason (97,500% of teeth in male patients and 98,125% of teeth in female patients had no bracket debonding for unknown reason during the first 26 weeks of orthodontic treatment). Consequently, the clinical efficacy of «Compofix-ortho» orthodontic adhesive during the first 26 weeks of orthodontic treatment, and 98,125% in male and female patients, and 98,125% in female patients.

The frequency of bracket debonding for unknown reason bonded with «Enlight» adhesive was 2,143% (2,143% in male patients and 2,143% in female patients groups) during the first 26 weeks of orthodontic treatment. In 97,857% of teeth in male and female patients groups, there was no bracket debonding due to unknown cause (in 97,857% of teeth for male patients and 97,857% of teeth for female patients, there was no brackets debonding due to unknown cause during the first 26 weeks of orthodontic treatment). Consequently, the clinical efficacy of «Enlight» orthodontic adhesive during the first 26 weeks of orthodontic treatment was 97,857% in male and female patients groups, 97,857% in male, and 97,857% in female patients groups.

SUMMARY

The process of bracket placement with the use of adhesives is the key process in the treatment of fixed orthodontic appliances. In 2023, there was a reduction in the range of foreign adhesives used on the market of the Russian Federation, along with an increase in their cost. In connection with the above circumstances, the development and use of alternative Russian analogues is an important element to ensure proper, high-quality, timely and affordable orthodontic care. Development, research of new Russian adhesives, approbation with their further application in clinical practice are necessary and relevant in the current conditions, contribute to the improvement of the quality of medical care of orthodontist.

On the basis of the study of literature sources, world experience of colleaguesresearchers the choice was made and the conditions of the protocol for determination of relative viscosity and ultimate shear strength of the adhesive bond of the new Russian adhesive «Compofix-ortho» and foreign adhesive «Enlight» in the experiment were justified.

Determination of relative viscosity was carried out in accordance with the recommendation of the American Dental Association to assess the fluidity of endodontic filling materials at a temperature of 24°C and relative humidity of 30% by one researcher. First, a portion of adhesive was placed on a slide and covered with three slides. After that, the area of composite discs of the two adhesives were evaluated using FIJI software. Both adhesives had almost the same average surface area of the composite disk: 39,330 mm² for «Compofix-ortho» and 39,399 mm² for «Enlight». The statistical analysis results of the mean composite disc area values was not rejected at the significance level of 0,05 the similarity of both adhesives, which provided the following desired characteristics of «Compofix-ortho» and «Enlight» orthodontic adhesives: low viscosity, no stickiness, easy penetration of the adhesives into the mesh base of the bracket, ensuring good marginal adhesion, reducing the risk of bacterial invasion, preventing postoperative enamel sensitivity, caries formation and its complications.

The determination of the shear bond strength of the adhesive bond was carried out in accordance with the conditions defined in GOST P 59423 - 2021 (ISO 29022 : 2013). Special attention was paid to the following laboratory test conditions: origin of the substrate; type of tooth; storage time before bonding; storage temperature before bonding; storage solution before bonding; cleaning of the specimens; material of manufacture of the brackets involved in the tests; type of brackets involved in the tests; type of enamel preparation before bonding; time of enamel etching; type of adhesives involved in the test; type of curing lamp used for photopolymerisation of the adhesive; time of photopolymerisation of the adhesive; direction of light during photopolymerisation; storage time of the specimens prior to testing; specimen storage solution prior to testing; specimen storage temperature prior to testing; thermocycling of specimens; type of testing machine used for testing; speed of the testing machine beam during testing; direction of shear load applied to the bracket; tip design of the testing machine; methodology for determining the Adhesive Remnant Index; the microscope magnification used in determining the ARI; methodology for analyzing data and presenting results of shear bond strength measurements; and methodology for measuring the adhesive strength of the bracket. Experimenta l groups were formed for the laboratory tests: in group 1 for direct bracket bonding «Orthos» the adhesive «Enlight» together with light-curing primer «Orthosolo» was used, in group 2 for direct bracket bonding «Damon Q» the adhesive «Enlight» together with light-curing primer «Orthosolo» was used, in group 3 for direct bracket bonding «Orthos» was used adhesive «Compofix-ortho» together with light-curing primer «Compofix-ortho», in group 4 or direct bracket bonding «Damon Q» was used adhesive «Compofix-ortho» together with light-curing primer «Compofix-ortho». The obtained values of shear bond strength of the adhesive bond were subjected to descriptive statistical analysis. In group 1, the mean value is 22,8 MPa ($\pm 6,6$), with values ranging from 14,4 to 30,5 MPa, in group 2, the mean value is 21,5 MPa ($\pm 0,6$), ranging from 20,9 to 22,4 MPa, in group 3, the mean value is 11,98 MPa (±4,5), ranging from 8,9 to 18,3 MPa, and in group 4, the mean value is 12,2 MPa (±0,95), ranging from 11,2 to 13,4 MPa. According to analysis of variance, the shear bond strength of the adhesive in groups 1 and 2 differ statistically insignificantly

on average (p > 0,05). The average shear bond strength of the adhesive in groups 3 and 4 also differed insignificantly (p > 0,05). At the same time, group 1 and group 2 differ in the mean shear bond strength of adhesive from group 3 and group 4 statistically significantly (p < 0,001). In groups 3 and 4, the mean adhesive shear bond strength is statistically significantly lower than in group 1 and group 2. The design of the self-ligating «Damon Q» and ligature «Orthos» bracket used did not statistically significantly affect the shear bond strength of the adhesive.

After experimental debonding, the tooth enamel surface and the base of the brackets were examined using an optical microscope in the laboratory, where the Adhesive Remnant Index was determined according to the method of Artun, Bergland (1984). The different ultimate shear bond strength of the adhesive had no effect on the enamel structure during debonding (occurrence of cracks and damage to the enamel structure). The values of the Adhesive Remnant Index in the experiment for most samples (88,0 to 96,0%) were equal to 3 ($\chi 2 = 14,63$, p = 0,03). This meant that all the adhesive remained on the tooth with the relief of the mesh base of the bracket.

To evaluate the shear bond strength of «Compofix-ortho» and «Enlight» adhesive, debonding rates were analysed in patients aged 14 to 18 years requiring orthodontic treatment with grade 1 and 2 orthodontic treatment complexity who signed patient informed consent. Patients with inflammatory periodontal diseases; severe somatic pathologies; hereditary and acquired malformations of dental hard tissues; tooth shape anomalies; restorations on the vestibular surface of teeth; occlusal interference; clinical cases of orthodontic correction that require extraction of individual teeth to normalise occlusal contacts; 3rd and 4th degree of complexity of orthodontic treatment, if the patient refused to participate in the study were not included in the study process. The patients included in the experiment were observed for the first 26 weeks of orthodontic treatment. Braces on the upper and lower jaw were bonded in a single visit. All patients were informed about the rules of eating behaviour during orthodontic treatment with brackets, and instructions were given on the peculiarities of individual oral hygiene. The frequency of check-ups for activation of the «Damon Q» brackets was every seven weeks. The frequency of debonding for known and unknown reasons was defined as the ratio of the

number of brackets that came off for known and unknown reasons to the total number of bonded brackets, expressed as a percentage. In the first 26 weeks of orthodontic treatment, the rate of debonding of brackets for known and unknown reasons bonded with «Compofix-ortho» adhesive was 3,750% (4,75% in male patients and 3,125% in female patients). In the first 26 weeks of orthodontic treatment, the incidence of bracket debonding for unknown cause bonded with «Compofix-ortho» adhesive was 2,188% (male patients -2,500%, female patients -1,875%). The frequency of debonding for known and unknown cause bonded with «Enlight» adhesive was 2,857% (male patients -2,857%, female patients -2,857%). The frequency of debonding due to unknown cause bonded with «Enlight» adhesive was 2,143% (male patients -2,143%, female patients -2,143%). To establish the relationship between the strength properties of the adhesive and the incidence of debonding, the field of interest of the study included data on debonding of brackets for an unknown reason. The results of the clinical study during the first 26 weeks of orthodontic treatment showed an almost identical incidence of debonding for unknown cause in the groups of patients with bonded braces using «Compofix-ortho» (2,188%) and «Enlight» (2,143%) adhesives. This can be explained by the similar chemical composite composition, rheological properties of both adhesives as well as their performance characteristics.

Adhesive Remnant Index values in the clinic were determined by examining the surface of the base of a bracket that had adhered for an unknown reason under an optical microscope according to the method of Artun, Bergland (1984). It was equal to 1 for the majority of brackets that had come off for an unknown reason ($\chi 2 = 3,34$, df = 1, p = 0,006). This meant that more than half of the adhesive remained on the base of the bracket.

The differences between experimental and clinical parameters of ARI are explained by the impossibility of full transfer of the conditions occurring in the oral cavity to the laboratory. Possible ingress of subgingival fluid on the enamel surface during bracket bonding, insufficient visibility of the working field and photopolymerisation of the adhesive, activation of the bracket bonding system when switching to more rigid arches, application of detailing bends that create loads in different planes on torsion, tension, and shear, distinguishes the conditions of the clinic from the experiment.

Clinical efficacy of orthodontic adhesive for bracket bonding was defined as the difference between the total number of teeth with bonded brackets, expressed as 100%, and the incidence of debonding for an unknown reason. The clinical efficacy of the orthodontic adhesive «Compofix-ortho» during the first 26 weeks of orthodontic treatment was 97,812% and that of «Enlight» adhesive was 97,857%. The clinical efficacy of adhesives «Compofix-ortho» and «Enlight» is almost comparable and differed by 0,045%.

The clinical and economic effectiveness of the compared adhesives «Compofixortho» and «Enlight» was evaluated using the CER and ICER criteria. Using highprecision laboratory scales, the average adhesive weight in grams required for bracket bonding was determined. For bracket bonding, 0,0063 g of «Compofix-ortho» adhesive and 0,0066 g of «Enlight» adhesive are required. The cost of adhesive for bracket bonding was calculated in rubles and was 2,420 rubles for «Compofix-ortho» adhesive and 10,720 rubles for «Enlight» adhesive.

The calculated value of clinical and economic efficiency according to the CER criterion as the ratio «cost-effectiveness» for the adhesive «Compofix-ortho» was 4,43 times higher.

Higher clinical and economical efficiency of the adhesive «Compofix-ortho» in relation to «Enlight» was confirmed by the ICER indicator. The calculations showed that the use of «Enlight» adhesive will require additional 18444,44 rubles to increase the clinical efficiency per one unit of a bonded tooth.

The results of the study substantiate the economic feasibility of using Russian adhesive «Compofix-ortho» (Vladmiva, Russia) for bracket bonding in the daily practice of an orthodontist.

Russian adhesive «Compofix-ortho» is recommended for wide application in the practice of orthodontist for bracket bonding of both self-ligating and ligature brackets, metal and ceramic brackets and can become a full quality substitute for its foreign analogue «Enlight» adhesive.

CONCLUSIONS

1 Chemical-curing, light-curing, hybrid, heat-curing, fluoride-containing and fluoride-free adhesives are used for bracket bonding. Each group of adhesives has unique chemical and physical-mechanical properties, advantages and disadvantages of use in different clinical situations and methods of bracket bonding. Light-cured adhesives are the most widely used group of adhesives in direct and indirect method of bracket bonding. The strength of light-curing adhesives is delayed polymerisation and high strength. The presence of fluoride in their composition helps to reduce the risk of enamel demineralisation around the brackets during long-term orthodontic treatment.

2 The shear bond strength of the adhesive in group 1, where «Enlight» adhesive with «Orthos» light-curing primer was used for direct «Orthos» bracket bonding, is 1,28 MPa higher than in group 2, where «Enlight» adhesive with «Orthosolo» light-curing primer was used for direct «Damon Q» bracket bonding, the average difference is statistically insignificant (p > 0,05). The average shear bond strength of the adhesive is also insignificantly different (by 0,19 MPa) in group 3, where the adhesive «Compofix-ortho» together with the light-curing primer «Compofix-ortho» was used for direct bracket bonding of the «Orthos» bracket, and group 4, where «Compofix-ortho» adhesive together with light-curing primer «Compofix-ortho» was used for direct bracket bonding of whete (p > 0,05). The bracket design used had virtually no effect on the shear bond strength of the adhesive. In groups 3 and 4, the mean value of the shear bond strength of the adhesive was 1,8–1,9 times lower than in groups 1 and 2, which was statistically significant (p < 0,001).

Adhesive Remnant Index (ARI) values in the experiment for most samples (from 88,0% for «Enlight» to 96,0% for «Compofix-ortho») are 3 ($\chi 2 = 14,63$, p = 0,03), in the clinic (from 83,333% for «Enlight» to 85,714% for «Compofix-ortho») are 1 ($\chi 2 = 3,34$, df = 1, p = 0,006).

The differences between experimental and clinical ARI values are explained by the impossibility of fully transferring the conditions occurring in the oral cavity to the laboratory. Possible ingress of subgingival fluid on the enamel surface during bracket bonding, insufficient visibility of the working field and photopolymerisation of the adhesive, activation of the bracket bonding system when switching to stiffer arches, application of detailing bends that create loads in different planes on torsion, tension, shear, distinguish the conditions of the clinic from the experiment.

3 Russian adhesive «Compofix-Orto» and foreign adhesive «Enlight» are lightcuring universal orthodontic adhesives used for bracket bonding of both metal and ceramic brackets. Both adhesives have low viscosity. The shear bond strength of the «Compofix-Orto» is lower than «Enlight» adhesive by 1,8–1,9 times. «Compofix-ortho» adhesive is fluorine-containing, «Enlight» adhesive does not contain fluorine. The incidence of debonding for an unknown reason during the first 26 weeks of orthodontic treatment with «Compofix-ortho» (2,188%) and «Enlight» (2,143%) adhesives was almost identical ($\chi 2 = 0,01$, df = 1, p = 0,97). The frequency of debonding was higher for premolars than for canines and incisors. Most debonding in both groups occurred at the end of the period between 14 and 26 weeks of orthodontic treatment.

4 When relative viscosity was determined, both adhesives had almost the same consistency and viscosity. The hypothesis that «Compofix-ortho» and «Enlight» adhesives are homogeneous in terms of their relative viscosity cannot be rejected at a significance level of 0,05. The low viscosity of «Compofix-ortho» and «Enlight» determined the convenience and speed of work for the orthodontist: no stickiness, easy penetration of the adhesive into the mesh base of the bracket, thus ensuring a good marginal fit.

5 The clinical efficacy values of the two adhesives compared differ slightly: «Compofix-ortho» is lower by 0,045% or, when expressed in units of teeth with bonded brackets, 0,45 fewer teeth can be bonded with «Compofix-ortho» than with «Enlight». At the same time, the cost-effectiveness ratio (CER) of the compared adhesives is 4,43 times more favourable for «Compofix-ortho». The higher clinical and economic efficiency of the adhesive «Compofix-orto» in relation to «Enlight» is confirmed by the ICER (Incremental Cost-Effectiveness Ratio) indicator: to increase the clinical efficiency per one unit of a bonded tooth using the adhesive «Enlight» will require additional 18444,44 rubles.

6 Based on the studied chemical, physical and mechanical properties, the results of tests to determine the shear bond strength of the adhesive and relative viscosity in the experiment, clinical studies, starting with the formation of groups of patients participating in clinical studies, and the subsequent implementation of bracket bonding to patients with the help of adhesives «Compofix-orto» and «Enlight», 26-week dynamic observation of groups of patients with installed braces, determining the frequency of debonding, as well as evaluation and analysis of clinical and cost-efficiency of the use of the investigated adhesives of Russian and imported production, clinical recommendations were developed and implemented in the work of the Department of Stomatology of the Federal State Budgetary Educational Institution of Higher Education «Saint-Petersburg State University» and the dental clinic «OMEGADENTAL» Ltd.

CLINICAL GUIDELINES

Russian adhesive «Compofix-ortho» is recommended for wide application in the practice of an orthodontist for bracket bonding of both self-ligating and ligature brackets, metal and ceramic brackets. Can become a full-fledged substitute for its foreign analogue adhesive «Enlight». Having the shear bond strength of adhesive bond in the safe range, this adhesive can be used both on teeth with healthy enamel and with atypical enamel. It may be recommended to reduce the risk of lesions of enamel demineralisation around the bracket during prolonged orthodontic treatment in children with partial brackets and adolescents with morphologically immature enamel. Low viscosity and the absence of flotation of the bracket during positioning is the advantage of this adhesive and leads to recommendations for its use in the area of second molars, partially erupted teeth, dystopian teeth, where it is especially necessary to perfectly adapt the bracket to the surface of the tooth enamel, often in conditions of insufficient visibility of the working field.

Bracket bonding with composite adhesive «Compofix-ortho» is sensitive to the execution technique, as with any light-curing composite adhesive. To avoid manipulative errors and failures, the manufacturer's instructions as well as the following clinical recommendations should be followed. A thorough isolation of the working field is mandatory, which can be done with a retractor, dry tips. When preparing the enamel surface for bracket bonding, use the technique of total enamel etching, guided by the postulate that it is better to etch a larger enamel area than a slightly smaller one. The importance of this recommendation is due to the fact that placing even part of the bracket on unetched enamel creates an unprotected retention point under the bracket, which can lead to caries. During positioning of the bracket, it should be kept in mind that pressing the bracket against the enamel surface can only be done after the bracket location has been finalised. If there is no certainty that removal of excess adhesive may disturb the rest of the bracket, it is necessary to postpone this procedure until after photopolymerisation.

When removing the brackets bonded with the «Compofix-ortho» adhesive, the orthodontist should take into account that most of the adhesive will remain on the surface of the enamel and will require consistent removal of adhesive residuals with the help of rotary diamond-coated instruments, finishing polishing discs and cones.

Loyal pricing policy of the Russian company-manufacturer of adhesive «Compofix-ortho» can be used to reduce the cost of bonding brackets in dental offices and will make orthodontic care more affordable for patients.

LIST OF ABBREVIATIONS

- GOST Government Standard
- DFA dentofacial anomalies
- ARI Adhesive remnant index
- ARIC Adhesive remnant index for «Compofix-ortho»
- ARIE Adhesive remnant index for «Enlight»
- CEB clinical effectiveness of bracket
- SEM scanning electron microscope
- Bis-GMA bisphenol A-glycidyl methacrylate
- CER Cost-Effectiveness Ratio
- CI Calculus Index
- DI Debris Index
- ICER Incremental Cost-Effectiveness Ratio
- ISO International Organization for Standartization
- OHI-S Oral Hygiene Index Simplified
- pH quantitative measure of the acidity or basicity of liquid solutions
- TEGDMA Triethylene Glycol Dimethacrylate

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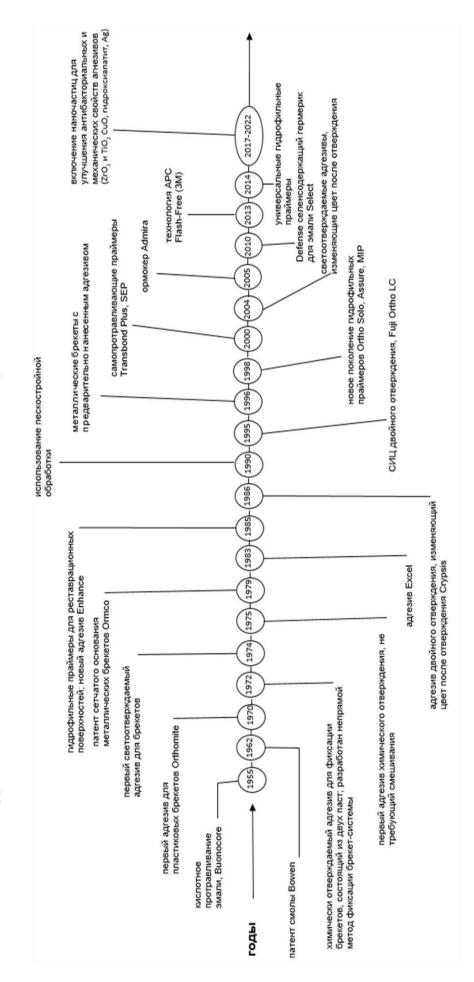
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APPENDICES

Appendix A (informative) Evolution of adhesive techniques in orthodontics



Appendix B (informative)

Form of informed voluntary consent to the processing of personal data

Дополнительное соглашение к договору № ____ от « ___ » ____ 20 ___ г.

Генеральному директору ООО «Омегадентал» Петровой Н.П.

СОГЛАСИЕ НА ОБРАБОТКУ ПЕРСОНАЛЬНЫХ ДАННЫХ

паспортные данные: серия ______, № _____, выдан ______

зарегистрированный по адресу ____

Я.

даю согласие ООО «Омегадентал» на обработку моих персональных данных (ПД) в соответствии со статьей 18.1 и 19 Ф3 от 27.07.2006 №152-Ф3 «О персональных данных» на следующих условиях: цель обработки – повышение качества обслуживания пациента и информирование пациента об акциях клиники.

 Перечень персональных данных, которые могут обрабатываться компанией: любая информация, включая дату и место рождения, биографические сведения, сведения о месте регистрации, контактная информация, паспортные данные.

Срок действия согласия – бессрочно.

 Компания вправе осуществлять любые действия по обработке моих ПД, в том числе: сбор, систематизация, накопление, хранение, блокирование, уничтожение, передачу третьим лицам.

4. Согласие может быть отозвано мной в любое время на основании моего письменного заявления, направленного по

указанному в настоящем согласии адресу Компании на генерального директора. Заявление должно содержать паспортные данные, сведения о дате выдачи указанного документа и выдавшем его органе.

5. Способ обработки автоматизированный/неавтоматизированный.

Уведомление о прекращении обработки ПД и уничтожении ПД предоставляется по запросу субъекта ПД.

Генеральный директор _____ Петрова Н.П.

ФИО пациента

Appendix C (informative)

Informed voluntary consent form for orthodontic treatment

Информированное добровольное согласие на проведение ортодонтического лечения

кдоговору №_

Настоящее добровольное согласие составлено в соответствии со статьями 30, 31, 32, 33 Основ законодательства Российской Федерации об охране здоровья граждан от 22 июля 1993 года №5487-1 и Приказом Министерства здравоохранения от 03.08.1999 №303

(Фамилия, Имя, Отчество – полностью)

м,____

законный представитель

(Фамилия, Имя, Отчество – полностью)

находясь на лечении в стоматологической клинике по моему добровольному желанию прошу провести мне все необходимые диагностические исследования и мероприятия, лечебные манипуляции и процедуры, а при необходимости, анестезиологическое пособие и операции, связаные с ортодонтическим лечением. Я осведомлен(а) о возможных осложнениях во время анестезии и приеме анальгетиков и антибиотиков, аллергических реакциях и проинформировал(а) лечащего врача-ортодонта _______обо всех случаях аллергии к препаратам в прошлом и об аллергии в настоящее время. Я несу полную ответственность за сведения, предоставленные в анкете пациента и понимаю, что непредоставление (умалчивание, искажение) данных о состоянии моего здоровья может отрицательно сказаться во время ортодонтического лечения и вызвать обострения. 1.Перед началом ортодонтического лечения я получил(а) от моего лечащего врача-ортодонта всю интересующую меня информацию о предстоящем лечении. Лечащий

врач внимательно осмотрел полость рта, разъяснил, на основании данных диагностики, преимущества и сложности выбранного метода лечения.

2. Я согласен(на), доверяю и предоставляю право лечащему врачу _____провести ортодонтическое лечение аномалии прикуса. В исключительных случаях (например, болезнь, увольнение врача) клиника производит замену врача, предварительно уведомив меня об этом. Я понимаю, что перед началом курса ортодонтического лечения необходимо произвести санацию полости рта и профессиональную гигиену полости рта в соответствии с рекомендациями лечашего врача-ортодонта.

 Я ознакомлен(а) с планом комплексного лечения и проведения мероприятий перед началом ортодонтического лечения.

 Я даю согласие на рентгенологическое обследование до, во время и после лечения согласно рекомендациям лечащего врача.

5. Я предупрежден(а), что до начала ортодонтического лечения и на его этапах врач выполняет диагностические фотографии, необходимые для контроля качества лечения. Я разрешаю использовать мои данные в образовательных целях и в демонстрационно - информационных целях, без указания персональных сведений.

6. Я был(а) предварительно проинформирована, что одним из основных факторов успешного лечения с применением ортодонтической аппаратуры (съемные аппараты и несъемная техника) является хорошая гигиена полости рта. При несоблюдении правил гигиены полости рта возможно развитие кариозных поражений, воспалительных очагов инфекции в зонах контакта ортодонтической аппаратуры с эмалью зуба и мягкими тканями полости рта (кариес, пигментации эмали, пародонтической аппаратуры с эмалью зуба и мягкими тканями полости рта (кариес, пигментации эмали, пародонтической аппаратуры с эмалью зуба и мягкими тканями полости рта (кариес, пигментации эмали, пародонтической аппаратуры с эмалью зуба и мягкими тканями полости рта (кариес, пигментации эмали, пародонтит, гингивит). Я согласен(а), что лечащий врач оставляет за собой право принятия решения о снятии ортодонтической аппаратуры на любом этапе лечения при неудовлетворительной гигиене полости рта. Деньги за проведенный объем лечения не будут возвращены.

7. Я согласен(а), что при возникновении заболеваний пародонта (гингивит, пародонтит, пародонтоз) необходимо проводить дополнительное лечение у врача - пародонтолога. Данное лечение оплачивается отдельно от стоимости ортодонтического лечения.

8. Я предупрежден(а), что при ортодонтическом лечении возможно возникновение заболеваний периодонта, обусловленных скрытыми очагами инфекции, неудовлетворительным эндодонтическим лечением. Я согласен(а) проводить необходимое лечение для устранения воспалительных очагов инфекции.

9. Мне известно, что для нормализации прикуса может потребоваться удаление отдельных зубов на верхней и нижней челюсти. О необходимости или возможной вероятности лечащий врач сообщает до начала ортодонтического лечения.

10. Мне известно, что адаптационный период (период привыкания к аппарату) в среднем, может длиться от 1 до 4-х недель. Во время адаптационного периода к ортодонтической аппаратуре могут возникать болевые ощущения в области верхней и нижней челюсти, натирание слизистой оболочки губы и щеки, нарушение речеобразования, другие явления дискомфорта.

11. Мне известно, что при назначении лечащим врачом дополнительных аппаратов и приспособлений (лицевая маска, лицевая дуга, дистализаторы, межчелюстные тяги, минивинты и др.) необходимо следовать всем

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рекомендациям лечащего врача. При невыполнении правил и сроков пользования вспомогательной аппаратурой, возможно изменение плана лечения (смена аппаратов, удаление зубов и др.) и, как следствие, снижение результата лечения. Сумма уплаченная за аппараты, к которым я не смог(ла) привыкнуть по различным причинам, не возвращается.

12. Мне известно, что необходимо производить активацию съемных аппаратов и несъемной техники строго в сроки, указанные лечащим врачом. При нарушении рекомендаций лечащий врач имеет право завершить лечение на данном этапе без возмещения стоимости ортодонтической аппаратуры или лечения. Необходимо проводить гигиеническую чистку ортодонтической аппаратуры в соответствии с рекомендациями лечащего врача.

13. Мне известно, что при невыполнении рекомендаций лечащего врача в процессе активного лечения и в период пользования съемными аппаратами срок лечения может удлиниться, а результаты лечения могут быть менее эффективными.

14. Мне известно, что в период активного роста лицевого черепа в некоторых случаях требуется повторное изготовление ортодонтического аппарата из-за роста костной ткани, но не чаще 1 раза в 8 месяцев. В этом случае я оплачиваю повторное изготовление аппарата.

15. Мне известно, что после окончания активного периода ортодонтического лечения необходимо носить ретенционный аппарат в течение всего периода, который требуется для закрепления результата лечения, в противном случае может развиться рецидив аномалии прикуса. Контроль за ношением аппарата осуществляет лечащий врач-ортодонт (контроль качества фиксации ретенционного аппарата в полости рта).

16. Я понимаю и согласен(а), что перелом, трещина ортодонтического аппарата или его металлических конструкций(после истечения гарантийного срока), приваривание новых элементов, утеря аппарата не являются гарантийными случаями и должны быть оплачены отдельно.

17. Я понимаю, что предложенное лечение поможет мне сохранить здоровье, тем не менее, ортодонтическое лечение является вмешательством в мой организм, и, как любое медицинское вмешательство, не может иметь стопроцентной гарантии на успех, даже при идеальном выполнении всех клинических и технологических этапов.

18. Я понимаю, что в период роста или при наличии заболеваний пародонта ортодонтическое лечение может существенно отклоняться от намеченного плана. Врач-ортодонт объяснил мне, что не реже 1 раза в 6 месяцев он объясняет мне выполнение намеченного плана лечения и при возникновении вышеперечисленных ситуация мы обсуждаем дальнейшие манипуляции и производим коррекцию плана на каждом этапе.

19. Понимаю сущность предложенного лечения и уникальность собственного организма. Я согласен(а) с тем, что не возможно предсказать идеальный результат планируемого лечения. Я понимаю, что мне не были предоставлены какие-либо гарантии об успешности результатах лечения, однако гарантировано проведение лечения специалистом соответствующей квалификации, применение им качественных материалов и инструментов, соблюдение методик в асептических условиях.

20. При возникновении каких-либо конфликтных ситуаций, я обращаюсь во врачебную экспертную комиссию в клинике, где специалисты необходимого мне профиля решают мой вопрос и выдают экспертное заключение.

21. Я даю разрешение лечащему врачу на предоставление информации, составляющей врачебную тайну, третьим лицам в интересах обследования и лечения,

22. Я даю разрешение моему лечащему врачу на предоставление информации, составляющей врачебную тайну, страховой компании с которой у меня заключен договор на оказание медицинских услуг по добровольному медицинскому страхованию (ДМС).

23. Я полностью принимаю и выражаю свое согласие на оплату услуг стоматологической клиники «ГЕРА».

24. Я подтверждаю, что прочитал(а) и понял(а) все вышеизложенное, имел(а) возможность обсудить с лечащим врачом все интересующие и непонятные мне вопросы, связанные с лечением моего заболевания и последующего реабилитационного периода. На заданные вопросы я получил(а) удовлетворяющие меня ответы и у меня не осталось невыясненных вопросов к врачу.

25. Настоящее информированное добровольное согласие содержит необходимую для меня информацию с тем, чтобы я ознакомился(ась) с предлагаемым лечением и мог(ла) дать свое согласие на проведение данного медицинского вмешательства, либо отказаться от него.

26. Мое решение является свободным и добровольным и представляет собой информированное добровольное согласие на проведение медицинского вмешательства.

Подпись пациента /Законного представителя

Фамилия (полностью) И.О.

Подпись лечащего врача_

Фамилия (полностью) И.О.

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Appendix D (informative)

Medical record of an orthodontic patient

Наименование медицинской организации:	Код формы по ОКУД Код организации по ОКПО
Адрес:	Медицинская документация Учетная форма № 043-1/у
	Утверждена приказом Минздрава России от "20_г. №

МЕДИЦИНСКАЯ КАРТА ОРТОДОНТИЧЕСКОГО ПАЦИЕНТА

.№_____

2. Пол: муж 1, жен 2		
3. Дата рождения: число	месяц	год
4. Место регистрации: респу	nene and her state even between between the state of the st	
	район	
	punon	
город	населенный пункт	
город улица		квартира
	населенный пункт	квартира

6. Семейное положение: состоит в зарегистрированном браке – 1, состоит в незарегистрированном браке – 2, не состоит в браке – 3, неизвестно – 4.

7. Образование:

профессиональное: высшее - 1, неполное высшее - 2, среднее - 3, начальное - 4;

общее: среднее (полное) – 5, основное – 6, начальное – 7, не имеет начального образования – 8, неизвестно – 9.

8. Занятость: занят(а) в экономике: руководители и специалисты высшего уровня квалификации - 1, прочие специалисты – 2, квалифицированные рабочие – 3, неквалифицированные рабочие – 4, занятые на военной службе – 5;

не занят(а) в экономике: пенсионеры - 6, студенты и учащиеся - 7.

9. Место работы_

10. Полис ОМС: серия	Ne	11. СНИЛС	
12. Наименование страхов	ой медицинской о	оганизации	
13. Паспорт: серия	N2	выдан	

14. Вид оплаты: ОМС - 1, бюджет - 2, платные услуги - 3, в т.ч. ДМС - 4, другое - 5.

15. Код категории льготы

16. Категории льготности: инвалид ВОВ – 1, участник ВОВ – 2, воин-интернационалист – 3, лицо, подвергшееся радиационному облучению – 4, в т.ч. в Чернобыле – 5, инв. II гр. – 7, инв. III гр. – 8, ребенок-инвалид – 9, инвалид с детства – 10, прочие – 11 (указать)

код по МКБ-10

1

- 17. Направлен мед. организацией _____
- 16. Диагноз направившей мед. организации:
- 16.1. основной:

16.2. осложнения основного:

17. ЖАЛОБЫ

17.1.□эстетические; 17.2.□морфологические, 17.3.□функциональные (со слов родителей):
□несмыкание губ, □ротовое дыхание, □инфантильное глотание, □бруксизм,
□нарушения произношения звуков речи (______), □вялое жевание,
□привычное смещение н/ч (□вперед, □в сторону), □нарушения функции ВНЧС.
Дополнительно:

18. AHAMHE3

18.1. Нарушение здоровья матери [триместр беременности: □I, □II, □III] (□нет)

- 18.2. Рожден (Пв срок, Пнедоношен);
- 18.3. Вид вскармливания (Пестественное, Пискусственное с _____мес., Псмешанное)
- 18.4. Начало прорез. первых временных зубов: _____мес.
- 18.5. Начало смены передних зубов: _____лет.
- 18.6. Наличие вредных привычек (Пда, Пнет):

□сосание пальцев, □в/губы, □н/губы, □языка, □предметов

18.7. Наличие врожденных аномалий развития челюстно-лицевой области: у родственников (□нет): □родителей, □братьев, □сестер, □др. родственников.

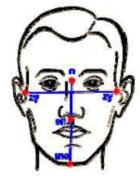
18.8. Перенесенные и сопутствующие заболевания (Пнет):

□Диспепсия	□Скарлатина	Заболевания нервной системы			
□Рахит	□Травма	□Иммунодефицит			
Ветряная оспа	□Заболевания ЛОР органов	☐Множественный кариес			
ПГепатит	□Заболевания опорно-дв. аппарата	Пародонтопатия			
ПДифтерия ПАллергия		Прочие:			
Шинф. паротит	Эндокринные заболевания				
□Корь	□Болезни ЖКТ, печени, почек				
ПКраснуха	□Болезни сердца				

18.9. Проводилось ранее ортодонтическое лечение (□нет); 18.9.1 Длительность лечения лет;

18.9.2. Вид аппаратуры (Псъемная, Пнесъемная)

19. ОСМОТР ЛИЦА. КЕФАЛОМЕТРИЯ

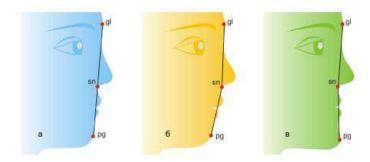


19.1. Лицо анфас:

19.1.1. Ширина лица: (zy-zy _____мм)
19.2. Высота лица: (n-me ____мм, n-sn ____мм, sn-me ____мм)
19.1.3. Лицо симметричное (□да, □нет)
19.1.4. Подбородок смещен □вправо, □влево, □нет
19.1.5. Выраженность надподбородочной складки: (□да, □нет)
19.1.6. Губы сомкнуты (□да, □нет)
19.1.7. Симптом «десневой улыбки» (□да, □нет)

19.2. Лицо в профиль:

- 19.2.1. Тип профиля:
- □прямой(а), □выпуклый(б), □вогнутый(в)
- 19.2.2. Положение верхней губы:
- □выступает, □западает, □правильное
- 19.2.3. Положение нижней губы: □выступает, □западает, □правильное
- 19.2.4. Положение подбородка: Прогения, Претрогения, Правильное.



20. ОСМОТР ПОЛОСТИ РТА

20.1. Мягкие ткани полости рта:

- 20.1.1. Уздечка верхней губы: Пкороткая, Пширокая, Пприкреплена низко, Пв норме.
- 20.1.2. Уздечка нижней губы: Пкороткая, Пширокая, Пприкреплена высоко, Пв норме.
- 20.1.3. Уздечка языка: Пкороткая, Пширокая, Пв норме.
- 20.1.4. Язык: Пмакроглоссия, Пмикроглоссия, Пв норме.
- 20.1.5. Преддверие полости рта: Пмелкое, Пв норме.
- 20.1.6. Слизистая оболочка: □гиперемирована, □отечна, □гипертрофирована, □афты, □язвы, □заеды, □в норме.

20.2. Зубы:

20.2.1. Прикус: Пвременный, Псмена зубов, Ппостоянный

20.2.2. Гигиена полости рта: Пхорошая, Пудовлетворительная, Пплохая

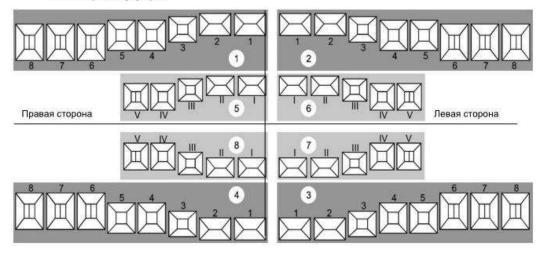
20.2.3. Аномалии зубов:

- цвета			1													
- структуры. тв. тк.								i i								li –
- формы		Č – Í			l i											1
- положения *	1							1 1								Ű.
- сроков прорез. **	1		lî .		i i	1		1								1
- количества ***			0					Ĩ)							L Ü	Ĩ
М/д размеры						ļ,		0 11								0
Верхняя челюсть	зач 18	17	16	55 15	54 14	53 13	52 12	51 11	61 21	62 22	63 23	64 24	65 25	26	27	зач 28
Нижняя челюсть	48 зач	47	46	45 85	44 84	43 83	42 82	41 81	31 71	32 72	33 73	34 74	35 75	36	37	38 зач
М/д размеры										1						
- количества ***																-
- сроков прорез. **								1								Ĵ.
- положения *																0
- формы								1								1
- структуры тв. тк.								[[]]								1
- цвета								1								1

* В - вестибулярное, О - оральное, Д - дистальное, М - мезиальное, С - супраположение, И - инфраположение,

Т - тортоаномалия, Тр - транспозиция, Пр - протрузия, Рт - ретрузия,
 Р - ретенция, П - персистентный, РУ - раннее удаление.
 АП - адентия переичная, АВ - адентия вторичная, СК - сверхкомплектный.

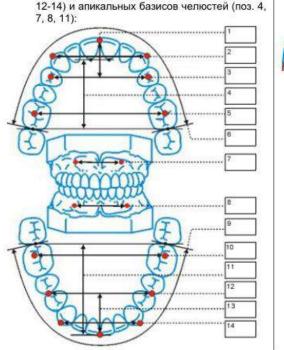
20.2.4. Зубная формула



С - кариес в стадии пятна К - кариозная полость П - пломба

Г- гипоплазия Ф - флюороз К - корень

20.3. Зубные ряды



20.3.1. Размеры зубных рядов (поз. 1-3, 5-6, 9-10,



20.3.5. Симметричность расположения зубов: (Сохранена, Пнарушена _____)

20.4. Окклюзия

20.4.1. Сагиттальное направление:

- 20.4.1.1. Окклюзия моляров справа (□I, □II, □III кл.), слева (□I, □II, □III кл.) смыкание моляров нарушено на (мм): справа_____, слева _____
- 20.4.1.2. Окклюзия клыков справа (ПІ, ПІІ, ПІІІ кл.), слева (ПІ, ПІІ, ПІІІ кл.)
- 20.4.1.3. Смыкание резцов: □в норме, □сагиттальная щель ____мм, □обратная резцовая окклюзия, □обратная сагиттальная щель ____мм.

20.4.2. Вертикальное направление:

20.4.2.1. Передний отдел (Пв норме):

□вертикальная резцовая дизокклюзия: верт. щель ____мм, в пределах ____зубов; □прямая резцовая окклюзия;

□глубокая резцовая окклюзия (величена перекрытия: □ >1/3, □ >1/2)

- □глубокая резцовая дизокклюзия (□травмирующая окклюзия);
- 20.4.2.2. Боковой отдел (Пв норме): дизокклюзия Псправа, Пслева
- 20.4.3. Трансверсальное направление:
 - 20.4.3.1. Передний отдел (Пв норме):
 - смещение косметического центра (Вправо, Влево) на ____мм; 20.4.3.2. Боковой отдел зубных рядов (В норме):

Перекрестная окклюзия	справа	слева
Палатокклюзия		
Лингвокклюзия		
Вестибулокклюзия		B

21. РЕНТГЕНОЛОГИЧЕСКОЕ ИССЛЕДОВАНИЕ 4 21.1. Ортопантомография челюстей (дата, возраст) лет. 21.1.1. Асимметрия развития тел челюстей и ВНЧС□ (□нет). 21.1.2. Врожденная расщелина □альвеолярного отростка, □нёба (□нет): □правосторонняя, □левосторонняя, □двусторонняя. 21.1.3. Деструкция костной ткани челюсти в области зубов (Пнет). зубов (□нет) +- до 1/3, ++ - до 1/2, +++ - более 1/2 длины корня 21.1.4. Атрофия костных перегородок в области 21.2. ТРГ головы в боковой проекции (дата, возраст) , ____лет. 21.2.1. Положение и наклон резцов и моляров Наклон резцов 1. <U1/NL (наружный) град. 2. <L1/ML (внутренний) град. 3. <1/1 "alfa" град. Положение резцов и моляров 4. U1-NA MM 5. L1-NB MM 6. U6-PtV MM 21.2.2. Продольные и вертикальные размеры челюстей Размеры основания черепа 7. N-S MM 8. < N/S/Ba _град. 9. < N/S/Ar __град. Сагиттальные размеры челюстей 10. Длина основания в/ч A'-Snp MM 11. Длина тела н/ч Pg'-Go _____MM 12. Длина ветви н/ч Co-Go ____MM Pg-NB 13. Длина подбородка _____MM Вертикальные размеры челюстей 14. Передняя высота в/ч UI-NL MM 15. Передняя высота н/ч LI-ML MM 16. Задняя высота в/ч U6-NL MM 17. Задняя высота н/ч L6-ML MM 21.2.3. Положение и наклон челюстей 18. < S/N/A град. 19. < S/N/B град. 20. < S/N/Pog град. 21. < Ar/Go/Me "Go" град. 22. < NL/NSL град. 23. < ML/NSL град. 24. < ML/OcL град. 21.2.4. Соотношение челюстных костей по сагиттали и вертикали 25. Межапикальный угол < A/N/B град. 26. Wits-число MM 27. Задняя высота черепа S-Go MM N-Gn 28. Передняя высота черепа MM 29. Передняя верхняя высота N-Sna MM 30. Передняя нижняя высота Sna-Gn MM 31. Задняя верхняя высота Snp-NSL MM 32. Задняя нижняя высота Ar-Go MM

32. Задняя нижняя высота Ar-Go _____мм 33. Межчелюстной угол ("B") < NL/ML ____град.

MM

21.2.5. Профиль мягких тканей лица

- 34. Угол профиля лица < gl-sn-род ____град.
- 35. Высота в/губы sn-st мм
- 36. Высота н/губы с подбородком st-me

37. Положение UL к эстетической плоскости по Ricketts (pn-pog):

- □на прямой, □кпереди на ____мм, □кзади на ____мм
- 38. Положение LL к эстетической плоскости (pn-pg):
- □на прямой, □кпереди на ____мм, □кзади на ____мм
- 39. Носогубной угол < col-sn-UL ____град.

21.2.6. Оценка положения и наклона челюстей

Ретропозиция	18. SNA	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	Антепозиция
Ретроинклинация	22. NL/NSL	16.5	15.5	14.5	13.5	12.5	11.5	10.5	9.5	8.5	7.5	6.5	5.5	4.5	3.5	2.5	1.5	0.5	Антеинклинация
	8. NSBa	146	144	142	140	138	136	134	132	130	128	126	124	122	120	118	116	114	
Ретроинклинация	23. ML/NSL	48	46	44	42	40	38	36	34	32	30	28	26	25	24	23	22	21	Антеинклинация
Ретропозиция	19. SNB	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	Антепозиция
Тип проф	иля:		Ретро	огнат	ичесі	кий			юрм	огнат	ичес	кий			Про	нати	ческ	ий	

21.2.7. Прогноз типа роста лицевого отдела черепа

		Горизонталь	ный	Нейтральный	Вертикальный			
S-Go : N-Gn (%)	75	71	67	62 - 65	58	54	50	
23. < ML/NSL	17	22	27	29 - 35	37	42	47	
33. < NL/ML	13	18	23	25 - 31	33	38	43	
40. sum. Bjork	381	386	391	393 - 399	401	406	411	
41. < N/Go/Me	62	65	68	70 - 76	78	82	86	
42. < N-Ba/Pt-Gn	99	96	93	92 - 89	87	84	81	
43. < ML/FH	13	15	17	18 - 26	27	29	31	
44. < S-Gn/FH "Y-ось"	49	52	55	56 - 62	63	66	69	

21.2.8. «К»-анализ

47.	"K"-Po	MM	51. "K"-L3 dist N	4M
48.	"K"-6 dist	MM	52. "K"-U1 tip	424
49.	"K"-L6 dist	MM	53. "K"-L1 tip	4M
50.	"K"-U3 tip	MM		

21.2.9. Оценка гармоничности окклюзии

Зубной ряд	PoNI	PoNM	MNI
верхний			
нижний			

22. ФУНКЦИОНАЛЬНЫЕ МЕТОДЫ ОБСЛЕДОВАНИЯ

22.1. Клинические функциональные пробы:

22.1.1. Проба Эшлера-Битнера (выдвижение нижней челюсти до смыкания моляров по I кл.).

Профиль: Пулучшился, Пне изменился, Пухудшился; Пвыдвижение невозможно.

- 22.1.2. Пробы Ильиной-Маркосян:
 - сдвиг нижней челюсти кзади до краевого смыкания резцов: □возможен, □невозможен.
 при открывании рта линия косметического центра:
 - □выравнивается, □не изменяется, □смещение усиливается.
- 22.1.3. Проба положения губ при сомкнутых зубных рядах.

Губы смыкаются: Пс напряжением, Пбез напряжения.

- 22.1.5. Измерение вертикальной щели между резцами:
 - при максимальном опускании нижней челюсти _____мм
 - при относительном физиологическом покое _____мм

22.2. Электромиография

Параметр		Справа		Слева				
Параметр	Височная	Жевательная	Надподъязычная	Височная	Жевательная	Надподъязычная		
Макс. амплитуда (µV)				2				
Период активности (mSec)								
Период покоя (mSec)				0 5				
Жеват. период (Sec)								
Кол-во жев. движ.	4 			-				
Коэф. коорд. за жев. движ.								
Коэф. коорд. за жев. период	8							

22.3. Миотонометрия

1		Справа		Слева				
Исследование	Покой	Первый контакт зубов	Максимальное сокращение	Покой	Первый контакт зубов	Максимальное сокращение		
1					1			
2								
3						2		

22.4. Периотестометрия

Дата	Значение												
Верхняя	челюсть	16	15	14	13	12	11	21	22	23	24	25	26
Нижняя	челюсть	46	45	44	43	42	41	31	32	33	34	35	36
Ната	Значение												

23. ДОПОЛНИТЕЛЬНЫЕ МЕТОДЫ ОБСЛЕДОВАНИЯ

снование предварительного д		

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новной		
сложиения		
опутствующие заболевания		
внешняя причина (при травмах и отравлениях):	код по МКБ-10	
5. План обследования		
6. План лечения		
9 <u></u>		

27. Информированное добровольное согласие пациента на медицинское вмешательство или **отказ** от медицинского вмешательства получен(о):

число месяц год время

28. Дневник врача-ортодонта

				До лечения	В процессе лечения	После лечения
1	Модели зубн	ых рядов				
2	Фотографии	фас/профиль / улыбка				
2	пациента	в полости	рта / с аппаратом			
	Фото	В.З.Р. спра	ава / фронт / слева			
3	моделей зубного ряда	Н.З.Р. справа / фронт / слева				
4	Ортопантомог	рамма челю	стей			
5 Телерентге		нтгенограмма боковая				
9	головы		прямая			
6	Томограмма		Томограмма			

ата	Наблюдение, Status localis	Коды выполненных		
		манипуляций		
1				
1				
1				