Aligner Systems in Invisible Orthodontics

Basic Concepts and Clinical Management

Stefan Abela

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Cambridge, UK

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Preface

This book provides the reader with an in-depth knowledge of the processes involved in providing aligner treatment and describes the techniques and biomechanics involved in providing orthodontic treatment solely with aligners or in combination with other types of appliances.

There has been, over the years, various opinions and contention with regard to the adequacy of providing orthodontic treatment with aligners. Some cases would certainly benefit from this technique in contrast to others that will be worse off in comparison to being treated with other techniques still considered to be the gold standard within the specialty.

Evidence supporting the clear aligner technique remains sparse; however, more studies are being carried out to prove the aligners' clinical abilities and compare them to more traditional techniques principally involving removable and fixed appliances.

Although a vast range of aligner manufacturers and types are available in the market, and this book is completely unbiased, Invisalign® by Align Technology, Inc., remains the market leader and the one most widely used by clinicians at an international level. Consequently, this position has been respected by the author and its usage was reflected during the composition and collation of the latest available information and scientific evidence for this book.

This book, innovative in nature, will provide the reader with an invaluable depth of knowledge with regard to the various types of aligners, the techniques used in their application, the practical aspects of delivery and the scientific data available to back their everyday use.

Cambridge, UK
September 2023

Stefan Abela

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Introduction

The increased demand for discreet orthodontic treatment is a widely perceived and accepted phenomenon, and this increased demand has been further exacerbated with the introduction of aligners. With the increased popularity of aligner systems, the number of adults seeking orthodontic treatment has similarly increased exponentially [1, 2]. The superiority over other orthodontic systems include the following:

- Aesthetic discreetness [3]
- Risk reduction of periodontal complications during active treatment [4]
- Comfort and adaptability [5]
- Freedom over masticatory choice [6, 7]
- Possibility of monitoring the progress of treatment remotely [8]
- Provision of efficient mechanics and satisfactory outcomes [9]
- Reduction in operator chair-side time [1, 10]
- Possibility of usage in conjunction with other orthodontic auxiliaries [11]

The current international aligner market is worth around 2 billion USD (US Dollar), but consumer data reports estimate a four-fold market increase by 2028. Reports by Statista, Inc., Ströer Content Group, GmbH, Hamburg, Germany, and by ©Grand View Research, Inc., Los Angeles, USA, are in agreement whilst reports by MarketStudyReport, Pune, India, have forecasted a year-on-year growth between 2021 and 2027 of 27 % leading to a global market value of 14 billion USD in value. The global oral care value is estimated to be around 55 billion USD by 2025, so one cannot leave the proportion dedicated to improving smile aesthetics unnoticed.

Analysis of web searching trends as a reflection of future patients' choices will also increase with a study suggesting an increase of a minimum of 6 % to a maximum of 13 % with the analysis extending to three European countries. This was drawn in direct comparison to the previous year (2021) [12].

On balance, although Align Technology, Inc., California, USA, might be viewed as the most popular aligner manufacturer, other leading aligner systems include: ClearCorrect by Straumann Group Basel, Switzerland;, Spark by Ormco™, California, USA; SureSmile® Dentsply North Carolina, USA; 3M™ Clarity Aligners, 3M Minnesota, USA; F22 Aligner by Sweden & Martina, Padua, Italy; Nuvola® Clear Aligners by GEO Srl, Vicenza, Italy; CA® Clear Aligners by Scheu-Dental GmbH, Iserlohn, Germany; iROK™ Aligners by iROK™ Digital Dental

Studio, California, USA; Angelalign by Angelalign Technology, Inc., Shanghai, China; Alineadent Aligners by Alineadent, Malaga, Spain; Orthocaps TwinAligner® System by Rocky Mountains, Indiana, USA; K Clear and Clear X by K Line, Düsseldorf-Benrath, Germany; EZ-X by DynaFlex®, Missouri, USA; eXceed aligners, by eXceed®, Witten, Germany; Accusmile® by Forestadent, Pforzheim, Germany; smart moves® by Great Lakes Dental Technologies, New York, USA; SLX™ Clear Aligner System and Reveal® by Henry Schein, New York, USA; Refine® by TP Orthodontics, Indiana, USA.

Direct consumer companies, most notably Smile Direct Club™ LLC, Tennessee, USA, aim at providing a direct aligner provision to the customers avoiding the doctor to patient interaction enabling direct entry into the market at a much lower price bracket. Other remotely monitoring aligner systems include Candid™ Aligners, New York, USA; NewSmile™ Aligners, Vancouver, British Columbia, and Byte® Aligners, California, USA, and AlignerCo, New York, USA. Emergence of new providers and cessation of existing ones is a continuously fluid model due to the related costs of production, shipping, marketing and other related costs. In-house production of aligners could also provide a challenge with increasingly user-friendly software and 3D printing facilities becoming more financially accessible.

Most of the scientific articles directly related to orthodontic aligners have been published in the last 10 to 20 years. This trend is also expected to increase as the technique becomes more widespread and clinical advances using this technique together with any accompanying auxiliaries, accomplished.

Clear aligners have seen a significant improvement in their accompanying attachments' design that play a key role with expressing the desired tooth movement [13]. The aligners' flexibility of being used with other appliances further expands their scope rendering their use in orthognathic cases very feasible [11].

The biomaterials, mainly in the form of thermoplastic polymers have also seen an improvement in their physical and mechanical properties and have been extensively researched [14, 15]. The thermoforming process normally takes place on an accurate representation of a patient's dental models and although at this early stage, the materials undergo a change in their properties, their clinical use is not compromised. Further changes to their properties are mediated with the exposure of the intraoral environment. Changes in the their physical composition are rendered tangible with the continuous exposure of moisture, elevated temperatures in comparison to room temperature, elastic deformation and increased stiffness with alterations to their crystalline morphological composition [16, 17]. This phenomenon has led to aligner manufacturers recommending a time interval between successive stages, i.e. between 7 and 14 days.

A key factor to the behaviour and characteristics of an aligner is the thickness used to manufacture it. In general, the thickness of aligners varies between 0.5 mm and 1 mm. The manufacturing process might also bear an influence on the final aligner thickness [18]. The thickness has a directly proportional relationship with the delivery of the orthodontic forces needed for tooth movement but also with the amount of ageing exhibited with intraoral use over time [19].

The future, as alluded to above, will not only see an increase and an improvement with the current techniques but also will progress to incorporate more complex digitisation processes. This will include incorporation of Cone-Beam Computed Tomography (CBCT) data to enable better prediction of crown-root movements and enable full customisation of the appliances, better integration with enhanced software systems to facilitate in-house production by individual clinicians and an increase in both industrial-scale production and direct home delivery systems.

The recently adopted technologies have helped propel aligners to an everyday proposition amongst both general dental practitioners and specialist practitioners. Technologies involving 3D printing, CAD-CAM, and thermoprocessing allowed this uptake and widespread acceptance. The next generation of aligners will adopt four-dimensional (4D) properties with the introduction of the shape memory polymers (SMPs). These new materials will possess the ability to allow changes to the aligners' shape during intraoral use to improve efficacy to yet another level [20].

Another prospective developmental advancement in aligner therapy could be in an extremely rapid turnaround time for production and delivery rendering same-day finalisation of the product very realistic, especially when considering the gigantic advancements in CAT technology. This leap could be potentially attained by the elimination of 3D model printing and thermoforming processes altogether.

The individual manufacturers claim unique selling points and advantageous characteristics over their competitors. These claims are hard to identify; however, the clinician remains solely responsible for ensuring the treatment efficacy and safety of the patient undergoing treatment. Precautions, such as optimal communication and clear outlining of expectations, will ensure successful outcomes. In the case of orthodontic aligners specifically, thorough treatment planning and an immeasurable knowledge of the planning software together with setting realistic tooth movement goals will be key in allowing the clinician to relay the results from a digital platform to a realistic dimension.

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Contents

Part I Basic Concepts and Materials

1 General Aligner Concepts . . . 3
- 1.1 Introduction . . . 3
- 1.2 Developmental Stages of Invisalign® . . . 3
- 1.3 G8 . . . 4
  - 1.3.1 Deep Bite Management with the Eighth Generation . . . 5
  - 1.3.2 CrossBite Management with the Eighth Generation . . . 5
- 1.4 ClinCheck® Pro 6.0 . . . 6
  - 1.4.1 ClinCheck® Pro 6.0 3D Features . . . 6
- 1.5 Space Closure Using Aligners . . . 8
- 1.6 Mode of Action of Aligners . . . 10
  - 1.6.1 Displacement-Driven System . . . 10
  - 1.6.2 Force-Driven System . . . 10

References . . . 10

2 Types of Aligner Systems Available . . . 11
- 2.1 Introduction . . . 11
- 2.2 Clear Aligners Available . . . 12
  - 2.2.1 Aligners Manufactured by a Certified Company Involving a Doctor-to-Patient Interface . . . 12
  - 2.2.2 Direct-to-Consumer Aligners Distributed Directly to the Patient . . . 13
  - 2.2.3 In-House Manufacturing by the Treatment Provider . . . 13

References . . . 14

3 Aligner Treatment Process . . . 17
- 3.1 Introduction . . . 17
- 3.2 The Treatment Journey . . . 17
  - 3.2.1 New Patient Consultation and Evaluation . . . 17
  - 3.2.2 Processes Involved for Obtaining and Uploading the Records . . . 19
  - 3.2.3 Invisalign Product Range . . . 24
  - 3.2.4 Submission of a New Treatment Prescription . . . 26
  - 3.2.5 Creation of 3D ClinCheck® Simulation . . . 26

3.2.6 ClinCheck® Approval by the Clinician 29
3.2.7 Tray Fabrication and Shipping 29
3.2.8 Starting the Treatment 30
3.2.9 Monitoring the Progress of Treatment 30
3.2.10 Finalisation of Treatment 32
3.2.11 The Retention Phase 32
References 32

4 Biomechanics with Aligner Treatment 33
4.1 Introduction 33
4.2 SmartForce® 33
4.2.1 Definition 33
4.2.2 Features 34
4.2.3 Prioritisation of Attachment Placement 41
4.2.4 Summary of SmartForce® Attachment Placement Protocol 42
4.3 Customising the Biomechanics 42
4.4 Factors Affecting the Biomechanics 45
4.5 Finishing and Detailing with Aligner Treatment 45
4.5.1 Overcorrectors 46
4.5.2 Overcorrection 46
4.5.3 Virtual C-Chain 47
4.6 Tray Trimming 47
References 48

Part II Clinical Management of Malocclusions

5 Navigating Through the Software 51
5.1 Introduction 51
5.2 The Patients' Online Folder 51
5.3 The Patients' ClinCheck Plan 52
5.4 Modifying the Patients' ClinCheck® Plan 54
5.5 Options for Modifying the Patients' ClinCheck Plan 55
5.6 New Features Available on the ClinCheck Pro® 6.0 56
5.6.1 Red Zones 56
5.6.2 ClinCheck Live Update 56
5.6.3 In-Face Visualisation Feature 56

6 Clinical Management of Class I Cases 57
6.1 Introduction 57
6.2 Align Technology Grading of Case Difficulty 58
6.3 Predicting Treatment Outcomes 58
6.4 Formulating the Treatment Plan 59
6.4.1 Optimised Attachments 59
6.4.2 IPR 60
6.4.3 Labial Segment Proclination 65

6.4.4 Arch Expansion . . . 65
6.4.5 Buccal Segment Distalisation . . . 66
6.4.6 TADS-Supported Mesialising or Distalising Appliances. . . . 66
6.4.7 Dental Extractions . . . 66
6.4.8 Surgical Correction . . . 67
6.5 Features of a Class I Malocclusion to Be Given Special Consideration . . . 67
6.5.1 Interdental Spacing . . . 67
6.5.2 Open Bite . . . 68
References . . . 68

7 Clinical Management of Class II Division 1 Cases . . . 71
7.1 Introduction . . . 71
7.2 Align Technology Grading of Case Difficulty . . . 72
7.3 Predicting Treatment Outcomes . . . 72
7.4 Formulating the Treatment Plan . . . 73
7.4.1 Class II Elastics . . . 73
7.4.2 Elastic Band Sizes . . . 74
7.5 Additional Treatment Considerations . . . 74
7.5.1 Fixed-Functional Appliances . . . 74
7.5.2 Upper First Molar De-rotation . . . 77
7.5.3 Passive Aligners in the Opposing Arch . . . 77
7.5.4 Pontics . . . 77
References . . . 77

8 Clinical Management of Class II Division 2 Cases . . . 79
8.1 Introduction . . . 79
8.2 Align Technology Grading of Case Difficulty . . . 80
8.3 General Concepts . . . 80
8.3.1 Relative Intrusion . . . 81
8.3.2 Pure Intrusion . . . 81
8.4 Features and ClinCheck® Pro 6 Considerations for Deep Bite Correction . . . 81
8.4.1 Optimised Attachments . . . 81
8.4.2 Bite Ramps . . . 82
8.4.3 Setting Up the ClinCheck® . . . 82
8.4.4 Retainers Post Deep Bite Correction . . . 84
8.5 Analysing Evidence on the Efficacy of Deep Bite Correction Using Clear Aligner Therapy . . . 84
References . . . 85

9 Clinical Management of Class III Cases . . . 87
9.1 Introduction . . . 87
9.2 Align Technology Grading of Case Difficulty . . . 88
9.3 Predicting Treatment Outcomes . . . 89
9.4 Formulating the Treatment Plan . . . 89
Reference . . . 90

10 Clinical Management of Anterior Open Bite Cases 91
10.1 Introduction 91
10.2 Align Technology Grading of Case Difficulty 92
10.3 Predicting Treatment Outcomes 93
10.4 Formulating the Treatment Plan 93
10.4.1 Type of Tooth Movements to Manage an Anterior Open Bite 94
10.5 Treatment Options for Managing an Anterior Open Bite 96
10.6 Unwanted Molar Intrusion with Aligners 96
10.6.1 Treatment-Induced Molar Intrusion with Aligners 97
10.6.2 Management of Unwanted Molar Intrusion with Aligners 97
10.6.3 Positive Aspects of Unwanted Molar Intrusion with Aligners 98
10.7 Features and ClinCheck® Pro 6 Considerations for Anterior Open Bite Correction 99
10.7.1 Optimised Attachments 99
10.7.2 Positioning of Attachments 99
10.7.3 Incomplete Levelling of the Arches 99
10.7.4 Maxillary Expansion 100
10.7.5 Monitoring Tracking Closely 100
10.7.6 A-P and Vertical Anchorage Considerations During AOB Closure 100
10.8 Relapse Rates of Anterior Open Bites 101
10.9 Retainer Considerations for Maintenance of Anterior Open Bite Closure 101
References 103

11 Clinical Management of Interceptive and Teenage Cases 105
11.1 Introduction 105
11.2 Classical Treatments Carried Out in Children and Teenagers with Aligners 105
11.3 Advantages and Disadvantages of Offering Early Aligner Treatment 106
11.4 Important Invisalign Features During Early Phases of Treatment 107
11.4.1 Eruption Compensation (EC) 107
11.4.2 Terminal Molar Tab 107
11.4.3 Attachments for Primary Teeth 107
11.5 Invisalign Mandibular Advancement (MA) 108
11.6 Retainers in Teenage Cases 109
References 110

12 Clinical Management of Surgical Cases 111
12.1 Introduction 111
12.2 Efficacy of Aligners for Surgical Cases 112
12.3 Objectives of Aligners Pre-surgery 112

12.4 Objectives of Aligners During Surgery or in the Immediate Postoperative Stage . . . 113
12.5 Objectives of Aligners Post-surgery . . . 113
References . . . 114

13 Clinical Management of Hybrid Approaches with Aligners and Fixed Appliances, Sectional Lingual Appliances and Mini-implants . . . 115
13.1 Introduction . . . 115
13.2 Overcoming Transverse Expansion Limitations . . . 115
13.3 Overcoming Rotational Movement Limitations . . . 116
13.4 Combining Aligners with Orthodontic Mini-implants . . . 117
13.4.1 Mesialisation or Distilisation of Buccal Segments with Aligners Orthodontic Mini-implants . . . 117
13.4.2 Correction of Maxillary Transverse Deficiency with Aligners Orthodontic Mini-implants . . . 118
13.4.3 Camouflaging Class II Malocclusions with Aligners and Orthodontic Mini-implants . . . 118
13.4.4 Provision of Indirect Anchorage with Aligners and Orthodontic Mini-implants . . . 119
13.4.5 Intrusion of Buccal segments with Aligners and Orthodontic Mini-implants . . . 119
13.4.6 Overbite Reduction with Aligners and Orthodontic Mini-implants . . . 120
13.4.7 Molar Uprighting with Aligners and Orthodontic Mini-implants . . . 120
13.4.8 Alignment of Impacted Teeth with Aligners and Orthodontic Mini-implants . . . 120
13.5 Combining Aligners with Lingual Fixed Orthodontic Appliances . . . 120
References . . . 121

Part III Clinical Tips and Techniques to Aligner Therapy

14 Limitations of Aligner Applications . . . 125
14.1 Introduction . . . 125
14.2 Decreased Efficiency in Comparison to Fixed Appliances . . . 125
14.3 Decreased Stability Postoperatively . . . 126
14.4 The Need to Undertake Multiple Refinement Stages . . . 126
14.5 The Need to Have a Separate Course of Fixed Appliance Treatment to Improve Outcomes . . . 127
14.6 Decreased Satisfactory Occlusal Outcomes . . . 127
14.7 Decreased Control of Crown-Root Movement . . . 127
14.8 Inaccuracies Between Predicted and Achieved Clinical Outcomes . . . 127
References . . . 128

15 Overcoming Aligners' Limitations 129
15.1 Introduction 129
15.2 Case Selection 129
15.3 Predominant Tipping Movements 129
15.4 Programming Less Movement 130
15.5 Extend Treatment Time 130
15.6 Increase the Rate of Tray Change 130
15.7 Choice of Aligner System 130
Reference 130

16 Patient Motivation for Long-Term Compliance for Complex Treatments 131
16.1 Introduction 131
16.2 Poor Compliance Indicators 131
16.3 Overcoming Poor Compliance 132
16.3.1 Log Book 132
16.3.2 Timers 132
16.3.3 Other Types of Technology 132
16.3.4 Compliance Indicator 133
References 133

17 3D Software Planning Considerations for Crown-Root Movements 135
17.1 Introduction 135
17.2 Power Ridges 136
17.3 Attachments 136
17.4 Divots 137
References 138

18 Clinical Tips for Treatment and Finishing 139
18.1 Introduction 139
18.2 Clinical Tip for Correction of Molar Rotations 139
18.3 Attachment Tips for Correction of Molar Rotations 140
18.4 Sequence of Tooth Movements for Maximal A-P Buccal Segment Correction 141
18.5 Overcorrections 142
18.6 Identification of Tooth-Size Discrepancies 143
18.7 Timing of IPR 143
18.8 Posterior Crossbite Correction 144
18.9 Altering the Rate of Staged Correction 144
18.10 Careful Selection Between Precision Hooks and Cut-Outs, Their Inclusion and Location 145
References 146

Part IV Technological Apps to Aid Aligner Therapy

19 Aligner-Related Apps 151
19.1 Introduction 151
19.2 Invisalign Photo Uploader 152
19.3 Invisalign Pro Consultation App 152
19.4 My Invisalign™ App 152
19.5 Other Available Apps 153

Part V Evidence-Based Aligner Therapy

20 Scientific Evidence of Aligner Treatment 159
20.1 Introduction 159
20.2 Changes in Chemical and Mechanical Properties of Aligners During Use 160
20.3 Periodontal Health During Aligner Treatment 161
20.4 Effect of the Type of Attachment on Aligner Treatment 162
20.5 Comparison Between Treatment with Fixed Appliances and Aligners 163
20.5.1 Efficiency of Aligner Treatment 163
20.5.2 Quantification of Efficiency of Aligner Treatment 164
20.5.3 Impact of Aligner Treatment on the Smile Outcome 165
20.5.4 Radiological Assessment of the Effect of Aligners on the Treatment Outcome 165
20.6 Aligner Treatment Effects on Root Resorption 166
20.7 Changes in Bacterial Counts and Groups 167
20.8 Comparing Outcomes in Orthognathic Surgical Cases 168
20.9 Comparing Pain Experiences of Patients Having Aligner Treatment 169
20.10 Effect of Aligner Treatment on the Quality of Life 170
20.11 Effect of Aligner Treatment on Speech 171
References 171

References 177

Index 189

About the Author

Stefan Abela, BChD, MFDS, MSc, MOrth Dr Stefan Abela is a Specialist, a distinguised Consultant in Orthodontics, directing private practices in London and in Ely, Cambridgeshire within the United Kingdom and an internationally renowned speaker. He obtained his first qualification from the Malta Medical School, University of Malta, Msida, Malta in 2003. To date, he has obtained numerous post-graduate qualifications from The Royal College of Surgeons of England and Edinburgh including a full membership and fellowship with consistent standout contributions to the international scientific community and to the profession. He has been actively involved in the UK's national education and training programme of postgraudate trainees and has been a former head of department at the Norfolk and Norwich University Hospital NHS Foundation Trust, Norwich, UK. Considered an international leader within the profession, he is an avid academic contributor and continuously publishes scientific articles in the highest ranking internationally peer-reviewed journals. He is also an internationally best-selling author of medical text-books with his previous textbook entitled *Leadership and Management in Healthcare: A Guide for Medical and Dental Practitioners*.

General Aligner Concepts

1

1.1 Introduction

Aligner treatment is very different to more widely used appliances such as fixed appliances. The biomechanics are consequentially very different too. This chapter aims at highlighting these differences and also gives an insight into the development of Invisalign® and its various iterations by evolving with each progressive generation. This chapter will also describe the process of force generation by aligners and how these forces are selectively transferred onto the surfaces of the teeth effectively with the ultimate aim being that of delivering a very efficient system to both the treating clinician and the end user, the patient.

Align Technology, Inc., albeit being the main and leading market provider of aligners, an uncountable number of companies are currently producing aligners with claims that they all have different features and provide added value to the clinicians' clients. In-house manufacturing of aligners is also currently commonplace with readily available digital intraoral scanners and software packages allowing the clinician to directly relay the prescription to the software and 3D printers, making small-scale production of aligners very feasible. A more contemporary approach to obtain a segment of this market is the direct consumer approach taken by several companies, also referred to as home aligners companies.

1.2 Developmental Stages of Invisalign®

The first stage of the development process came about with the use of PC30, Proceed30, the preferred polymer at the time, back in 1999. One of the first reported uses of Invisalign® aligners for space closure and relief of mildly crowded cases was available shortly afterwards in 2001 [1]. PC30 had both physical and chemical limitations which in turn limited the range of orthodontic cases that aligners could be used for [2].

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Within 8 years, in 2009, the second generation of aligners by Align Technology, Inc. was available featuring the inclusion of attachments to render specific tooth movements more easily. These were called SmartForce® features aimed at addressing vertical and rotatory movements of teeth.

The third generation (G3) followed the year after in 2010 offering the user the possibility of inserting precision cuts for the use of inter arch elastics. G3 has also allowed the introduction of lingual root torque (LRT).

G4 or the fourth generation followed closely in 2011 with the aim of improving the management of anterior open bites and root tip control. Further improvements were seen in 2013 with the use of SmartTrack® for improved control of tooth movements by increasing the efficacy of tooth to material interface. G5, introduced the year after, in 2014 allowed deep bite correction improvements, deemed a feature of malocclusion that aligners were not on par with conventional appliances. Bite ramps, an added feature on the palatal aspect of the upper incisors, were designed to mimic the effect of anterior bite planes used in conventional appliances.

The launch of G6 ensued in 2015 with the aim of improving anchorage control for extraction cases. The seventh generation, G7 launched in 2016, decreased aligner time to 1 week at a time decreasing treatment duration and introduced molar attachments to minimise posterior open bites due to buccal segments disocclusion. In 2017, Invisalign Teen® expanded the scope of use of aligners to a younger age group making allowances for the various mixed dentition stages.

Prior to the launch of the current generation, G8 introduced in 2020, Invisalign Go and Invisalign First were also introduced by Align Technology, Inc. The former provided a chair-side platform for general dental practitioners whilst Invisalign First allowed an initial phase for younger patients acting as an interceptive phase that is known to take place in more conventional orthodontic pathways prior to the definitive fixed appliance phase for the final correction of the malocclusion. The G8 expanded the scope of aligners once more providing correction possibilities for crossbites and more severe cases of dental crowding. In 2021 and 2022, further advancements and improvements to ClinCheck® Pro 6.0 software were witnessed by the users. These included:

1. “In-face” visualisation to preempt the facial changes visually following Invisalign treatment.
2. CBCT integration to enable 3D visualisation of the patients’ dentoalveolar complex including roots, crowns, and alveolar bone.

1.3 G8

Invisalign latest generation, the eighth, referred to G8 remains the most contemporary version of aligner from Align Technology, Inc., San Jose, California, USA.

G8 utilises SmartForce® activation to enable specific areas within the aligner surfaces to act on specific areas of a tooth to bring about more efficient and targeted tooth movements. These innovations that pertain to G8 will have been applied to all the aligners fabricated prospectively from 2021. Certain features of SmartForce®

are automatically triggered by ClinCheck® Pro 6.0, and the priority hierarchy for the G8 protocol is pre-set by the software's algorithm.

The hierarchy prioritisation is in the order listed below:

1. Premolar extraction and multi-tooth extrusion movements
2. Optimised expansion support
3. Root movements
4. Single tooth movements including vertical and de-rotations
5. Anchorage for intrusion
6. Power ridge for adequate lingual root torque (LRT)

The acclaimed advantages over the previous generations are mainly two:

(i) Improved ability to manage deep bites
(ii) Improved ability to manage crossbites involving the upper arch

1.3.1 Deep Bite Management with the Eighth Generation

The features introduced to G8 that were designed to manage deep bites more effectively include the following:

- Automatic software addition of bite ramps on the palatal aspect of the upper incisors when vertical correction is equal or greater than 1.5 mm.
- Overcorrection of lower incisor intrusion to flatten the curve of Spee. This is automatically incorporated by the software's algorithm.
- Optimised attachments to the lower lateral incisors with a dome-shaped design to provide vertical anchorage for neighbouring incisors when vertical discrepancies are present in the lower labial segment. The threshold for this discrepancy is when the vertical discrepancy is equal to or greater than 1 mm.
- En-masse intrusion to provide optimised intrusion on each individual incisor tooth. This is even more relevant if the initial position of the incisors differ vertically.

1.3.2 CrossBite Management with the Eighth Generation

The features introduced to G8 that were designed to manage crossbites more effectively by posterior arch expansion include the following:

- Individual posterior expansion forces for a more balanced expansion within the buccal segments and within the arch.
- Automatic placement of buccal root torque to avoid a consequential tip of palatal cusps and a reduction in overbite and less than ideal palatal cusp to lower occlusal surface contact.

– Optimised horizontal dome-shaped attachments on premolars and first molars with a de-rotatory movement which is invariably needed especially to the mesial aspect of the first molars.
– Prioritisation of expansion as the second most important movement with a threshold level of 0.5 mm.

1.4 ClinCheck® Pro 6.0

This proprietary software by Align Technology, Inc., San Jose, California, USA, is a cloud-based system that allows the capturing of a patient's virtual arches separately or in occlusion. The software is accessible by clinicians only; however, it is beneficial for both patients and clinicians. For the former, the visualisation of their occlusion at the start and the simulation of the treatment effects makes it easier to follow the tooth movements required to obtain the desired outcome. For the latter, the online 3D rendition can be used for visualisation purposes too, edited to improve outcomes, and usage as a monitoring tool to follow their progress. Both clinicians and clinical staff have access to the tools that the software provides to permit the greatest potential of tooth movement for the patient.

The latest innovations that have been introduced to the software include the following:

– Live or real-life updates to the corrections submitted on the Invisalign Doctor Site (IDS)
– CBCT integration to allow user manipulation of both the coronal and radicular aspects of the teeth
– "In-Face visualisation" that portrays the facial effects with the end result following treatment

1.4.1 ClinCheck® Pro 6.0 3D Features

The features available for the clinical team are available on the IDS (Invisalign Doctor Site) once the logging process has been completed.

Figure 1.1 below illustrates the second bar on the IDS with all the features at the disposition of the clinicians.

The icons representing the various features on the IDS represent different visualisation modes, diagnostics or tools to enhance the patients' outcomes. The features included in the treatment plan are represented with a blue dot next to the icon whilst those visible on the IDS platform are represented by a blue line under the

Fig. 1.1 The second bar on the IDS depicting all the 3D features available for the user. This diagram has been obtained from the ClinCheck Pro 6® software and reproduced by kind permission of Align Technology, Inc. (San Jose, California, USA)

icon. Starting from the far left, for visualisation purposes, the user has the following features listed below as they appear on the IDS from the left side.

1. "Zoom + or Zoom −" allows the user to magnify or minimise the view.
2. "Rotate" function allows the user to rotate the 3D virtual models.
3. "Pan" function to shift the position of the virtual models within the screen to allow the user to magnify an area of interest.
4. "Upper" allows the user to view the frontal aspect of the maxilla in isolation.
5. "Maxil" allows the user to view the occlusal aspect of the maxilla in isolation.
6. "Right" allows the user to view the right-hand side of the 3D models.
7. "Anterior" provides the user with a frontal view of the 3D models.
8. "Left" allows the user to view the left-hand side of the 3D models.
9. "Mand" allows the user to view the occlusal aspect of the mandible in isolation.
10. "Lower" allows the user to view the occlusal aspect of the mandible in isolation.
11. "Comp" short for composite view which allows the user to visualise five aspects of the 3D models: frontal, right, left, maxillary and mandibular occlusal views.
12. "Roots" allows the user to visualise the position of roots, bone and unerupted teeth.
13. "Smile" allows visualisation of the patient's postoperative results in the facial mailing extraoral photo.
14. "Super" short for superimposition visualises the original position of the teeth in comparison to the predicted end result. The original tooth position is coloured on the IDS.
15. "Grid" allows the user to have the 3D virtual models against a gridded background where each pixel of the grit is equivalent to 1 mm.
16. "Attach" allows the user to visualise the use of attachments, precision cuts, bite ramps and other auxiliary features included in the treatment plan.
17. "Occlus" allows the user to visualise the degree of inter arch contact points. Upon activation, the 3D models are rendered translucent to visualise the contact points better. A red dot next to the "Occlus" icon represents heavy contact points whilst green shows normal occlusal contact points. The red and green colours are used on the occlusal surfaces of the 3D models and equally represent the degree of inter arch occlusal contact points.
18. "IPR" represents interproximal reduction showing the amount of IPR prescribed by the clinician. This icon also represents any residual spacing present in the predicted outcome.
19. "TMA" represents tooth movement assessment and allows the user to verify the tooth movements incorporated to generate the end result on the ClinCheck®.
20. "Pontic" allows the user to activate the visualisation of any Pontics in sites where teeth are missing, unerupted or impacted.
21. "Stages" tab activation allows the user to:
    (i) Visualise the stage of specific tooth movements in their ClinCheck® simulation via the "Staging Panel"
    (ii) Visualise the bite corrections via the "Bite correction visualisation"
    (iii) Visualise any overcorrective tooth movements via the "Overcorrection" tab

22. "Tables" which allows the user to access the "Tooth movements table," the "Bolton Analysis," the "Arch width table," the "Overjet and overbite table" and the "Tooth numbering." Further details about tooth-size discrepancies can be found in Sect. 6.4.2.
23. "Tools" allows the user to access the "Eruption compensation" and "Occlusal plan inclination."

The "Sidebar" can be activated on the right-hand side of the IDS and allows the user to visualise previously agreed ClinCheck plans and instructions given to the Align Technology, Inc. technicians.

1.5 Space Closure Using Aligners

The indications for space closure with aligners as with other type of orthodontic appliances are brought about with increasingly difficult occlusions to manage. This is certainly the case when crowding is assessed as moderate or severe with over 6 mm of crowding in one or both arches and when the occlusion demands an extraction approach [3].

Classically, in orthodontics cases that need to be treated on an extraction basis require first or second premolar extractions. This renders the treatment more complex independent of the type of appliances used; however, the complexity of tooth control is even higher with clear aligner therapy. The main challenge is to control the tipping of the teeth adjacent to the extraction site with some authors suggesting a combination approach involving both clear aligners and fixed appliances [4].

Space closure and space management can be managed in one of the three ways listed below:

1. Predominant labial segment retraction.
2. Predominant buccal segment protraction.
3. A combination of the above.

Using clear aligners to retract incisors poses two main problems to the clinician:

(a) Torque loss in the labial segments.
(b) Exhibition of the bowing phenomenon.

In fixed appliance therapy, although the clinician can face the same clinical challenges, a selection of different archwires with varying degrees of stiffness enabling space closure without biomechanical sequelae are available. With clear aligner therapy, the flexibility inherent in the materials used to manufacture clear aligners will lead to unwanted movements as follows:

– Anteriorly, a clockwise movement with extrusion and relative increase in overbite leading to premature contacts with torque loss of the incisors.

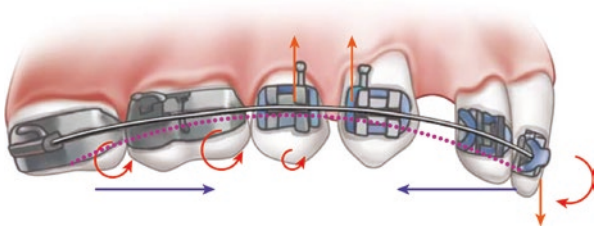

Fig. 1.2 Illustrates the "bowing" effect that could be seen during space closure during aligner therapy

– Posteriorly, an anticlockwise movement of the molars.
– Mid-arch in the premolar section, vertical intrusion is apparent earlier on in the space closure phase leading to a mid-arch open bite.

This phenomenon described above is known as "bowing" and is illustrated in Fig. 1.2 below.

Overcoming and minimising the bowing effects in clear aligner therapy warrants the following:

1. Additional anchorage reinforcement with the use of:
   (a) Inter arch elastics.
   (b) Orthodontic mini-implants.
2. Controlling the amount of tooth movement found in each tray. This can be done by either:
   (a) Minimising the quantity of space closure prescribed in each tray.
   (b) Alternating the treatment stages between active and passive aligners.
   (c) Alternating between space closure and specific tooth movements in the anterior or posterior segments.
   (d) Prescribe specific distalisation movements for the upper canines between space closure stages. This will decrease the risk of torque loss to the upper incisors and relative extrusion, maintaining overall control of the incisor inclination.
3. Introduction of a positive curve of Spee in the upper arch to counteract the negative sequelae described above.
4. Prescription of antagonistic tooth movements in the space closure phases such as extrusion of premolars, proclination of upper incisor crowns, intrusion of incisors and distal tipping of the molar crowns.
5. Strategic use of attachments that provide more vertical control of the incisors, premolars and molars, bilaterally. The attachments could be used for both active and retentive purposes such as optimised extrusive attachments and optimised retention attachments, respectively.
6. Use of vertical inter arch elastics in the premolar section using buttons to allow more efficient extrusive movements.

1.6 Mode of Action of Aligners

The clear Aligners' mechanism of tooth movement revolves around two main types:

1. Displacement-driven system.
2. Force-driven system [5, 6].

1.6.1 Displacement-Driven System

Aligners relying on a displacement-driven system need to have the sequential tooth movements staged and the aligners produced for each stage with the respective tooth movements in-built within each individual tray. The movement is solely based on the individual aligners' shape and once the aligner actuates the movements for each stage, it is rendered passive.

This process entails a more laborious and time-consuming approach with limited control of root movements. The obtainable movements for this type of system are primarily tipping and mild de-rotatory movements.

1.6.2 Force-Driven System

With aligner systems utilising this mode of action, the tooth movement predictions are mainly accomplished with CAD-CAM systems. Algorithms play a main role and are the main driver determining the sequential tooth movements. Placement of attachments and the stages are also based on algorithmic calculations. Biomechanically, tooth movements with these types of aligners are produced by changing the shape of the aligners at every stage. Obtaining a close adaptation of the aligner to each individual tooth surface creates strategic pressure points on the surfaces in addition to those generated by the presence of attachments. Other auxiliary features such as power ridges may also enhance tooth movement.

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Types of Aligner Systems Available

2

2.1 Introduction

The increased uptake of clear aligner therapy has certainly been multifactorial. The CAD-CAM technology has rendered the delivery of aligners very tangible and eased production whilst social media and the search for more discreet solutions has fuelled this uptake further especially in adults.

In practice, there are three main types of aligners as follows:

1. Aligners manufactured by a certified company involving a doctor-to-patient interface
2. Direct-to-consumer aligners distributed directly to the patient
3. In-house manufacturing by the treatment provider

Public availability of direct-to-consumer aligners has raised concerns due to potential clinical risks of unsupervised treatment. The most notable ones amongst others are listed below:

1. Lack of caries detection
2. Development of working and non-working side interferences
3. Root resorption
4. Instability of periodontal disease
5. Loss of vitality monitoring

It is indisputable that clear aligners are more convenient and are a much more attractive orthodontic solution to patients. This is equally valid for both adults and teenagers with a better overall experience when compared to other types of orthodontic appliances. Studies have reported a lower impact on the quality of life during treatment with clear aligners when compared to fixed appliances [1]. Similarly, clear aligner therapy resulted in better pain perception by patients and overall satisfaction levels [2].

S. Abela, *Aligner Systems in Invisible Orthodontics*,
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Despite the above-mentioned positive outcomes and a better perceived outlook by patients, aligner treatment does not have the same scientific backing as other appliances. Despite being in the market for over 20 years, evidence remains sparse and of low levels. There are certainly disagreements amongst clinicians as to what type of malocclusions aligners can be successfully applied to. There are also uncertainties with regard to their efficiency, efficacy of tooth movements and cost-effectiveness. Doubts also remain with regard to the predictability of the clinical outcomes and the real-life replication of the software's 3D prediction.

Aside from the fact that patients' compliance is key to successful outcomes, it is well-known that aligners are not very efficient at specific types of tooth movements. The latter include de-rotatory movements, transverse expansion, management of deep bites, root movements and movement of diminutive teeth and teeth with very short clinical crowns [3–5]. These are the same reasons that overcorrections and a combination approach involving both aligners and fixed appliances are frequently recommended. Evidence has only been very recently emerging about the possible use of aligners for more complex cases involving extractions. A trial comparing clear aligners to fixed appliances showed no significant differences in post-treatment Peer Assessment Rating (PAR) scoring nor treatment duration [6].

2.2 Clear Aligners Available

The clinician has now got almost an endless list of brands of aligners to choose from. This chapter intends to describe the most notable of aligner brands; however, it can neither be exhaustive nor be fully comprehensive as brands are continuously innovating their own products launching new aligners and new brands are also being formed in a continuously evolving market. The process commences with the type of aligner selected for use. The classification used, similar to how they have been classified in the section above will be based on the mode of delivery to the patients.

2.2.1 Aligners Manufactured by a Certified Company Involving a Doctor-to-Patient Interface

In alphabetical order, the brands producing these types of aligners include the following:

- 3 M™ Clarity Aligners by 3 M Minnesota, USA
- Accusmile® by Forestadent, Pforzheim, Germany
- Alineadent Aligners by Alineadent, Malaga, Spain
- Angelalign by Angelalign Technology, Inc., Shanghai, China
- CA® Clear Aligners by Scheu-Dental GmbH, Iserlohn, Germany
- ClearCorrect by Straumann Group Basel Switzerland
- eXceed aligners, by eXceed®, Witten, Germany
- EZ-X by DynaFlex®, Missouri, USA

- F22 Aligner by Sweden & Martina, Padua, Italy
- Invisalign by Align Technology, Inc., California, USA
- iROK™ Aligners by iROK™ Digital Dental Studio, California, USA
- K Clear and Clear X by K Line, Düsseldorf-Benrath, Germany
- Nuvola® Clear Aligners by GEO Srl, Vicenza, Italy
- Refine® by TP Orthodontics, Indiana, USA
- Reveal® by Henry Schein, New York, USA
- SLX™Clear Aligner System by Henry Schein, New York, USA
- Smart Moves® by Great Lakes Dental Technologies, New York, USA
- Spark by Ormco™, California, USA
- SureSmile® Dentsply North Carolina, USA
- TwinAligner® Orthocaps System by Rocky Mountains, Indiana, USA

2.2.2 Direct-to-Consumer Aligners Distributed Directly to the Patient

In alphabetical order, the brands producing these types of aligners include the following:

- AlignerCo, New York, USA
- Byte® Aligners, California, USA
- Candid™ Aligners, New York, USA
- NewSmile™ Aligners, Vancouver, British Columbia
- Smile Direct Club™ LLC, Tennessee, USA

2.2.3 In-House Manufacturing by the Treatment Provider

3D printing, over the years has been consistently improving and nowadays has also become available to mainstream businesses including dentistry and orthodontics. The advantages of adopting in-house 3D technology to manufacture aligners is threefold:

(i) Reduced delivery time
(ii) Cost-efficiency
(iii) Implementation of a skill-mixed team
(iv) Item customisation
(v) Design variation

An array of various materials is now available to clinicians who opt to produce aligners in-house. These include stereolithographic materials, epoxy resins, glass-filled polyamides, polylactic acid, acrylonitrile-butadiene-styrene and photopolymers amongst others [7].

2.2.3.1 Pre-printing Process

The initial process invariably starts with a Computer-Aided Design (CAD) model that is obtained after the acquisition of an intraoral scan. This is subsequently modified with the use of a compatible software to the 3D printer which in turn is exported in Standard Tessellation Language (STL) or Object (OBJ) file-readable formats.

Some 3D printers use a laser to cure liquid resin into a hardened form whilst others fuse small particles of polymer powder at high temperatures to build parts. Most users of 3D printers allow them to run unattended until the print is complete. More complex printing machines can also refill the tanks with the necessary material.

2.2.3.2 Post-printing Process

Once the printing of the model has been completed, depending on the type of printer and materials used, several steps would still be needed to attain the final model. The printed parts may require the following:

- Rinsing in alcohol to remove any excess and/or uncured resin from the surfaces
- Further curing to stabilise the mechanical properties
- Manual trimming of the model to eliminate support structures
- Cleaning of the final model

2.2.3.3 Types of Printing Processes

The three most readily accessible types of 3D printers for plastics used for aligner production are as follows:

- Stereolithography (SLA)
- Selective laser sintering (SLS)
- Fused deposition modelling (FDM) also referred to as Fused filament fabrication (FFF)

Both SLA and SLS 3D printers use lasers. In the case of SLA printers, the laser is used to cure liquid resin into hardened plastic in a process called photopolymerisation, whilst in SLS 3D printers the laser is used to sinter small particles of polymer powder into a solid structure.

In the case of FDM/FFF, 3D printers work by extruding thermoplastic filaments through heated nozzles and layering down each level incrementally until the production is completed.

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Aligner Treatment Process

3

3.1 Introduction

Any aligner treatment journey partaken by a new patient should be a standardised process, and the pathway should be extremely similar between different patients. The recommended initial step is an initial consultation and evaluation followed by a full dental examination. This is closely followed by acquisition of dental records and the submission of a full prescription by the treating clinician. The patient should be given the opportunity to accept or refuse the proposed treatment via a consenting process. Once the above steps are completed, the clinician will be able to proceed with the submission of the case online, provide treatment, monitor and provide retainers at the end. This chapter will provide an insight into the individual steps involved in an entire treatment journey from start to finish. A greater emphasis is placed on the records part of the journey due to the importance of this phase of treatment.

3.2 The Treatment Journey

The difference between patients' treatment journeys should be negligible or vary minimally if at all. The flow diagram illustrated in Fig. 3.1 demonstrates the entire pathway for a new patient consisting of 11 individual stages.

3.2.1 New Patient Consultation and Evaluation

The first step is a consultation between the treating doctor and the potential new patient. Establishing the complexity of treatment and the possibility of aligner treatment is a fundamental step in initiating the process. Online evaluation tools are available by the aligner manufacturers to support the clinicians' with their decision-making with regard to the grading of complexity of a case.

S. Abela, *Aligner Systems in Invisible Orthodontics*,
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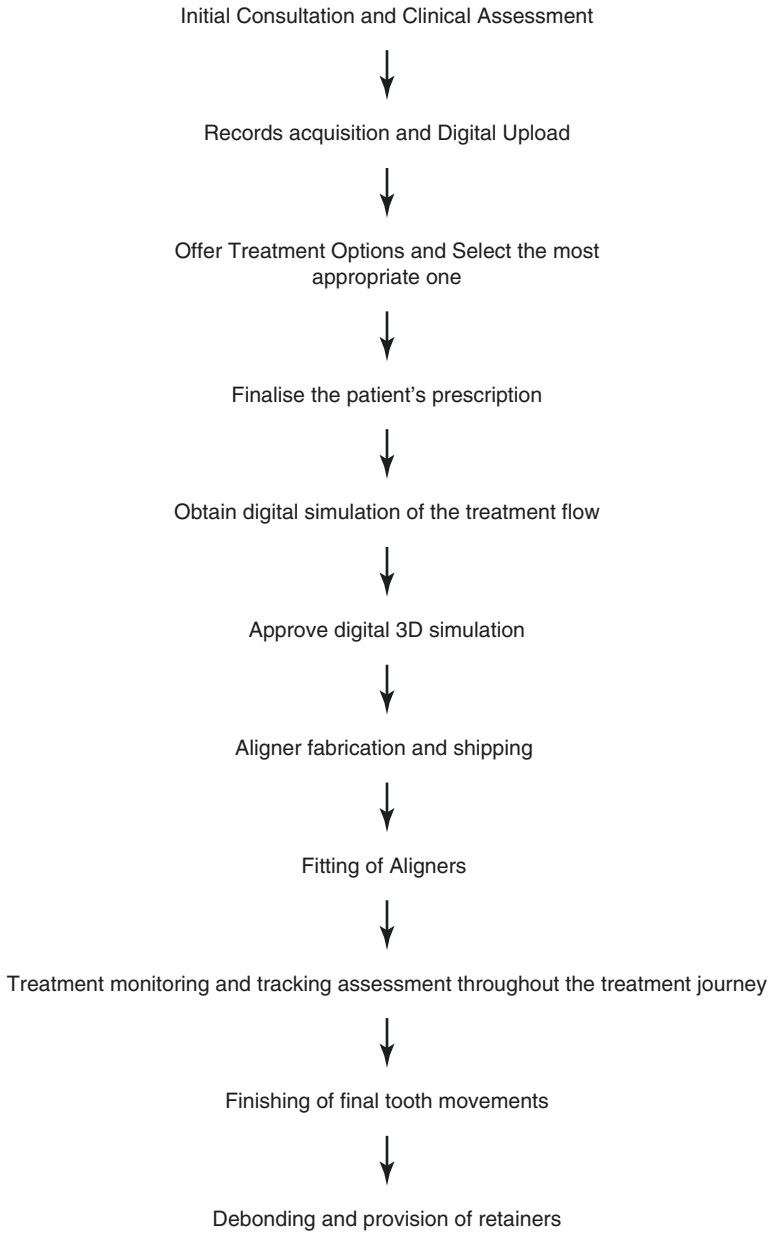

Fig. 3.1 Flow diagram depicting the entire patient journey for aligner treatment

In the case of Align Technology, Inc. (San Jose, Calif., USA) a colour scheme is used to help users differentiate between the different complexities of tooth movement involved; green for simple treatments with very predictable outcomes, blue for

moderately difficult cases with variable predictability and black for the least predictable cases with very difficult tooth movements.

3.2.2 Processes Involved for Obtaining and Uploading the Records

The dental records involves obtaining three different aspects of the patient's dentition under examination:

1. Dental impressions for the upper and lower arches
2. Photographic records including extra- and intraoral photographs
3. Dental radiographs

3.2.2.1 Dental Impressions

The purpose for the dental impressions at the beginning of treatment is twofold: study models (SM) and working models (WM) fabrication. Alginate is the impression material classically used for study model production; however, the working models need to be obtained from polyvinyl siloxane (PVS) impression material in heavy body and wash forms. The technique also referred to as putty-wash impression can be obtained as one-stage or two-stage. For most aligner systems, a two-stage approach is preferred. The spacers can be either pre-fabricated or made chair-side allowing at least 2 mm clearance for the wash. The PVS material provides excellent tear strength, maintaining integrity on removal, stability long term and as a result produces a more precise type of impression eliminating remakes. The impressions are then processed by Aligntech's scanners converting them into a digital format with a three-dimensional imagery of the teeth. The format commonly used is Standard Triangle Language (STL) which in turn would need a software package to handle the raw data of the STL format rendering them more user friendly.

Align® provides the clinicians with their own approved impression trays. The sizes available on order are small, medium, large and extra large. The sizes are denoted as S, M, L and XL, respectively, on the tray handle and are all perforated.

3.2.2.2 Digital Dental Scanning

Intraoral scanning is a contemporary way of obtaining arch recording and has modernised impression-taking techniques. It is an alternative to conventional dental impressions with Align Technology, Inc., offering their own brand of intraoral scanners, the iTero scanner range. They currently have the following range of digital scanner products:

- iTero Element Plus Series
- iTero Element Flex
- iTero Element 2
- iTero Element 5D

The scanning process involves the following stages:

- Creating a new patient prescription
- Ensuring a good ergonomic set-up
- Using the correct scanning technique
- Following the recommended scanning protocol
- Utilising the corrective tools available
- Completing the recommended checklist
- Submission of a new case with the appropriate prescription
- Using the 3D viewer to enhance the user's interface

The scanning process is initiated by the user logging into *MyiTero.com* and opening the dashboard allowing the selection of the "New Scan" icon on the screen. A new navigation toolbar appears with four options:

1. To create a new treatment (new patient) or open an existing treatment (existing patient)
2. To enable commencement of scanning
3. To evaluate the scan obtained
4. To send the scan for processing by Align Tech, Inc.

The start of a new treatment entails entering the patient details into the respective fields specifying whether Near InfraRed Imaging (NIRI) is to be used, the type of case being submitted and the lab that the scan should be sent to in case the practitioners is using it for restorative treatment.

In addition, the treatment stage should also be specified. A case is usually considered as a start, mid-treatment or at a final stage where final records are being registered.

The scanning technique should include the entire arch starting from the terminal molar of either side reaching the midline before starting the contralateral side. The scanner head should be rolled from the lingual to the buccal side. Finalisation of the arch should be completed in the anterior region by rolling over the incisors from the lingual to the buccal side similar to the molar region. The "rolling" technique entails the clinician to shift the wand over the occlusal surface from a lingual to a buccal direction maintaining contact with the surface of the tooth at all times to complete the image successfully. In case soft tissue capture is needed, the initial capture should start directly posterior to the central incisors progressing further posteriorly. The intersection between the midline and the dentition should be completed by applying the scanner from the midline to the palatal aspect of the teeth. The soft tissue capture obtainable is clinically useable with evidence available supporting this [1]. On completion of this process for both arches, the clinician should register the scan by obtaining the patient's bite registration. This is captured by asking the patient to replicate the intercuspal position (ICP), and the scanner is placed in the upper and lower premolar region bilaterally and applying a wave-like motion perpendicular to the dentition. In case of multiple bites such as when a functional

appliance is needed, this is also possible. The viewing display will annotate the first and second bites as "Both 1" and "Both 2." The clinician has the facility to monitor the time taken to scan and obtain bite registration and also have the deficient areas of the scan highlighted in purple. In case of an oversight where an arch has been missed, a warning message stating "Additional Scans Expected" is also very obvious in the middle of the viewer impeding the clinician from progressing to the next stage. This is very similar in case the bite registration has been overlooked or if a discrepancy between the two sides is detected.

The minimal requirements for acceptance of a scan are as follows:

- An extension of 2 mm gingival tissue scan beyond the zenith of the tooth.
- The entire tooth surface has to be scanned without any deficiencies including the incisor surfaces and occlusal surfaces for the buccal segments.
- The scan should extend to the distal aspect of the terminal tooth (that is the second or third molar).
- An accurate bite registration with the patient in ICP.
- Completion of prescription with all essential details required registered accurately.

Once the capture is completed the clinician has the possibility of correcting and modifying the captured scans before submission. A "fill" option highlights the deficient area by highlighting it and allowing a rescan to "fill" the void. In case of irregularities arising from problems with excessive gingival tissue or gingival exudate, an "Eraser" icon allows this area to be erased to improve the captured image. Another feature is the "Edge Trim" tool which allows for removal of unwanted areas by using a scissors icon. The user also has the facility to delete a section or an arch to be able to rescan it by choosing the "recycle bin" followed by the "broom" icon to control the selected area and once the area is confirmed for deletion, an improved scan will replace the rejected part or arch. Another potential error that can be easily rectified is the bite registration in ICP. Once noticed, by observing the number of contact points within the arch, the user can retake the bite registration.

On submission, the case is available on the Invisalign doctor site after 15 min and is also available on the 3D viewer on the original scanner and on MyiTero.com.

One final option available to the clinician prior to the submission is showing the potential new patient his or her final result by running the Invisalign® Outcome Simulator (IOSim).

3.2.2.3 Dental Photographs

Photographs are also an essential part of record taking. Extra- and intraoral photos are normally taken in order to have a baseline reference to be able to monitor progress during the treatment.

Two options are available for extraoral photographs; Two-dimensional (2D) or three-dimensional (3D). The latter can be used for radiographic superimposition and to establish treatment predictions and soft tissue effects, postoperatively. Intraoral photographs are taken to monitor the tooth movement.

At the start of the treatment, a set of eight photographs is usually the recommended amount; however, nine is also acceptable with the addition of a three-quarter facial view. The reason for taking this photo is that most times, patients are seen by this view rather than at full profile. The set of pre-operative photographs would consist of four extraoral and five intraoral types.

The extraoral photographs needed are:

- Frontal
- Frontal smiling
- Three-quarters view (optional)
- Full profile view

The intraoral photographs needed include:

- Frontal
- Right buccal
- Left buccal
- Upper occlusal view
- Lower occlusal view

Figure 3.2 below is a template showing the ideal mounting of the extra- and intraoral photographs.

Align Technology, Inc. have a downloadable mobile app, Invisalign Photo Uploader which is directly linked to the individual doctor's online platform. This allows clinical usage of the app via the doctor's mobile with automated features and step-by-step instructions on how to use it successfully.

3.2.2.4 Dental X-Rays

X-rays are primarily used for diagnostic purposes. The commonly used X-rays include:

- Periapical radiographs
- Orthopantomogram
- Lateral cephalogram
- Cone beam computed tomography

Periapical radiographs offer excellent diagnostic value. They are very useful in diagnosing dental pathology, bone levels and give an accurate dimension of root lengths. They are not affected by the focal trough and exhibit no distortion in the labial segment region. They can also be taken to determine the precise location of unerupted teeth using the "SLOB" principle' with the describe the parallax technique, an acronym that stands for same lingual and opposite buccal with specific reference to the X-ray tube shift in relation to the ectopic tooth on the image.

Orthopantomograms (OPGs) are advantageous when a general overview of the dentition is needed and for an assessment of the dental development when patients

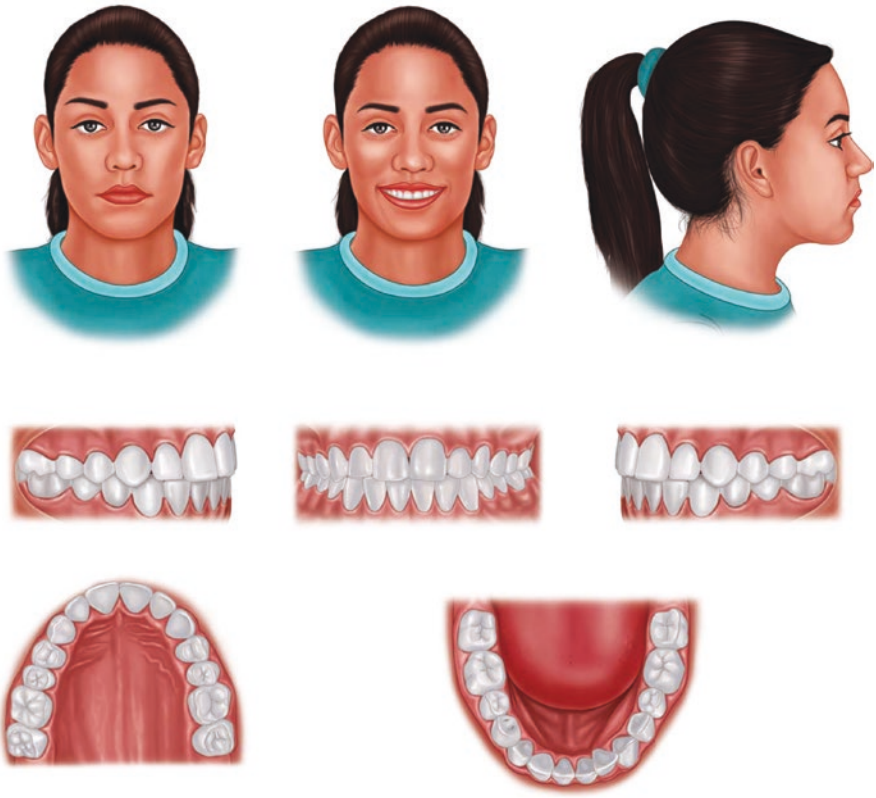

Fig. 3.2 A photographic template showing the ideal mounting of the extra- and intraoral photographs

present in a mixed dentition stage. Although they are not indicated to diagnose decay, carious lesions can also be identified on OPGs. This is indicated in most cases before the start of treatment.

Lateral cephalograms are used to provide an assessment of the skeletal base relation together with the labio-lingual positioning of the incisor teeth to enable precise planning of the tooth movements required. A secondary indication includes the localisation of unerupted teeth.

Cone beam computed tomographs (CBCTs) are fully justified when they are used to augment the diagnostic capability of 2D radiographs. The scope of CBCTs can be fully justified for cases presenting with impacted canines with or without incisor root resorption, impacted teeth close to important oral structures, supernumerary teeth and complete or incomplete alveolar bone clefts.

The specific indication for each type of X-ray can be found in the fourth edition of The Guidelines for the Use of Radiographs in Clinical Orthodontics. The last update was completed in 2015 [2].

3.2.3 Invisalign Product Range

The treating clinician has to be very familiar with the products available for the patient and to be able to choose the product which best suits the patient. The product selected can be for active treatment with an aligner package or passive with Invisalign-designed retainers, Vivera® retainers.

Align Technology, Inc. provide the following the range of aligner products:

1. Express Package consisting of seven consecutive aligners with one additional set of seven aligners to compensate for lack of tracking. The treatment activity duration is 1 year.
2. Lite Package consisting of 14 consecutive aligners with two additional set of 14 aligners included to compensate for lack of tracking. The treatment activity duration is 2 years.
3. Moderate Package consisting of 20 consecutive aligners with two additional sets of up to 20 aligners. The treatment duration is 2 years.
4. Comprehensive Package consisting of as many aligners as needed to reach a clinically acceptable result with additional aligners included in the package until the original targeted result is obtained. The additional aligners have to be ordered prior to the treatment expiration date and the treatment duration is 5 years.
5. Invisalign Teen Package specifically aimed at correcting malocclusions in teenagers with an unlimited amount of trays accounting for mixed dentition phases and transition periods to secondary dentition. Application can start as early as mixed dentition as an interceptive treatment, during a mixed dentition phase and once the secondary dentition is established.
6. Vivera® retainers are the only available retainers by Align Technology, Inc. with claims by the company that they are a third stronger, twice as durable and the patient in the United Kingdom is provided with three sets per jaw to provide long-term retention and have spare retainers at hand in case of loss. They are manufactured using similar 3D imaging and proprietary thermoplastic materials as the aligners.

3.2.3.1 Invisalign Protocol for Placement Hierarchy

The ClinCheck Pro® 6 has a placement prioritisation which is based on the type of individual tooth movement needed. The clinical features presented to the clinician and in turn captured by the software, triggers a cascade of movements based on chronological clinical prioritisation. This allows the software to place the features to obtain movements of the highest importance first followed by those which are less important.

The list of placement in chronological order is as follows:

1. Movement in extraction cases and/or multi-tooth optimised extrusion
2. Root control movement
3. Multi-plane movement such as rotation with or without intrusion or extrusion
4. Extrusion with or without de-rotational movements
5. Optimised support for retention or anchorage for intrusion movements
6. Power ridge feature for Lingual Root Torque (LRT)