Automated custom-manufacturing technology in orthodontics

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The ability to consistently fabricate dimensionally accurate, custom-made, removable orthodontic appliances in large quantities is a manufacturing challenge that has only recently been met through advances in scanning and automation technology. The production of the Invisalign orthodontic appliance[1-8] (Align Technology, Inc, Santa Clara, Calif) is a complex process that uses innovative solutions to accurately and efficiently fabricate orthodontic appliances.

Most removable orthodontic appliances, including retainers and positioners, are made from plaster reference models; individual teeth on these models can be manually sectioned and repositioned with wax.[9] An orthodontic product like Invisalign requires from 6 to 40 sequential appliances per arch; manual fabrication of this many appliances would be prohibitively expensive, and it would be difficult to maintain the required accuracy.

Instead, Align Technology uses stereolithography technology to create its reference models, making the orthodontic industry the first to bring on-demand digital manufacturing to commercial production. Each set of aligners begins with a series of positive plastic resin models made from photoactivated polymer. From these plastic resin models, clear removable appliances (aligners) are made, each corresponding to a 2-to-3 week interval of treatment. Unique to the Invisalign process is the ability for the clinician to view, modify, and approve the actual arrangement of all appliances before they are fabricated.

Before any of this can happen, the patient's polyvinyl siloxane (PVS) impressions and bite registration must first be converted into dimensionally accurate 3-dimensional electronic study models. Scanning techniques have evolved over the years, from the relatively simple laser scan to complex computed tomography (CT) scanning.

In a laser scan, a positive model is first created, and laser light is then reflected from the surface of the model. The resulting scatter pattern is captured by an optical sensor, and the original shape is reconstructed with mathematical algorithms. Laser scanning is relatively inexpensive, but the process is slow, and the resolution is limited to about 300 microns. Only 1 object can be scanned at a time; this limits the number of models that can be processed per day. Laser scanning cannot be used to accurately scan impressions directly, because undercuts in the impression create hidden surfaces that are inaccessible by the laser beam.

In a destructive scan, a positive model is created and encased in a contrasting urethane resin. Paper-thin slices of the encased object are incrementally removed by a computer numerical-controlled machine cutter. After each increment is removed, a digital picture of the exposed area is captured. The scanned layers are electronically combined to recreate the original geometry. Destructive scanning technology is accurate to about 50 microns, but the object is destroyed in the process (hence the name). The preprocessing step (encasing) can be messy, but many objects can be encased together and scanned at once for efficiency. Impressions and bite registrations are not typically scanned directly because (1) rubbery materials such as PVS are difficult to slice cleanly in the scanner, (2) the wide variety of PVS colors available makes calibration difficult, and (3) the destructive process allows only 1 chance to correctly acquire the scan.

A white-light scan is similar to a laser scan, but white-light interference patterns (moiré patterns) are reflected instead of laser light; this improves resolution

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Editor's note: Although this article focuses on techniques used by Align Technology, several other companies rely on scanning technology, including Cadent (OrthoCAD, Fairview, NJ), Geodigm (eModel, Chanhassen, Minn), Orametrix (Sure Smile, Dallas, Tx), and Ormco (Insignia, Orange, Calif). We hope that this explanation of how one company used CT scanning and robotic cutters will help readers to evaluate other systems that use scanning of dental arches in their processes.

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Am J Orthod Dentofacial Orthop 2003;123:578-81
Submitted and accepted, December 2002

0889-5406/2003/$30.00 + 0
doi:10.1016/S0889-5406(03)00051-9

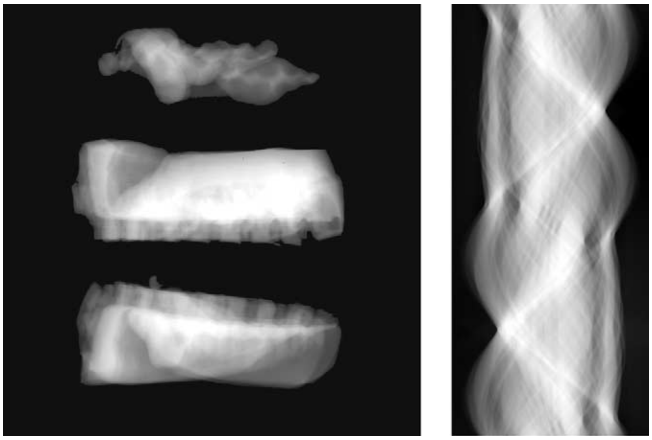

Fig 1. A, CT-generated radiographs of PVS bite registration projected onto stone model (*top*), upper PVS impression (*middle*), and lower PVS impression (*bottom*); **B**, sinogram.

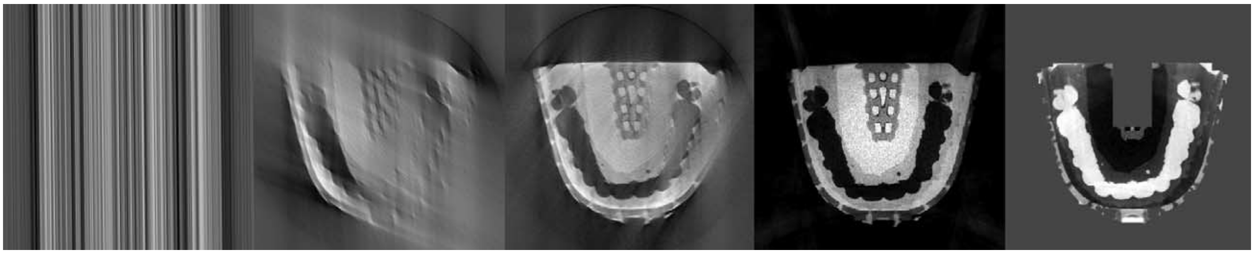

Fig 2. Frames of 116 μm-slice reconstruction from sinogram: (left to right) initial, early, late, final, and final inverted.

and reduces scan time. Direct line-of-sight of all surfaces of the object is still required for accuracy, so a plaster model must first be made.

In a CT scan, a series of digital radiographs of the object is captured, and the images are electronically processed to generate an extremely detailed 3-dimensional reproduction of the object. The scanner can scan both stone models and impressions (if the tray is not steel or other high-density material), because any undercuts are completely visible to the scanner. Many objects can be scanned at once for maximum efficiency. PVS bite registrations can also be scanned.

CT impression scanning is the preferred method because of its speed and accuracy. To create a virtual dental model directly from the impression with CT scanning, the impression is mounted on a platform that rotates in front of an amorphous silicon x-ray sensor (HYTEC, Inc, Los Alamos, NM). Hundreds of digital radiographs of the impression (Fig 1) are captured as it rotates 360°. These radiographs are converted to images called sinograms (Fig 1, *B*), which represent the data from a horizontal line of the detector as the part rotates. A 16 central-processing-unit fiber-optically linked computing cluster uses the sinograms and a series of mathematical algorithms to create 116-micron thick reconstruction slices of the object (Fig 2). These slices are stacked electronically and inverted, and the resulting surface is smoothed to yield a raw electronic study model (Fig 3, *A*). The maxillary digital model is electronically registered to the mandibular digital model in centric occlusion (maximum intercuspation). The raw electronic models are "detailed" by using software that simulates standard dental lab procedures, such as bubble removal, void filling, and gingival-line definition. The teeth are then electronically separated with an algorithm that recognizes interproximal embrasures and gingival lines around each tooth. Computer-modeled gingiva is placed around the cut teeth (Fig 3, *B*), and landmarks such as the facial axis of the clinical crown[10] of each tooth are identified (Fig 3, *C*). The technician then moves the teeth to the desired location, according to the doctor's prescription.

Upon the prescribing clinician's approval of the diagnostic setup and the treatment animation (staging), each stage of treatment is converted into a physical model with a machine called a stereolithography appa-

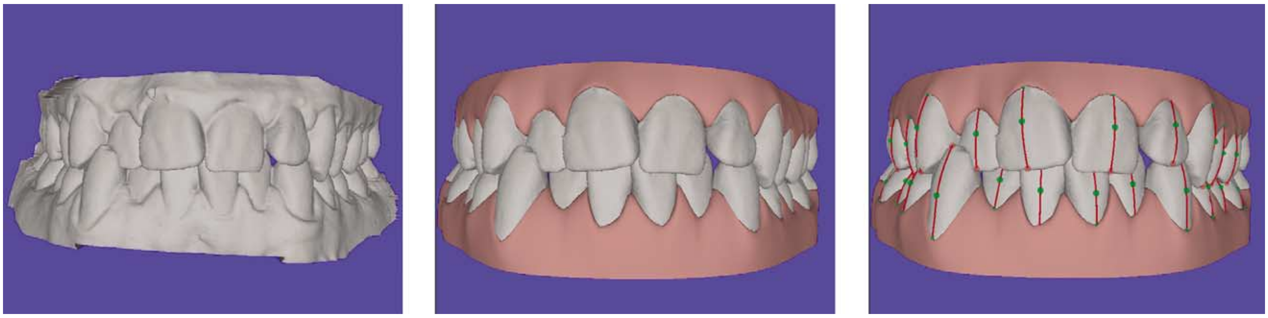

Fig 3. A, Raw registered model; **B**, detailed model with gingiva; **C**, with facial axis of clinical crown lines added.

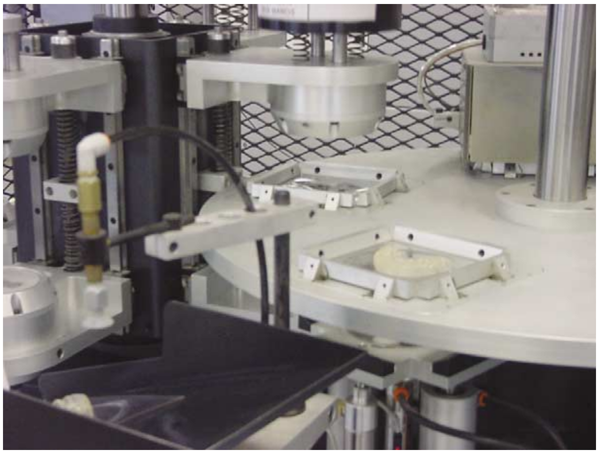

Fig 4. Automated aligner former.

Fig 5. Conveyor to robot (*yellow*).

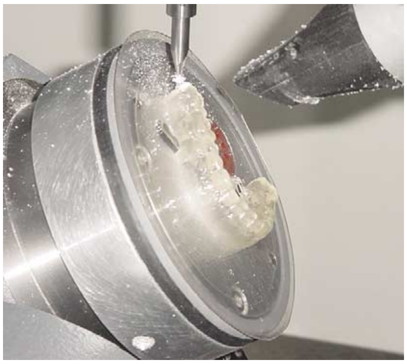

Fig 6. Automated aligner cutter.

ratus (SLA). These SLA resin models are loaded into an automated aligner-forming system (Fig 4) that heats, forms, and laser-marks sheet plastic over each plastic model. These parts are transported on a conveyor belt to a robotic arm (Fig 5) that loads each part into an automated cutting machine for trimming (Fig 6). Automation enables aligner trimming to be completed in less than 30 seconds. Once trimmed, the part is ejected, and the aligner is separated, polished, disinfected, and packaged for shipment to the customer.

The benefits to the clinician of direct impression scanning and automated aligner fabrication can be significant. By eliminating the plaster model step, turnaround time is improved, and the opportunity to introduce distortion and error into the process is reduced. Automation means that appliances can be made very quickly in a repeatable, consistent fashion; this is important, for example, in case of a lost or broken aligner. However, the sophisticated manufacturing technology behind the Invisalign appliance is not intended as a substitute for careful diagnosis and treatment planning. As with any other appliance, success depends on sound understanding of the device's strengths, limitations, and applicability to each patient's malocclusion.

The authors thank the staff at Align Technology, Inc, and HYTEC, Inc, for their technical support with this article.

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