

ALIGNER CORNER

This new JCO column is compiled by Contributing Editor William V. Gierie, DDS, MS. Every few months, Dr. Gierie will introduce a pertinent article related to clear aligner therapy. Your suggestions for future topics or authors are welcome.

Clear Aligner Therapy: An Overview

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Digital clear aligner therapy (CAT) began in earnest when Invisalign became commercially available in 1999. Few in the orthodontic industry realized what an explosion of interest aligners would create and how many other companies would scramble to en-

ter this space. Several dozen companies around the globe are now manufacturing aligners, with the number increasing every year. Other companies are providing in-house aligner platforms so that orthodontists can create practice-branded aligners to distribute to patients. Combine this with such direct-to-consumer approaches as Candid, Smile Direct Club, Smilelove, and Snapcorrect, and interest in CAT has never been higher.

Having paved the way for this treatment revolution, Invisalign is the dominant player in terms of brand recognition, research and development, manufacturing, training, and sales. It is unclear whether any of the competing companies or modalities will have a significant impact on the CAT market. Most likely, a rising tide will raise all boats, and the CAT industry will grow to penetrate segments of the market that have not previously sought orthodontic services.

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Types of Clear Aligner Therapy

Clear aligners can be either analog or digital. Analog CAT involves a physical model that is modified either by resetting the teeth or creating divots and voids in the model prior to vacuum-forming the aligner. Digital CAT starts with a three-dimensional scan of the dental arches, an impression, or a plaster model. All tooth movement is performed digitally, and the trays are fabricated from a series of 3D-printed models. Digital CAT has several advantages over analog CAT and is required for any corrections beyond mild spacing or crowding.

No company has yet offered a directly 3D-printed aligner, but that is the next evolution of CAT. Indeed, Dr. Sherif Kandil, founder of K Line Europe, stated in a July 11, 2018, interview that K Line could introduce 4D-printed aligners as early as 2019. Dr. Kandil holds a patent for 4D printing in orthodontics and is applying this technology in his research and development labs in Düsseldorf, Germany. The prospect of being able to directly print aligners whose properties change when they are introduced to saliva and heat in the oral cavity is an intriguing one.

Same-day aligner delivery will soon be made possible by quick digital scans coupled with artificial intelligence-driven digital tooth setups that can be modified and approved by the clinician in an interactive diagnostic exercise with the patient. This will allow truly customized, patient-centric treatment planning. Once consumers get a taste of same-day aligner delivery, they will gravitate to companies and orthodontic practices that can provide such a service. That is the future.

In the present, however, many of the major orthodontic companies, who have the advantage of large existing customer bases, have launched or will soon be launching CAT products. The following overview is not meant to be exhaustive, but to cover the principal players in the U.S. market, along with some notable providers based in Europe. The descriptions and accompanying tables are based on information supplied directly by the companies or from their websites. I have purposely omitted any direct-to-consumer operation in which the patient does not consult with a doctor face-to-face.

Align Technology

Invisalign is the juggernaut of the CAT category, with a 35% share of the adult orthodontic market and a 5% share of the teen orthodontic market, based on a second-quarter 2018 corporate fact sheet. More than 6.1 million people, including more than 1.4 million teens, have been treated with the Invisalign system, according to a third-quarter 2018 financial report. Still, the recent launches of numerous companies aimed at assisting doctors with in-house aligner fabrication seem likely to challenge Align Technology's business model.

Align has invested heavily in research and development, continuing education, and marketing. Several of its innovations, including SmartTrack aligner material, SmartForce features, optimized attachments, Invisalign First, mandibular advancement, and one-week aligner changes, have enhanced CAT development and acceptance. Invisalign is essentially a closed manufacturing system, with treatment-planning tools provided to the doctor through ClinCheck Pro. With the 2011 acquisition of scanner manufacturer iTero, Align has been able to drive the development of scanner technology such as the Invisalign Outcome Simulator, which allows the doctor to demonstrate simulations and modify treatment plans with real-time patient input.

ClearCorrect

ClearCorrect was founded in 2006, making it one of the earliest CAT suppliers. In 2017, the company was acquired by the Straumann Group for \$150 million. Although the majority of ClearCorrect's customers are currently U.S. general dentists, Straumann's international footprint will likely mean global expansion. ClearCorrect already operates in Canada, Europe, Israel, Australia, and New Zealand.

ClearCorrect offers either an Unlimited option that includes all aligners, revisions, and retainers for five years or a Flex option in which the clinician pays per aligner. Interproximal reduction (IPR) is allowed, and attachments called "engagers" can be designed through the web-based treatment portal. The greatest drawback I see in the

TABLE 1
GENERAL INFORMATION

Company	Name of Aligner	Time on Market	Prospective Patients	No. Patients Treated
Align Technology	Invisalign	Over 20 years	Adults, teenagers, children	More than 6 million
ClearCorrect	ClearCorrect	12 years	Adults, adolescents, children	Not available
Dentsply Sirona	SureSmile Aligners	One year	Adults or teenagers	More than 50,000
Dynaflex	EZ-Align	More than 10 years	Adults or teenagers	"Thousands"
eXceed Technologies	eXceed Aligners	Five years	Adults or adolescents	About 20,000
Forestadent	Accusmile	Three years	All patients	"Thousands"
Great Lakes Dental Technologies	smart moves	Nine years for smart moves classic; smart moves complete just launched	Patients in permanent dentition	"Hundreds"
K Line Europe	K Clear*	Four years	All ages (average age 8)	More than 30,000
Rocky Mountain Orthodontics	orthocaps Twin Aligners	12 years in Europe; just launched in U.S.	Adults	More than 30,000
Henry Schein Orthodontics	SLX Clear Aligners	One year	Patients in permanent dentition, regardless of age	More than 50,000
Scheu-Dental	CA Clear Aligners*	11 years for Clear Aligner analog, six years for Clear Aligner digital; Clear Professional just launched	Adults or adolescents	More than 250,000
3M	3M Clarity Aligners	One year	All patients	In clinical trials for many years
TP Orthodontics	Refine Complete Aligner System	Several years	Adults or teenagers	"Thousands"

*Not available in United States.

software is the inability to make changes to the digital setup without working through a technician. This was one of the most frustrating aspects of Invisalign prior to the introduction of 3D controls.

Dentsply Sirona

According to Dentsply Sirona's website, the **MTM Clear Aligner** "is designed to treat the

common minor anterior misalignments." The system is available as an in-office option or a Service Center (turnkey lab) version focusing on the "social six" anterior teeth. MTM Clear Aligners use "open pathways" (blocked-out areas) and "force points" (pressure points or dimples added with pliers in the office) but no attachments. There is no limit on the initial number of aligners per case; one refinement or course correction is included.

TABLE 2
DIAGNOSIS AND CASE SUBMISSION

Company	Software	Procedure	Required for Submission	Optional for Submission
Align Technology	ClinCheck Pro	Technicians create 3D setup according to prescription and records; doctor approves or modifies using 3D controls and digital tool or communicates changes to technician	Prescription form, patient photos, physical impressions or intraoral digital scan	Radiographs
ClearCorrect	ClearComm portal	Technicians create setup and online animation according to prescription; doctor communicates changes to technician	Polyvinyl siloxane impression or STL file, clinical photographs	–
Dentsply Sirona	SureSmile Aligner	Technicians create setup according to prescription; doctor can modify or submit changes to technician	Intraoral STL file, diagnostic photographs	Cephalogram
Dynaflex	Treatment Review	Doctor submits requests, and technicians make changes (direct modification by doctor in development)	Prescription, digital scan or working models or impressions	Intraoral and facial photographs, panoramic or periapical radiographs, cephalograms or analyses
eXceed Technologies	eXceed Lab	Doctor reviews treatment plan in cloud-based 3D viewer or in standalone program; experienced user can make adjustments	STL file in occlusion, facial and intraoral photographs, panoramic radiographs, treatment objectives	–
Forestadent	OnyxCeph	Doctor can modify treatment plan or ask lab to adjust	STL file in occlusion	–
Great Lakes Dental Technologies	Smart moves portal	Case submitted and simulation reviewed through cloud-based portal or by phone; change requests submitted to U.S.-based technician	Intraoral scans or polyvinyl siloxane impression, panoramic radiograph, intraoral and facial photographs	–
K Line Europe	klineportal.com	K Line doctors create treatment plan according to submitted records and comments; doctor can comment on initial plan	3D scan, silicone impression, clinical photographs, radiographs, bite registration	–
Rocky Mountain Orthodontics	i-Setup	Doctor can modify treatment plan or ask technician to adjust; specific prescriptions (such as Roth) can be requested	Intraoral scans, radiographs, photographs	–
Henry Schein Orthodontics	DDX SLX Approver portal	Technicians create setup; doctor can modify by requesting changes through Approver	Patient photographs, STL file	–
Scheu-Dental	CA Digital Treatment Manager portal	Technicians create setup according to choices made on website and patient records; doctor can comment during approval process	Intraoral STL file or plaster model or polyvinyl siloxane impression	Radiographs, photographs
3M	Tx Designer (TxD) Oral Care portal	Doctor can modify treatment plan or ask technician to adjust	Intraoral STL file, patient photographs	Digital scans of both arches, left and right bite scans, polyvinyl siloxane impression
TP Orthodontics	TPRX portal	Technicians create setup according to prescription and send to doctor for review (doctor can request changes) and approval	Prescription, digital scan or working models or polyvinyl siloxane impressions	–

Dentsply Sirona announced that it had acquired OraMetrix and **SureSmile** software in March 2018. SureSmile's cloud-based 3D software, which the company has been refining for more than 15 years, can link cone-beam computed tomography (CBCT) with a 3D model from the intraoral scan to provide a true biological picture of the root structure. The software allows the doctor to place labial or lingual attachments and to move teeth in all planes of space, with automated staging of tooth movement. The 3D models can be printed in-house, exported to a commercial lab, or printed by SureSmile for aligner fabrication.

According to the Dentsply Sirona brochure, SureSmile aligners are "ideal for cases requiring moderate tooth movement." Packages include a Complete setup with unlimited aligners for as long as three years, or a Select system in which aligners are purchased as needed.

Dynaflex

In the Dynaflex **EZ-Align** system, the clinician views a digital setup on the web-based Treatment Review software. The EZ-Align aligner plastic, called FasTrac, was designed for strength, stain resistance, and ductility, according to the company. IPR and attachments are allowed, but changes must be requested from a technician.

Dynaflex Complete, aimed at moderate to comprehensive cases, includes as many as 20 trays per arch over six years of alignment and retention. The Perfect 10 system, for moderate cases involving the premolars, includes as many as 10 trays per arch. Individual trays can also be ordered for minor anterior tooth movement. The Plus System incorporates the EZ-X Appliance for lateral expansion prior to CAT. A second impression or scan is sent after the expansion for fabrication of the aligners. EZ-X can also be used independently of the aligner systems for mixed and permanent dentitions.

eXceed Technologies

The **eXceed Aligners** system is really a treatment-planning software: eXceed Technologies provides the design and manufacturing protocols,

and offices or labs produce the models on 3D printers and vacuum-form the aligners. The appeal of this decentralized process is that it can be used without shipping, but the disadvantage is the inability to make high-quality, in-house aligners using the most up-to-date technology. The eXceed Lab software does have some interesting features, like being able to turn off the gingiva. Attachments and IPR are allowed; as eXceed's website states, "Experienced users can also change the setups themselves."

Two plans are available: Express, with as many as 20 aligners for minor tooth movement, and Light, with 21 or more aligners for moderate cases. One refinement is included. If the patient declines treatment after viewing the setup, the fee still applies.

Forestadent

Accusmile is also a digital treatment-planning service in which the practice prints the 3D models and fabricates the aligners; alternatively, Forestadent can do the printing and manufacturing. Technicians use OnyxCeph software to create the digital setups, and the doctor views these setups with Accusmile 3D software (apparently based on the Orchestrate 3D program). The website says the doctor can take over the tooth-movement planning or have a technician perform the digital setup.

Great Lakes Dental Technologies

Great Lakes' new **smart moves complete** system, designed for full-arch treatment, uses a cloud-based portal for submitting and viewing cases; alterations to the setup are made by request to the technician. Smart moves complete uses Invisacryl Ultra, which is available only in a 1mm thickness (prior to vacuum-forming). Patients may find this material more cumbersome than the typical .75mm aligner plastic. In the older smart moves classic system, designed for anterior tooth movement, the patient wears a soft and then a hard tray for a maximum of three stages.

TABLE 3
MATERIALS AND PROTOCOLS

Company	Materials	Standard Change Interval	Options
Align Technology	Invisalign SmartTrack (multilayered polymer)	One week	Full Teen Assist First Lite Express 10, Express 5
ClearCorrect	Specially formulated polyurethane plastic	Two weeks (options for one and three weeks)	Unlimited Flex
Dentsply Sirona	Essix plastics	Two weeks	Complete Select Hybrid treatment with brackets and aligners
Dynaflex	FasTrac	Seven to 10 days	Complete System Perfect 10 Individual System Plus System with EZ-X Appliance
eXceed Technologies	Recommended: .75mm Biolon (Dreve) or .75mm Duran (Scheu-Dental)	Two weeks	Express Light
Forestadent	Forestadent Track V (thickness can be changed every third aligner)	Two weeks	–
Great Lakes Dental Technologies	Invisacryl Ultra Invisacryl Hard/Soft	Two weeks	smart moves complete smart moves classic
K Line Europe	Polyethylene terephthalate glycol-modified and other additives	Two weeks (one month if extrusion or eruption guidance needed)	–
Rocky Mountain Orthodontics	Dual-layer polymer with hard outer tray and soft inner tray (thinner aligner for daytime wear, thicker for night)	Two weeks	Pro Noctis Plus Basic
Henry Schein Orthodontics	ClearWear	Two weeks	Full Treatment Light Treatment Express Treatment May be used with AcceleDent and similar devices
Scheu-Dental	CA Foils (biocompatible, thermoforming polyethylene terephthalate)	One week	CA Clear Aligner Aesthetic CA Clear Aligner Essential CA Professional
3M	Technology designed for specific applications	Varies	–
TP Orthodontics	Thermoplastic polymer	Varies	Refine Basic 5 Refine Total 10 Diagnostic only Quick-Start Option (Spring Aligner)

K Line Europe

K Line was founded in 2014; the **K Clear** aligner is available in 70 countries, not including the United States. According to Dr. Kandil, the doctor uploads the case information and reviews the treatment plan through a web-based portal. Comments can be added or the case confirmed, and the aligners are then shipped to the practice.

Ormco

Ormco uses the Insignia Advanced Smile Design software as the interface for its **Insignia Clearguide** aligners. The initial digital setup is performed by a technician, but the doctor can then modify tooth positions using the Insignia Approver program. A Heat N Bite bite-registration appliance is used for a midtreatment progress check—a rather low-tech solution with digital scanners so readily available. Each Insignia Clearguide case includes as many as 20 aligners.

Rocky Mountain Orthodontics

The **orthocaps TwinAligners** received U.S. Food and Drug Administration clearance in October 2018, although they have already been used in Europe for 12 years. Manufactured by Orthocaps in Hamm, Germany, this is a dual-layer system consisting of a hard outer tray with a soft inner tray. According to the company, the inner tray grips the teeth and expresses movement, so that fewer attachments are needed. A thinner aligner is used for daytime wear and a thicker one at night. The virtual tooth movement is performed in the i-Setup software, and the doctor can modify positions and attachments with 3D controls or by request to the technician. A unique feature of orthocaps is that the attachments come built into the aligners.

Four options are available: Pro, for comprehensive treatment; Noctis, for nighttime wear only; Plus, with 10 sets of aligners; and Basic, with five sets of aligners. Individual aligners can also be purchased.

Henry Schein

The **SLX Clear Aligner** system was launched at the 2018 AAO meeting in Washington, D.C. Henry Schein is emphasizing its philosophy of Sagittal First, which encourages clinicians to use Motion 3D appliances to correct Class II or III sagittal discrepancies prior to aligner treatment. Cases are entered through the Digital Dental Exchange DDX SLX Approver online portal. Technicians perform the digital setup, which can then be modified by the doctor.

Available options include Full Treatment, with 21-30 aligners for moderate to severe cases; Light Treatment, with 10-20 aligners for moderate cases; and Express Treatment, with fewer than 10 aligners for anterior tooth movement. One set of retainers is included.

Scheu-Dental

CA Clear Aligners are advertised as a three-splint system using three different material thicknesses. The softer trays (.5mm and .625mm) are worn for one week each, followed by the stiffer trays (.75mm) for two weeks per stage to increase pressure on the teeth over time. A unique feature is that the aligners are designed with 2-3mm of gingival coverage for improved anchorage and force transmission. The CA Smart 3D software is based on OnyxCeph 3D. Scheu-Dental will either supply the aligners or allow the clinician to outsource the digital setup and fabricate the aligners using material provided by Scheu. Based in Germany, this is one of the few CAT companies offering a training program for clinicians.

CA Clear Aligners can be ordered in one of two packages: Aesthetic for anterior tooth movement, with a maximum of five stages; or Essential for tooth movement involving the premolars, with a maximum of 10 stages and new impressions required after the fifth stage. The new CA Professional, for more complex cases, uses only medium (.625mm) aligners and a new stage every week, with intermediate impressions possible for mid-course corrections after 20 stages.

TABLE 4
AUXILIARIES AND RETENTION

Company	Attachments	Elastics	Retention
Align Technology	SmartForce attachments: Automatically placed by software, minimum movement thresholds for placement, removed at any time Conventional attachments: Variety of shapes and sizes, placed or removed at any time	Precision cuts for use of elastics, designed to eliminate need to manually cut aligners	Invisalign single- or dual-arch retainers: Purchased separately Vivera single- or dual-arch retainers: Purchased separately in sets of four
ClearCorrect	Rectangular “engagers,” horizontal or vertical and beveled occlusally; typically placed on facial surface, but lingual placement possible; placed or removed at any time	Doctor makes cuts in aligner; can also accommodate buttons	Included in Unlimited plan
Dentsply Sirona	Conventional attachments in multiple shapes and sizes, placed or removed at any time	Doctor makes precision cuts in aligners	Will provide free STL export file or 3D-printed models for small fee, so doctor can fabricate retainers
Dynaflex	Basic geometry designs, placed immediately as prescribed	Aligners cut to accommodate buttons	Included in Complete System; fee for all other systems
eXceed Technologies	Various types and shapes, placed or removed at any time	–	Print files included
Forestadent	Customizable	–	Can be ordered with final aligners; prices vary
Great Lakes Dental Technologies	Multiple designs with flexible planning	–	One set of retainers included
K Line Europe	Vertical or horizontal rectangular, beveled	Can accommodate buttons instead of elastics	Removable retainer included; custom-made polymeric retainer available for purchase
Rocky Mountain Orthodontics	Prefilled in aligners with nano-ceramic resins, placed or removed at any time; .3-.5mm friction pads also available	Company places cuts in aligners	Essix-type retainers included
Henry Schein Orthodontics	Placed for entire length of treatment	Buttons can be placed	One set of retainers included
Scheu-Dental	CA Professional: Classic horizontal or vertical squared shapes, placed or removed during setup planning	Applied manually in practice with special cutout pliers and mini-mold system from company	Memotain CAD/CAM nickel titanium lingual retainer or CA Retention Foil available
3M	Beveled or bar-shaped, formed in mouth with light-cured composite and 3M Attachment Template	Doctor specifies placements for cutouts and hooks	Priced separately; can be ordered at any time
TP Orthodontics	Basic geometry design	–	Custom Refine Finishing Appliance included upon request

**TABLE 5
DELIVERY AND COSTS**

Company	Delivery	Cost of Treatment	Cost of Reboot	Cost of Refinement
Align Technology	Thermoformed on progressively staged 3D-printed models	Varies by product	Varies by product	Varies by product
ClearCorrect	Thermoformed on 3D-printed models	Unlimited: Varies with treatment plan Flex: \$30 per aligner	Unlimited: No additional cost for five years Flex: \$30 per aligner plus \$95 per additional setup	–
Dentsply Sirona	Vacuum-formed aligners, 3D model file, 3D-printed model	Varies with product and annual volume	–	Complete: Unlimited refinements for three years Select: Pay for each aligner
Dynaflex	Industry-standard fabrication processes and procedures	Contact company	Contact company	Contact company
eXceed Technologies	Print files	\$220 for as many as 20 aligners \$270 for 21 or more aligners	One reboot or refinement included; additional, \$110	One reboot or refinement included; additional, \$110
Forestadent	3D-printed models and aligners	Contact company	Doctor provides treatment plan: Cost only for new model and aligners Lab provides treatment plan: Cost is adjustment fee plus new model and aligners	Doctor provides refined treatment plan: Cost only for additional model and aligners Lab provides refined treatment plan: Cost is adjustment fee plus additional model and aligners
Great Lakes Dental Technologies	Pressure-formed on 3D-printed models	Varies by tier	One additional setup included for reboot or refinement	Five refinement aligners included
K Line Europe	Thermoformed on 3D-printed models	Contact company	35 euros to remake aligners	Included in complete treatment
Rocky Mountain Orthodontics	Thermoformed	Contact company	Contact company	Contact company
Henry Schein Orthodontics	Thermoformed	Contact company	Aligners not tracking: New aligners based on new records provided at no charge New setup required midtreatment or later: \$100 plus \$15 per aligner	Included for five years
Scheu-Dental	CA Clear Aligner: STL files, 3D-printed models, or finished thermoformed aligners CA Professional: Thermoformed aligners	With finished aligners, starts at about 20 euros per aligner for CA Clear Aligner and 27.50 euros for CA Professional	CA Clear Aligner: Not available CA Professional: No cost during active treatment	As many as two correction steps included; additional, 300 euros for CA Clear Aligner or 500 euros for CA Professional
3M	Thermoformed on 3D-printed models	Contact company; no additional charge for more than 18 aligners	Contact company	As many as 18 treatment stages: One refinement included More than 18 stages: Reasonable number of refinements included
TP Orthodontics	Thermoformed on 3D-printed models	Contact company	Contact company	Contact company

3M

Also launched at the 2018 AAO annual meeting, **3M Clarity Aligners** are suitable for minor to moderate malocclusions in the permanent dentition. On May 4, 2018, 3M announced an exclusive North American license with uLab Systems treatment-planning software, which can import 3D digital scans and develop a treatment setup in as little as 10 minutes. The uLabs software allows auto-segmentation after the clinician identifies the teeth, or the company can generate a treatment plan through its 3M Oral Care Portal. Educational courses and webinars are offered through the 3M Healthcare Academy.

3Shape

3Shape’s business model differs from others in that it offers an **Open Clear Aligner Workflow** digital solution to clinicians and labs for creating in-house aligners or exporting the scans to outside manufacturers. According to its website, 3Shape represents more than 40 orthodontic treatment providers and the “widest range of integrated clear aligner providers.” The Clear Aligner Studio and Ortho Analyzer software programs include full-color treatment simulators. One notable feature is the ability to merge CBCT data with a scan.

TP Orthodontics

The **Refine Complete Aligner System** is “designed to correct minor to moderate anterior crowding or spacing,” according to the TP Ortho website. Cases are submitted through the TPRX portal. Options include Refine Basic 5 (as many as 10 trays) or Refine Total 10 (11-20 trays). Each option comes with retainers and a “finishing appliance” (a tooth positioner). A Quick Start Option employs the removable Spring Aligner to promote faster initial tooth movement.

Conclusion

There are many other CAT suppliers around the world that I was unable to review, including Air-

Smile, Alineadent, allRight, AngelAlign, Arc Angel, ClearCaps, Clearline by Protec Dental, ClearSmile Aligners, Compass OrthoAligner, DentCare Clear Aligners, Esthetic Aligner, Flash Aligners by Flash Orthodontics, Invisible Orthodontie by Uzege Ortho, iROK, Lyralign, Neo 3D, Nuvola by GEO, Open Aligner System by Kika Ortodontia, OrthoFolio, OrthoLab 3D, Perfect Aligner, Perfect Arch, Prestige Clear Aligners, RXaligners, Seq-Ret by tdl Precision Orthodontics, Smartee, SmileStyler, Smile-TRU, SureCure, 3D-Aligner by EVIDENT, and Trueline. Most of these have not entered the U.S. market, where Invisalign continues to dominate.

As technology advances and 3D printers are able to turn out aligners with 4D properties cheaply enough for individual practitioners to make their own, the CAT market will be controlled by the best software. Unlike the Eastman Kodak Company, which ignored digital photography to protect its film business, the dominant players in CAT need to be ready for the day when they no longer manufacture aligners for the majority of their customers. Likewise, we clinicians need to prepare ourselves for the growing direct-to-consumer model of orthodontics. To quote author William Gibson, who coined the term *cyberspace*, “The future is already here—it’s just not evenly distributed.”

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- eXceed Technologies, Witten, Germany; www.exceed-ortho.com/aligners.
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