Computer-assisted technologies used in oral rehabilitation and the clinical documentation of alleged advantages - A systematic review

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Abstract:

The objective of this systematic review is to identify current computer-assisted technologies with any clinical documentation for managing patients with a need to re-establish craniofacial appearance, subjective discomfort and stomatognathic function. Electronic search strategies were used for locating clinical studies in MEDLINE through PubMed and in the Cochrane library, and in the grey literature through searches on Google Scholar. The searches for commercial digital products resulted in identifying 225 products on the market per November 2016. About one third of the products were described in clinical human studies (n=458). The great majority of digital products identified in this review has no clinical documentation at all, while the products from a distinct minority of manufacturers have frequently appeared in more or less scientific reports. Two factors apply, which is that new digital appliances will continue to be faster and with lower cost per performance unit and (2) innovative software programs will harness these improvements in performance. The net effect is that the product life cycle of digital products are relatively short-lived. Clinicians must request clinically meaningful information about new products and not accept only technological verbiage.

Introduction

Clinicians have continuously implemented innovations with the aspiration to provide safer and speedier patient care with less inconvenience and more predictable diagnoses and treatment outcomes. Over the last decades and in an increasing pace, we have seen a shift away from a range of manual tasks and use of analogue appliances to computer-assisted concepts and digital technologies. The digital technologies that have emerged in the past within the field of oral rehabilitation have at regular intervals been described in more or less comprehensive review articles (1-3). Some reviews have focused specifically on chairside computer-aided designing and -manufacturing (CAD-CAM) of dental restorations (4-6). More recent systematic reviews emphasize the merits of digital technologies for virtual placement of dental implants for surgery planning purposes and the fabrication of the implant abutment, crowns and different types of superstructures (7). All the named dental items above are defined by regulatory authorities in most parts of the world as a medical device, and hence the term “dental device” is used throughout this article to describe any of these items.

The product lifecycle of digital technologies in dentistry is, like everything else in computing and information technology, synchronized with the consequences of “Moore’s law or prediction” made in 1965. In short, twice as many semiconductors can be placed on an integrated electronic circuit every second year. The effect is a continuous increase of the capacity of microprocessors in terms of speed and memory, and invariably also in better stability and lower price versus performance. Any type of electronic appliance will improve by an upgrade to new microprocessors, including computers intended for the consumer market. Since the introduction of the first micro-computer with a 4-bit Intel 4004 processor in 1971, such computers have switched internal architecture to 8-bit (1974), 16-bit (1976), 32-bit (1985) and 64-bit (2003) and some containing multiple microprocessors. The net result is that the capacity of computers has increasing tremendously and thus continuously created opportunities for a wider spectrum of computer-assisted applications (Figure 1).

Consequently, every time a major electronic manufacturer such as Intel or AMD release news of the launch of a new microprocessor on the market, thousands of software programmers globally prepare for the rush to develop an innovative software product with new algorithms that can harness the enhanced performance of the new microprocessor, and hopefully without too many “software bugs”. The flip

side is that new softwares developed for computers with the last generation microprocessors instantly renders existing softwares not only obsolete, but next to worthless. While major computer companies such as Microsoft and others must invest time and money to accommodate “the new software” to work more or less smoothly on “the old computers” to keep their past customers satisfied, the smaller high-tech research and development companies can ignore such extravagance. Perhaps the best demonstration of the consequence of Moore’s law within dentistry is the turnover of digital tooth shade guides over the years. On a website like alibaba.com, one can today find several digital tooth shade guide products selling for less than $500, while in 1985, a product such as the Chromascan (Sterngold, USA) sold at a five-digit price and had by today’s standards inferior speed and accuracy. A few “winners” may perhaps be identified amongst the products available since 1985, but the majority of companies have pulled their product from the market for obvious reasons (Figure 2).

Arguably, the objectives of oral rehabilitative therapy have not changed much over time. Individuals with a congenital absence or an acquired loss of oral tissues will to various extent experience altered craniofacial appearance and stomatognathic functions, likely feel subjective discomfort, and potentially experience reduced oral and general health. While the clinical discipline of oral prosthetics focus on the methods for, and assessment of whether more good than harm is done by inserting artificial devices made from alloplastic materials to change these conditions (8), oral rehabilitation encompass a range of other rehabilitative interventions. The objective of this systematic review is to identify current computer-assisted technologies with any clinical documentation for managing patients with a need to re-establish craniofacial appearance, subjective discomfort and stomatognathic function.

Materials and methods

This systematic review focus on commercially available computer-assisted technologies used within oral rehabilitation and the clinical documentation of the identified products, i.e., the clinical research that has focused on either methodological validation, or used in context with some form of patient management. For editorial reasons, the references of clinical performance is in a separate supplement that is available on the JOR website.

The original protocol of this review was registered in the PROSPERO database (registration number CRD42016050771, URL: crd.york.ac.uk/PROSPERO).

Eligibility criteria and PICO questions

Any clinical study on humans were considered as eligible that included n+1 subjects, that addressed the PICO question formulated to focus on diagnosis and therapy, i.e., For *patients in need of oral rehabilitation, which computer-assisted technologies for diagnostic purposes or for designing and manufacturing a customized dental device are manifested by commercial products, and are the products documented with any clinical data?* Both cross-sectional studies as well as prospective or retrospective follow-up studies of any length were considered acceptable as clinical documentation of the commercial product. The search was limited to publications in English, and published since January 1st,2007.

Information sources

MEDLINE was searched through PubMed (URL: ncbi.nlm.nih.gov/pubmed/), as was the Cochrane Central Register of Controlled Trials (URL: onlinelibrary.wiley.com/cochranelibrary). The last search date was on November 15, 2016. The reference lists of publications identified in these sources were examined for further articles. No study authors or manufacturers of digital products were contacted to solicit their knowledge of any clinical studies. Clinical documentation in the grey literature was sought in Google Scholar (URL: scholar.google.com). Moreover, the infomercials, marketing brochures and advertisements in journals or on Internet were scrutinized for any references to scientific publications. Testimonials presented in these sources were not considered as clinical documentation.

Search

The electronic search strategy for locating clinical studies in MEDLINE through PubMed was: *(("computer-assisted" OR digital) AND dent*) OR (("computer*" OR digit*) AND dentistry) OR (("computer-a*" OR digit*) AND dentistry) OR (("computer-assist*"[ti] OR "computer-aid*"[ti] OR digital*[ti]) AND dentistry) OR (("computer-assist*"[ti] OR "computer-aid*"[ti] OR digital*[ti]) AND restorative dentistry).*

Moreover, once a commercial product had been identified in any source, the product name was matched with dentistry and filtered for clinical study on humans: i.e., *(<productname>[All Fields] AND ("dentistry"[MeSH Terms] OR "dentistry"[All Fields]) AND ((Clinical Study[ptyp] OR Clinical Trial[ptyp] OR Clinical Trial, Phase I[ptyp] OR*

Clinical Trial, Phase II[ptyp] OR Clinical Trial, Phase III[ptyp] OR Clinical Trial, Phase IV[ptyp]) AND "humans"[MeSH Terms])

Finally, the search included also the use of search strategies developed and adopted by other authors of relevant SRs, to capture recent publications since their reported cut-off search dates (Table 1).

One individual identified products based on computer-assisted technologies in use within the domain of oral rehabilitation, including screening for any clinical studies to support the products. Extracted data including risks of bias and summary measures of the individual studies will be presented in a separate review paper.

Results

The searches for commercial digital products resulted in identifying 225 products on the market as of November 2016. Less than one third of all products were described in about 350 reports from clinical human studies. The digital products have been used within four domains, i.e., for (1) computer-assisted patient diagnostics, (2) computer-assisted communication, (3) computer-assisted patient therapy and (4) other computer-assisted applications in context with oral rehabilitation.

1. Computer-assisted patient diagnostics

Individuals that seek care from a health professional present a medical and dental history, which forms the basis for specific examinations to detect parafunction from orthofunction and to differentiate pathology from physiology.

Information technology researchers reasoned some 30 years ago that patient-provided information could possibly be interpreted by computer algorithms built on Bayesian statistical inference to provide a likelihood of a condition, alternatively to create reiterative sets of follow-up questions to limit the range of differential-diagnoses. These computerized clinical decision support systems became also known as “(case-based) expert systems” and construed somewhat overstated as computerized “artificial intelligence” (A.I.). Several products were promoted for dentists in the 90ies, principally in radiology, orthodontics and oral medicine. They have since disappeared (18), and little has been written about A.I. in the dental scientific literature since. Today the term “neural network” is a more common descriptor for the software algorithms, and is today mostly used for research purposes. Although A.I. softwares are used in some fields of medicine (URL:

openclinical.org/aisinpractice), it is perhaps far less than originally anticipated (19). To the author's knowledge, the only available commercial products today relevant to oral rehabilitation is for estimating caries risk. Furthermore, a few radiography softwares include algorithms for providing likelihood estimate of caries on digital radiographs (e.g., Logicon, Carestream, USA).

Detecting parafunction versus orthofunction

Examinations to detect parafunction from orthofunction include the diagnosis of potential temporomandibular dysfunction (TMD). Some clinician-investigators have continued to explore particular facets of the kinetics of the mandible and condyles to study the etiopathology of TMD, eventually in combination with recordings made by use of different electrophysiological techniques. Several tracking technologies have been adopted with the most common being magnetic, ultrasound and opto-electronic appliances. The jaw or condyles kinetics are recorded by tracking fiducial markers in space relative to a position specified by a calibration conducted prior to commencing the recording. Once calibrated, the fiducial marker position can be expressed in a cartesian coordinate system by their relative xyz-positions, which in turn can be exported as tabular data for further statistical analyses or displayed as dotted trajectories on a monitor.

The improved capability of computers have enabled the use of multiple fiducial markers and hence record the movements of an object in space with six degrees of freedom rather than only three, i.e., not limited to only up-down, sideways and protrusion-retrusion, but also the planar rotations of the mandible. The sampling frequency used in the past around 20-40 Hz has also been increased about ten-fold (Figure 3).

Akin to other fields where a digital appliance is developed specifically for dentistry, manufacturers and commercial technologies have come and gone, and it is difficult to keep track of which ones that are still available on the market. In North America, it is somewhat remarkable that one pioneering company, i.e., Myotronics, still manufacture their magnet-based Kinesiograph, now designated as version K7, which was launched as early as in the seventies. All other products in Europe are made by manufacturers located in Germany and Austria. One system is based on optoelectronic technology, i.e., the Freecorder Bluefox developed from the former Condylocomp LR3, which again was an improved version of String LR-Recorder launched in the mid-eighties. The product is described on the websites of several

companies (URLs: orangedental.de, freecorder.com, dentron.de, ddi-group.de) and it is not entirely clear who is the manufacturer today. Gamma Dental (Austria) markets the product Cadiax, which rely on electronic potential dividers, while three other products are based on ultrasound technology. I.e. JMA+Analyser (Jaw Motion Analyser) (Zebris, Germany), ARCUSdigma II (Kavo, Germany) and Axioquick Recorder (SAM Präzisionstechnik, Germany).

“Functional diagnosis (of TMD)” by electronic means has not really gained much popularity, unknown for which reasons. It may be partly explained by a general sentiment amongst many dentists that there no need for sophisticated condylar movement recording equipment to diagnose a disc displacement, since a clinical examination will usually suffice (20). Many have also regarded the adoption of digital tracking tools with skepticism, because of the potential for misapplication of the technology to influence patients to undergo extensive occlusal rehabilitation (21). Nevertheless, tracking devices seem to have reappeared lately, likely because functional data may now be imported and integrated into a virtual patient profile. E.g., The Sidexis system (Sirona, Germany) allow the data from a Galileo cbCT (Sirona, Germany) to merge with functional data recorded with the SICAT Function recording appliance (Sirona, Germany). A comparable feature can be identified in the Romexis system (Planmeca, Finland), that merge data recorded by their cbCT tomographs with their newly developed product named *4D Jaw Motion system* (Planmeca, Finland). (Further details are presented in relevant section under computer-assisted therapy).

There is little doubt that these electronic tracking appliances are accurate. However, the controversy is how tracking findings should be interpreted in terms of best management and therapy (22, 23). Contentious assumptions in particular are the claims that (i) the trajectories of the mandible or the condyles may be examined in detail and therefore provide an improvement for decision of appropriate therapy. (2) the “optimal” neuromuscular indices can be identified and form the basis of a new therapeutically built vertical dimension and (3) the minute displacements of the condyle in the fossae can be established during function, and therefore provide an improvement for decision of appropriate therapy. Even more debatable practice is to combine recordings from a digital pressure-sensitive film (T-Scan-III, Tekscan, USA) with EMG to identify a so-called “disclusion time”, i.e., the time the molars and nonworking premolars remain in contact during excursive movements, as a justification for complete occlusal rehabilitation to establish an ‘immediate complete

anterior guidance development". Recent attempts to establish guidelines for the use of digital appliances for studying stomatognathic functions have published for examination protocol (24) and for diagnostic criteria of dysfunction (25).

TMD is by many associated with *bruxism.* Although this condition is somatotrophic rather than dental, it is nevertheless studied by dental researchers to clarify any possible etiological contribution to TMD. An electronic product launched some years ago named Bitestrip (URL: up2dent.com) was promoted as a low cost appliance for measuring sleep bruxism. There are no publications about the merits of the appliance and it is unclear if it still on the market. Moreover, small portable digital appliances have been developed to monitor and disrupt the parafunctional activities with auditive or haptic feedback, labeled as biofeedback *(*26). For daytime bruxism, the assumption is that a stimulus upon registration of active bruxism will make individuals aware of the craniofacial muscle activity and facilitate an 'unlearning' behavior, while for night bruxism the stimulus upon registration of active bruxism will actively reduce the craniofacial muscle activity without disrupting the sleep negatively. Several experimental systems with pressure sensors embedded in a splint exists, but to the authors knowledge, only four digital products are currently on the market. I.e., the Bruxane splint (Bruxane, Germany) splint will vibrate and the OralSensor splint (Cycurea, USA) delivers a sound, although it is unclear whether the product has been withdrawn. The SleepGuard appliance (Holistic Tech, USA), which until 2001 was sold as Grindalert (BruxCare, USA) emits also a sound upon emg registration of masticatory muscle activity. Finally, the GrindCare device now manufactured by Butler (USA) and previously by Medotech (Denmark) sends out an electrical impulse upon emg registration of masticatory muscle activity. Grindcare is the only digital appliance amongst the cited that has been studied scientifically (27).

Differentiating pathology versus physiology

The diagnosis of diseases of hard tissues is today made possible with a range of different digital technologies. Digital radiography has matured tremendously since the introduction of the first system named RVG (Trophie Radiologie, France) towards the end of the 80ies. Digital radiography is an extensive theme and falls outside of the scope of this review.

Detecting caries at an early stage to enable possible reversal of the demineralization process without a surgical intervention has been at the forefront of minimal invasive dentistry for a decade. New digital appliances can detect early stage caries lesions

by measuring enamel fluorescence induced by laser (DIAGNOdent, KaVo, Germany) or by light (QLFPatient, Inspektor Research systems B.V., The Netherlands), alternatively by detecting photothermal radiometry and modulated luminescence induced by infrared laser light (Canary System, Quantum Dental Technologies, Canada). Even more promising is the advancements of optical coherence tomography (OCT), and not only for primary caries detection. The versatility of OCT opens for other applications in dentistry, including its implementation into future 3D scanner for intraoral use to allow recording of subgingival surfaces. OCT show also promise for assessing periodontal pocket depth and detecting structural microcracks in hard tissues, including the detection of secondary caries and voids under dental restorations (28, 29).

All tomographic technologies rely explicitly on dedicated software algorithms for reconstruction, regardless of the source or wavelength of the penetrating electromagnetic wave. Perhaps the most celebrated algorithm is the *back projection reconstruction algorithm* for x-ray tomography developed by Sir Godfrey Hounsfield in the U.K. in the early seventies, while in dentistry *the cone beam algorithm* for x-ray tomography developed by Piero Mozzo in Italy in the early nineties has made a tremendous impact. The engineering advancements in computer tomography methodologies are rapid, both as a reflection of Moore's law and accrued improved understanding of interactions between electromagnetism and tissues. Tomographic appliances of relevance for oral rehabilitation are in four categories, as defined by the type of electromagnetic wavelength. I.e., by use of ultrasound (30) or by x-rays in a conventional or a cone-beam computer tomograph (31), alternatively by use of radiofrequency waves in MRI appliances or by electron-positron annihilation in PET machines (32). The many innovative tomographic tools have been extensively used to diagnose and study diseases of the craniofacial complex, including the temporomandibular joint (33), as well as the salivary glands (34). Further details about existing commercial products and their performance can be obtained in these two review papers.

2. Computer-assisted communication

In line with analogue wrist-watches, film cameras become outdated so rapidly over the last decade that even the once mighty company Eastman Kodak had to file for bankruptcy in 2012. While analogue wrist-watches have resurfaced at the extreme high-end market, the effects of Moore's law have enabled the production of digital

cameras so cheaply that the era of photographic film has ended. Still, digital photography in a clinical dentistry context needs to be mastered (35) , and additional requirements apply if presenting in front of a critical peer audience or a board examination panel. Novel 3D cameras, by some termed stereo cameras are now available at a reasonable price for consumers , but seems not to have been implemented into clinical dentistry yet.

Communicating with the patient

In 1988, one could buy for the neat sum of $35.000 the “Dentalvison” intraoral camera that would project digitized images on a monitor, while “cosmetic imaging” was accomplished with cellophane tape and a soft pencil on paper printouts. Very rapidly the market became saturated with new products, e.g., AcuCam, CygnaScope, Dentacam, Intraview, OralScan and Ultra-eye and the prices dropped rapidly. Then years later a CRA newsletter from 1998 listed 13 manufacturers that by then had begun to diversify their products. Sony had some limited success upon launching their wireless DigitalDOC, and Dürr made several refinements of their VistaCam . over the years. Their latest version (version iX) included interchangeable components that allowed either imaging, high-zoom imaging, light curing or emitted violet light (405 nm) for caries and plaque detection. Yet, today it appears as the fascination for intraoral cameras has dwindled, and to the authors knowledge the few appliances that remain on the market are sold under the category “digital impression appliance”.

A number of companies, as well as a few academic institutions have produced softwares showing animations of clinical procedures, with the intention to enhance patient information as a basis for informed consent. Several software products have come and disappeared again over the years (remember Moore’s law), but multiple sophisticated products remain. The American Dental Association lists 30 commercial products on their website (36), but there are numerous more, amongst these, e.g., Bite FX (D2Effect, USA), Consult PRO Suite (ConsultPRO, Canada), CurveED (CurveED, USA), Dental Explorer 3D (Quintessence Publishing, Germany), Dental Master (Mdsimulation, Israel), Dental Patient Information (3d4Medical, USA), Dental Patient Education Software (MediaMed, USA) and Orasphere Patient Education system (Orasphere, USA).

An even more advanced form of computer-assisted communication software enable a graphic representation of the intended treatment outcome as a basis for patient-provider deliberations. Dedicated softwares were first used in orthodontics some

three decades ago, including the term “visual treatment objective (VTO)”. Even though VTO at the time was principally associated with computerized cephalometric analyses, the term as used today in orthodontics encompasses all kinds of pre-and-post records. Outside the field of orthodontics, a relatively recent proliferation of manufacturers have developed solutions that may be labeled under the category of “smile design” softwares (Table 2).

To the author’s knowledge, there are no studies that have compared clinically the performance of the different products one-to-one, and only sporadic case reports of different products have been identified in the scientific literature. The smile design software products are mostly stand-alone, but some are modules integrated into more less full virtual patient software solutions (CEREC 4.2, Sirona, Germany; Romexis, Planmeca, Finland; Dental System, 3Shape, Denmark). Yet, an experienced user of Photoshop (Adobe, USA) can accomplish much of the same cosmetic imaging effects as in some of these commercial softwares, and to lesser extent also in Keynote (Apple, USA) or Powerpoint (Microsoft, USA).

Even though many colleagues are rightly concerned about the potential of such tools to encourage patients to undergo “complete make-over”, one needs to be reminded that the idea of creating a strong visual impact has been available in cosmetic dentistry for at least 20 years. E.g., already in 1994 “IMAGE-IT” was trademarked as a “software that allows a dentist to capture pictures of a patient's teeth onto a computer and then manipulate those images with the software”. A more in-depth evaluation of several of the smile design products cited above has recently been published (37).

Communicating with other health professionals

“Teledentistry” has been hauled for decades as a promising approach to better delivery of quality care and has been applied within different fields, including in the planning of oral rehabilitation (38,39). Current evidence indicates that teledentistry has many merits (40) and will likely distribute better and more equal access to care in underserved populations (41). Yet, both teledentistry and telemedicine services appear to be under-utilized (42).

Several commercial solutions exists in some countries for disseminating patient data for discussions in cyberspace with other health professionals. However, in many countries, such activities are strictly regulated or even illegal due to patient-privacy considerations. National regulations must be followed and patient identifiable data

should never be communication over open lines, but over encrypted networks, alternatively over virtual private networks (VPN), if organized over the Internet.

3. Computer-assisted patient therapy

Digital technologies associated with the provision of oral rehabilitation therapies are e.g., for tooth shade matching, preoperative planning of surgical therapies including implant surgery and implant restorations, the designing and manufacturing of dental devices and some uses for the assessment of outcomes of therapy.

Tooth shade-matching

As alluded to earlier in this review, the life-span of some of these digital appliances have been very short because of the frequent improvements of the microprocessors. Perhaps the most successful product is the VITA Easyshade, which now is in its third generation and named Easyshade V. Some appliances support only a single or handful of ceramic manufacturers, while e.g. the Spectrashade supports currently roughly 30 different ceramic brands (Table 3). Further details about the characteristics of the different spectrophotometers, colorimeters and imaging systems can be found elsewhere (43).

It is likely that the recent innovation to include shade matching capabilities in an intraoral 3D scanner (Trios Color, 3Shape A/S, Denmark) will also be implemented by other manufacturers in their products.

Preoperative planning of surgical therapy

Two general approaches for preoperative planning of surgical therapy based on computer technologies can be identified. The first method is by additive manufacturing of anatomical models based on tomographic data from various sources. The second approach is to fuse the 3D tomographic data with some form of 3D surface data.

Tomographic data are exported by use of an internationally standardized file format named DICOM (Digital Imaging and Communications in Medicine). A wide range of software products can convert DICOM data to render a 3D model, and many are free for use. Free DICOM softwares include 3DSlicer (Surgical planning lab), Drishti (ANU Vizlab), GIMIAS (Cistib), Ginkgo CADx (Metaemotion), ImageJ (NIH), InVesalius (CTI), MeVisLab (MeVis Medical solutions), MIPAV (NIH CIT), MITK (German Cancer Research centre), OsiriX (Pixmeo) and Orthanc (Univ of Liege). Most of

these software products can via a more less sophisticated user interface perform image segmentation and also export the data as 3D surface format. There is not much reason anymore to purchase an expensive commercial product.

One of the pioneering companies within additive manufacturing is Materialise (Belgium) who enjoyed a formidable success when they launched in 1991 a product named MIMICS (Materialise Interactive Medical Image Control System). MIMICS enable rapid prototyping of anatomical models that may even be multicolored by using resins that undergo color change depending on the input of energy level. Few other manufacturers have achieved a comparable economic success, perhaps except Medical Modeling, now part of 3D Systems Corp. (USA).

A sophisticated vector-based 3D software named 3D Doctor was developed by Able Software Corp (URL: ablesw.com) about a decade ago. The software enable multiple advanced functions such as imaging, modeling and measurements for quantitative analysis in combination with exporting 3D data files in multiple formats for rapid prototyping. Yet, in spite of its advanced features, the software appears to not have been used much in dentistry except for research purposes (44).

Fusing tomographic and 3D surface data sets for planning complex surgery require advanced software algorithms. E.g., craniofacial skeletal data has to be fused with soft tissue landmarks, alternatively with the dentition with or without an interocclusal index recorded in the retruded contact position (13, 45). Although data of existing conditions can be fused with appropriate software, another matter is to predict how soft tissues will change as a a function of change of hard tissues and vice versa following surgery, and software algorithms otherwise used in computer-aided engineering need to correct for the anisotropic scaling of the different tissues. Most concepts described in the literature have been developed by clinician-researchers working in hospitals, and relatively products are today available commercially for planning complex craniofacial surgery. Some products described in the literature are Vector Vision (BrainLAB, Germany), VSP Orthognathics & Surgery (3D Systems Healthcare in alliance with Stryker, USA), Simplant CMF (Materialise, Belgium) and CT Based Surgical Planning (KLS Martin Group, Germany/USA). In addition, an older version of StealthStation (Medtronic, USA) named Treon Navigation System was used in the past for craniofacial surgery, but the manufacturer has currently limited the use of the product only for neurosurgery.

Dental implant surgery guidance (dynamic /static)

Perhaps unknown for many, the majority of publications about dental implant surgery guidance a decade ago focused on dynamic, rather than on static guidance via a fabricated template. One of the institutions that spearheaded dynamic surgery was the University of Vienna, who also developed their own system (VISIT) in competition with the commercial entrepreneurs that have since disappeared. Interestingly, of the seven products currently on the market, four have been launched within the last 24 months (Inliant, IRIS-100, Navident and X-Guide). All the products are based on some form of optoelectronic tracking of fiducial markers on a frame attached to a handpiece, or are engraved on the handpiece itself (Inliant). As a consequence of the relatively short time these products have been on the market, only case reports and in-vitro data are available, with a exception of a recent publication on the x-guide (Table 4).

Static guidance by use of a surgical template

The list of manufacturers that offer a product whereby a surgical template can be created from the planning has grown quite long, but three different concepts can be identified. The first concept was a mechanical transfer process spearheaded by Fortin and colleagues in France in the mid-nineties (46), which led to the product CadImplant (Praxim, France) and subsequently to the Easyguide (Keystone dental, USA). The next proposed concept was to make templates by rapid prototyping of a medical grade resin (47), which matured into the Simplant system (see below). A third concept came later and involved the milling of some form of resin ordered from a laboratory or larger production centre. Recent products enable also the production of such templates in a milling machine located in the clinic, e.g.,the Cerec Guide 2 milled an MC XL milling unit (Sirona, Germany). .

In 1991, the company Columbia Scientific Incorporated (CSI, USA) developed a software product that allowed the clinician to place graphical implants into images from CT tomographies and visualize their intersection with the surrounding anatomy. The product was originally named ImageMaster-101, but changed to Sim/Plant two years later. In 2001, Materialise (Belgium) purchased CSI and proceeded rapidly to merge their product, named SurgiCase with the former Sim/Plant. The new product was named SimPlant (version 8.0) and enabled the added possibility to order surgical templates made from a biologically inert stereolithographic resin, a product brand-named as SurgiGuide. In parallel, another concept for fabricating static surgical

templates by rapid prototyping from virtual implant placement was developed by professor van Steenberghe and colleagues at the University of Leuven, which was labelled "Leuven information tech-based oral rehabilitation by means of implants", or by acronym to “Litorim” (48). The production was outsourced to a spin-off company from the university named Medicim, who promoted the product as “Oralim” until Nobel Biocare purchased the company in 2008 and nested the invention into their portfolio of Procera products.

It must be realized that even if the software is promoted as a pre-operative planning tool, it is not necessarily constructed for all implant brands, nor fully compatible with different options for creating surgical templates. Most products enable fabrication of surgical templates achieved either by mechanical transfer or by use of a subtractive or an additive manufacturing process, of which stereolithography is the most common. Beware that regardless of technology, one needs to verify that the template is made from a medical grade highly polymerized biocompatible resin (Table 5).

It is disturbing that the majority of these products have been appraised in any clinical studies. Even if trueness and precision of some of the products without clinical data have been assessed in vitro (49), their performance under realistic conditions remain largely unknown. Even though data based on laboratory measurements may appear impressive, there are multiple potential sources for errors in handling and storing templates, including effects of sterilization/disinfection procedures. As one may anticipate, templates supported by teeth are more stable than if supported by bone and definitely more than if supported only by mucosa. In general, the reasoning should be what is reflected in the name of this dental device – it is a surgical guide and not a rigid scaffold for aligning a drilling tool. This lesson was learned the hard way upon attempts to combine the fabrication of a surgical stent in parallel with a prefabricated permanent fixed superstructure to deliver “instant teeth” from scratch in a single clinical session (50). Subsequent “teeth-in-an-hour” –alike solutions have switched instead to reinforced acrylics, with the added benefit that the healing and patient-reported outcomes can be assessed prior to finalizing the therapy with a permanent solution some months later.

Tracking of the mandible and condylar movements

An indispensable appliance used by dentists and dental technicians for fabricating prostheses was developed in 1840 and is recognized by all to be imperfect, i.e., the mechanical articulator. True, some mechanical articulators can be adjusted, fine-

tuned and adapted following cumbersome and technique-sensitive procedures for creating graphical tracings of the condyle kinetics, and these articulators are labeled as “fully adjustable” to give the false impression of a capability to replicate nature. At some stage, manufacturers replaced the graphite styluses and millimeter-paper with electronic components and marketed these as “electronic articulators”. However, it was first in the mid-eighties that digital products were developed that enabled 3D tracking of the kinetics of the mandible and the condyles, i.e., ARCUS digma (Kavo, Germany) and Axioquick/Axiograph (SAM, Germany) and later JMA+ (Zebris, Germany). However, in spite of the debatable benefit of studying the kinetics of the mandible or the condyles on a monitor, fabrication still relied on a mechanical articulator. It is only recently that it has become possible to export the kinetics data to a dental designing software, which facilitates the designing of the dental device to a correct occlusion with the antagonist dentition. One of these products has been developed by Sirona (Germany), whereby the mandible-condyle kinetics data is recorded by use of SICAT Function (Sirona) is integrated with data from a Galileo cbCT (Sirona) in combination with the data from a CEREC 3D Intraoral scanner (Sirona). It can be expected that Planmeca (Finland) in the near future will develop a similar concept for their products.

An alternative approach to create a virtual articulator is by scanning a completed tooth set-up or stone models mounted in a mechanical articulator, and import into the software the articulator settings such as condyle and Bennett angles, side-shifts, vertical dimensions, etc. This concept is used by several manufacturers of dental designing softwares, e.g., 3Shape (dynamic virtual articulation), Amann Girrbach (Ceramill mind+artex), Zirkonzahn (virtual articulator) and Exocad (virtual articulator module). One may even transfer the maxilla-mandibular relations without actually scanning the whole articulator by using transfer plates for the relevant articulator model.

Designing and manufacturing dental devices – “CAD-CAM”

Almost any article about CAD-CAM in dentistry begin with a debate of who were the “originators”. Amongst the names are Drs. W. Mörmann and M. Brandestini at the University of Zurich in Switzerland who built a contraption in the early eighties that was capable of milling a block of ceramic material to fit exactly into a scanned inlay cavity. The product was subsequently launched on the market in 1987 by Siemens (Germany) under the brand name CEREC. The product was later renamed to

CEREC 2 in 1994 and to CEREC 3 in 2000 by the new subsidiary company Sirona, to reflect the expanded range of indications and improved marginal fit of the dental devices. There is no doubt that the CEREC concept has been the most commercially successful chairside scan-plan-mill machine ever manufactured (51).

The effects of Moore's low has enabled tremendous improvements of the technologies used for the CAD-CAM of dental devices within three domains. The 3D surface and 3D volume rendering is faster and more accurate than before, the designing and manufacturing softwares are faster and more flexible and the actual manufacturing has expanded from originally only subtractive methods to include a wide range of additive manufacturing processes (Figure 4). The net benefit of these changes is that the end user today can select the most cost-effective digital softwares and appliances for their particular use, instead of more inflexible scan-plan-mill units. The drawback is that the end user must have a higher understanding of how CAD-CAM technology and the digital communication between different appliances.

Surface and volumetric rendering

The very successful CEREC machine launched in the late eighties included a 3D optical scanner for intraoral use. A few of the early scan-plan-mill machines developed by competing manufacturers contained also an optical 3D scanner, but there was really no need to transfer data files in cyberspace until two further historic developments occurred.

The first development was the establishment of large production centres for dental devices in the late 90ies and spearheaded by DCS-Precident (Switzerland) and Nobel Biocare (Sweden) with their Procera centre. The technology for recording 3D data was by use of mechanical scanners and in this era just before the initiation of the internet revolution, the data were sent by "fast" (33.6 kb/s) or "superfast" (56 kbit/s) modem connection.

The next development occurred around the millennium when CAD-CAM softwares were developed for dental laboratories who choose either to invest into expensive mid-size milling machines or to focus on the designing only while leaving the production to others. Booth process chains would required the use of 3D scanners, but the latter group of dental technicians would benefit from using a 3D scanner that would allow the exporting of data files with an open format. Hence, two 3D scanners developed around this period came with the option to export the 3D data using a .stl

data file format. I.e., the *Scanner es* (Etkon, Switzerland) from 2000 and the *BEGO Medifacturing system* (BEGO Medical, Germany) from 2002.

It was first in 2007 that the first 3D scanner for intraoral use arrived on the market , i.e., the Itero 3D scanner (Cadent, Israel) followed by the Lava Chairside Optical System (COS) scanner (3M ESPE, USA) in 2008.

Digital appliance developed for surface or volume rendering can be categorized by whether the surface acquisition is recorded intra- or extraorally, and by the type of digital workflow and format, generally categorized as either open format or closed.

The marketing brochures tend to focus much on the type of technology inside their product. Different concepts include mechanical-electric units with or without laser-adjustment, optical units with or without confocal lenses that use structural white or blue light or laser that is either photographed or video sequenced and even a 3D scanner built on conoscopic holography was for a short period on the market. While the technology inside the product may perhaps interest the technophile dentists, clinicians should rather focus on aspects that will affect daily practice. Some, but not all products can export data in an open file format. However, another concept require a digital workflow whereby large amounts of data, also known as point-cloud data, have to sent over the internet to the manufacturer to “clean-up” the data before 3D rendering becomes possible. In this respect, clinic owners may want to check their existing network cabling and payment plans with their network company before entering a business based on sending several hundreds of megabites every day. (and perhaps also try to recall how often their “network is down” per month or week). Moreover, the flexibility with regard to export from the impression appliance software to different designing softwares vary. While some manufacturers lock you completely to one particular software, others offer a capability to export as an option for purchase, while others have not created any barriers. Finally, the pricing of the impression appliances are quite creative, ranging from low purchase fee but high scanning fees and vice versa, which is discussed later in this review.

Digital appliances for volume rendering is based on some form of tomography technology, and in the field of oral rehabilitation the most common by far is the use of x-ray tomography.

Intraoral 3D scanners

Until very recently, only a handful of 3D scanners for intraoral use were available and these were based either on laser triangulation or by use of confocal light. However,

multiple commercial products have recently become available over a short period in what appears to be a very volatile market. E.g., several products have recently been sold and the product name has either changed, e.g., PlanScan by Planmeca acquired from E4D in 2014, alternatively not changed, e.g., IOS Fastscan by Glidewell Laboratories acquired in 2015 from IOS technologies. There are also examples of manufacturers who have acquired a product and kept is away from the market – possibly temporarily, e.g., the Aadva by GC Europe acquired in 2015 from the Bluescan I made by a.tron 3D and KaVo Lythos acquired in 2015 from the Ormco Corporation. (Table 6)

A peculiar phenomenon is that the same hardware product is sold under different names, perhaps with a proprietary 3D scanner software and/or payment plan. E.g., the only apparent visual difference between the *i/s/can* appliance (Goldquadrat, Germany), the *Cyrtina intraoral scanner* (Oratio, The Netherlands), the *organical oral scan* (R+K, Germany), the *detection eye* (Zirkonzahn, Italy) and the *3D progress* (MHT, Italy) differ only by the logo and perhaps some shade variation (Figure 5).

The manufacturers tend to focus in their marketing material on the particular technology inside their product rather than on clinically relevant aspects. Estimates of trueness and precision of 3D scanners are based on measurements done in vitro and is of course important (54). However, experimental setups in laboratories can be manipulated to produce biased results and reported numbers in the literature from a particular group apply only to the specific defined circumstances and cannot be generalized to clinical reality. ISO TC106 SC9 has worked several years to develop uniform standards for CAD-CAM use and appliances in dentistry, but this endeavour is still ongoing. Regardless of lack of international standards, it seems prudent that clinicians should carefully scrutinize aspects such as the size and weight of the actual camera, which may be designed as a hand- or pistol-grip (read: “heavy”) alternatively as a pen-grip (read: “light”). The height and width of the camera head is for some products ~16 mm x16 mm and a larger camera head may preclude the use for some patients with a limited mouth opening capability. Several intraoral 3D scanners depend on powdering the surfaces to be recorded, which can be tricky in some clinical situations. Some 3D scanner softwares allow selective retakes of areas of interest e.g., after some preparation touch-up, while others require a new full impression sequence. If it is planned to use the 3D scanner for impressions of dental implants, it is essential that implant impression copings are available for the particular 3D scanner, which is not always the case. A few products have an unsatisfactory

disinfection protocol, although the majority include some form of plastic protective sleeves. Finally, the device configuration varies considerably, which may be relevant in a crowded clinical setting. Some users may have a preference for a USB cable connection, others for a tabletop device and some perhaps a full trolley with or without the use of a touchscreen and/or foot pedal.

The “stitching” or superimposition of the scans from different angles must be accurate and some products have more problems than others once the impression area becomes bigger, alternatively contain steep alveolar ridges. Currently, none of the existing 3D scanner softwares can stitch pictures from a jaw that is fully edentulous or with wide spaces between dispersed teeth or dental implants because of an inability to stitch pictures that do not contain recognizable patterns or structures. Some situations may be rectified by adapting over the mucosal areas a thin tray that contains some form of surface configurations (53).

Extraoral 3D scanners

Currently, more than 60 different extraoral 3D scanners are being advertised for use in the field of oral rehabilitation. We can expect that likely, at least 20 more will be launched at the next IDS exhibit in Cologne in March 2017. Moreover, they will likely outperform many of the existing products with regard to speed and accuracy. Besides categorizing 3D scanners in general as described in the introduction of this section, extraoral 3D scanners can also be categorized by which items that can be scanned and the maximal dimensions of such items. Scannable items may include one or multiple of several items such as occlusal indices, singe or full arch dies, implant abutments, models, prostheses or wax-ups. Some of these items will require particular surface preparation or even coating before the scanning process since even the technologies that normally do not require coating may in case of high translucency be affected by specular and subsurface reflections. The extensive range of products and large variations of performances precludes further in-depth descriptions of these products.

Facial 3D scanners

Facial 3D scanners are based on different technologies, of which the three most common are structured light, laser triangulation and stereophotogrammetry. Several commercial products exist for recording static face expressions, and they are priced within a wide range. Higher end products such as the Space Spider (URL: artec3d.com, Artec, Luxemburg) are priced at ~$28K, while the Intel RealSense 3D

camera at the fraction of this cost will likely become a standard component on most computer monitors in the near future, principally for internet video-game users, but also useful for iris scanning, real-time 3D scanning and 3D printing and reasonably good facial rendering on the screen. With regard to current facial 3D scanners, some manufacturers have attempted to target dentists, but subsequently pulled the product for unknown reasons. E.g., Dental Wings (Canada) introduced in 2013 a “DWOS Smile Maker module” and a 3D face scanner, but the product vanished just a year or two later. Various products cited in the scientific literature used for facial scanning have been manufactured by 3dMD (USA), BWHX(China), Canfield (USA), GFMesstechnik, (Germany), Minolta (Japan), Polhemus (USA), Shining 3D (China), Steinbichler (Germany) or Zeiss(Germany). To the author’s knowledge clinically relevant comparisons between these products within a dentistry context have not been published.

A recent development is the possibility to merge the facial soft tissues with the bony structures. The new cbCTs from Planmeca (Finland) enable the possibility to merge the face contours with the cbCT data. One may expect that other manufacturers of cbCTs will likely implement this feature too. Another approach has been to import the cbCT data file into a proprietary software that is able to segment soft and hard tissues and hence merge the facial surfaces with the bony structures (3dMDvultus, 3dMD, USA).

Admittedly, clinicians would rather study the dynamics of the head and face rather than a static recording of the face for assessing the impact of an intra- or extraoral prosthesis on different stomatognathic functions. However, while the technologies for recording dynamic facial expressions are rapidly being developed mostly for the film industry, there are to the author’s knowledge no commercial products available yet for dental applications.

Softwares for designing “CAD” and manufacturing “CAM” dental devices

More than 100 different 3D data file formats are currently being used, but the three most common in use today for designing and manufacturing dental devices are .stl, and to lesser extent .obj and .amf. Examples of proprietary 3D data file formats that are being used in dentistry are e.g., .ccd (3M ESPE), .dxd (Sirona), .lab (Sirona), .dcm (Wieland), .neu (Hint-Els) and .pts (3Shape). The .stl (standard tessellation language) is supported by near most software products and therefore used extensively. The .stl file format, which strictly speaking is in either a binary or an ascii

format, describe a surface geometry by triangle vertices using a simple three-dimensional cartesian coordinate system, but without representation of color, texture or other surface attributes. In contrast, 3D data files stored as .obj (“object”) include surface texture/color as a reflection of its intended use in 3D graphics animation applications. The third file format, .amf (additive manufacturing file) contain descriptors of color, materials, lattices, and constellations of objects for additive manufacturing processes, e.g., for scaffold manufacturing by 3D printing. It is likely that new non-proprietary formats to describe 3D data will replace .stl, and one promising format is .3mf (3D manufacturing format). It is also likely that due to the increased exchange of open format data globally that there will be a better adherence to the .step format, i.e., described in ISO standard 103030 and titled "Standard for the Exchange of Product model data". Beware that there are no ISO-standards specific to data file formats in dentistry, apart from the more universal DICOM (Digital Imaging and Communications in Medicine) file format.

Several manufacturers over the years have developed designing software targeted specifically for use in the field of oral rehabilitation, but many have since disappeared. Currently, the market is dominated by products from seven manufacturers (table 7).

In contrast to older software products that addressed CAD-CAM restorations specifically fabricated with a particular hardware, the dominating softwares today contain an extended range of modules or offer optional modules for purchase to design just about any kind of dental device. It is difficult to compare and rank the products, because as soon as a new and clever feature appear in one product it tends to be rapidly copied and implemented by the other manufacturers. Apparently, the copyright / patent -protection is difficult to maintain in the software industry. The designing software needs to interact with the manufacturing software, which for most of the products in the previous table are integrated into the product. Using an older or less advanced dental designing software may create a nightmare for the dental technician to identify a manufacturing software that is fully compatible with both the designing software and the manufacturing appliance used in their dental laboratory. The complexities of the file exchanges has been very nicely presented in a recent review (54). The most common manufacturing softwares used today by dental laboratories and milling centres that produce dental devices are presented below (Table 8).

As the assessment of performance of these softwares is more an engineering science instead of a dental science it is perhaps not surprising that there are no clinical studies where the different products have been matched. It is perhaps an anomaly that the clinician with the intimate perspective of the intraoral conditions is not the individual that undertakes to customize the designing of the dental devices. The designing process rely instead on a traditional transfer of conventional indices and written instructions to the dental laboratory. Part of the explanation of this peculiarity is the often high licensing fees that manufacturers have charged in the past for the rights to use their product. It is likely that in the future the option will become an integrated module in the new generation of 3D intraoral scanner softwares.

Designing of removable partial dentures

Softwares for designing removable partial dentures is another example of how Moore's law impact negatively on the sustainability of products that are released commercially within the small field of dentistry. Products that were "sophisticated" at their time of release to disappear rather rapidly afterwards were the MacRPD (USA) (55), the Stelli-Pro (France) (56) and the RaPiD (U.K.) (57).

For several years there no commercial products on the market. Then, in 2010 a company named SensAble Technologies (USA) together with Geomagic (USA) launched a concept whereby RPD designs could be made digitally by use of a haptic device named (SensAble)PHANTOM Desktop touch-enabled modeling stylus in combination with a designing software named (Geomagic) Piano. Subsequently, Dentsable (USA) was established as a spin-off company, and in addition to developing a new designing software named *Intellifit Digital Restoration System,* the former product changed name to the *Dentsable Dental Lab 3D modeling software.* An added element to the business model was that the actual RDPs would be fabricated at so-called Dentsable Authorized Production Centers. The fate of the business plan remains unclear, but judged by the website of the company (URL: Dentsable.com) that has remained unchanged since 2011 something may have gone wrong.

More recently, RDP designing softwares has become available as add-on modules to existing dental designing softwares from 3Shape (Denmark), (AmannGirrbach (Austria), Dental Wings (Canada), Excocad (Germany), Renishaw Dental studio (U.K.), Zirkonzahn (Italy) as well as in the Partial Framework option for inLab SW 15.0 (Sirona). It is unclear whether the different software favor a subtractive or an

additive manufacturing process or perhaps a combination, or if the software allows for optional choice. Like many other questions about data transfer and compatibility issues, open data can in theory be transferred between products from different manufacturers, but it happens seldom in practice until some form of a business deal has been worked out beforehand between the manufacturers.

Designing and manufacturing of full dentures

Two companies advertise a concept for computer-assisted designing and manufacturing of full dentures, i.e., Dentca (Dentca Inc, USA) and Avadent (Global Dental Science, USA). The marketing highlighted originally the possibility of delivering a new denture at a second clinic appointment, which is still emphasized on one website (URL: dentca.com) but more tempered on the other (URL: avadent.com). Perhaps it is in recognition that the clinician needs to be very experienced to avoid errors while recording maxilla-mandibular relations, and the patient has little possibility to consent to tooth setup and shape prior to receiving the completed denture. In sum, the products are perhaps more about the “manufacturing” component of CAD-CAM rather than on the “designing” part. Nevertheless, the two products seem to be endorsed by a handful of positive clinical studies (see supplement).

In contrast to the named products above, several designing softwares include optional modules for denture fabrication, but without the need to purchase particular components from a specific manufacturer. Modules for designing dentures exist for e.g., 3Shape Dental system (3Shape, Denmark), DWOS (Dental Wings, Canada), Excocad (Exocad, Germany), Ceramill mind denture option (AmannGirrbach, Austria) and Model-easy-fix (Zirkonzahn, Italy). The modules enable designing a denture from an individualized occlusal wax rim and stone model, either mounted in a conventional mechanical articular or merged with the data from a virtual articulator. An emerging concept is to ability to blend the denture planning with a virtual smile design software. These softwares are either proprietary, e.g., the Smile composer (3Shape, Denmark), or imported from third party softwares (see section on virtual smile design).

The CAD denture modules described above allows both subtractive and additive manufacturing processes, but there is no documentation anywhere which solutions are used or what is preferred by dentists or dental technicians.

Designing and manufacturing of customized implant components

Some companies adopted a business model limited to making CAD-CAM dental devices specifically for use in dental implant therapy. Two well-known products made originally for one particular implant system were a concept for customized CAD-CAM abutments, i.e., Atlantis (Astra Tech, Sweden) and a concept for customized CAD-CAM meso-structures, i.e., ISUS by Compartis (Degudent, Germany). Since the two companies now have merged, the products have been rebranded to Atlantis Abutments and to Atlantis Suprastructures (Dentsply, USA). Moreover, the solutions are available for a much wider range of dental implant brands. Also the CAD-CAM solutions from Nobel Biocare (Switzerland) has expanded from only their own product line previously to now cover multiple implant brands. All three products rely on milling the dental device.

Currently, there are about 50 products that enable the designing and/or manufacturing of a customized abutment, mesostructure or superstructure. A distinct minority of these products are supported by at least 125 clinical papers, which mostly report outcomes following the use of the three products named above (see supplement). A detailed review of the merits and flaws of the many other products is beyond the scope of this review. A caveat is that the “life-time” guarantees that many of the major implant brand manufacturers offer for their dental implant apply only if “original components” have been used. Experiencing vertical fractures in internal connection implants due to hoop stresses created by ill-fitting “customized” CAD-CAM abutments is not a happy prospect for anyone.

Computer-assisted manufacturing of dental devices

Following the success of the CEREC machine, several companies across the globe launched comparable scan-plan-mill machines, but with far less commercial success. Examples were the Cicero (Computer Integrated Crown Reconstruction) by Elephant (The Netherlands), DENStech by Dens (Germany) and Decsy by Media Corp (Japan).

An alternative route for manufacturing dental devices became possible a few years later, whereby digitized data, obtained by use of initially a mechanical 3D scanner, were transferred to a large production centre. The first centres were located in Switzerland, i.e., the DCS Precident centre established in 1989 (58) and in Sweden, the NobelPharma Procera centre was established in 1993. In Procera’s case, an oversized titanium replica copy-milled from the stone die was combined with spark-

erosion to create a coping (59), and a few years later 20% oversized copy-milled replicas were covered by aluminium oxide and subsequently sintered. Other production centres started to appear a few years later either entirely dedicated to manufacturing dental devices by milling fully sintered zirconia blocks (DECIM system (cad.esthetics, Sweden) or offering a full spectrum of CAD-CAM services (etkon, Switzerland).

The next important development was the launch of mid-size milling machines for the dental laboratories, which occurred around the millennium. The most successful brand-names that remain on the market have undergone considerable upgrades of both the hardware and software. Examples are the Digi Cut (Girrbach, Germany) from 1999 that is the predecessor of the Ceramill system (Amann Girrbach, Austria), the CEREC inLab (Sirona, Germany) and the Cercon smart ceramic concept (Degudent-Dentsply, Germany) launched in 2001, and the KaVo Everest (KaVo, Germany) that appeared in 2002. Although some of manufacturers claimed at the time that their products could mill fully sintered zirconia blocks, the majority advised milling the non-sintered zirconia blocks.

The manufacturing processing technologies within the field of oral rehabilitation field have since expanded rapidly and encompass today a range of products for processing alloys, ceramics and polymers or combinations thereof.

Subtractive manufacturing

Subtractive manufacturing methods used in oral rehabilitation is dominated by milling, although forming by electrical currents also fall into this category. Electrical discharge machining, alternatively named spark erosion was an essential element of the original Procera system developed by NobelPharma in the early nineties, but was later abandoned and replaced by milling. To the authors knowledge, only one manufacturer offer this production method, principally for fabricating telescopic superconstruction (URL: sae-dental.de, SAE Dental, Germany).

Modern milling machines are digitally automated by numerical control (NC) and a good machining software enables the user to define instructions with regard to cutting motion and torque, rotation speed and feed-rate of the machine tools, automated changes to the most efficient machining tools, which may be cutting or abrasive, in addition to other supplementary functions.

The anticipated dental device that is formed from a workpiece, i.e., “a blank” is mounted in a workpiece holder. Kinematics is obtained by translatory movements of

the spindle horizontally (x axis), vertically (y axis) and forward (z-axis) and rotations of the spindle around these linear axes (rotary axes A, B and C respectively). Spindle movements can also be combined with movements of the workpiece and milling machines can operate with more than one spindle. It is not always obvious is meant when advertisements claims that a product operate with e.g., 3+ or 4+ or 5+5 axes.

Even though the robustness of the milling machine has to be high it is also important that the software include algorithms that compensate for errors that are introduced during milling processes. These can generalized as geometrical compensation, force compensation and thermal compensation. Any errors in the final dimensions of the machined part are determined by the accuracy with which the commanded tool trajectory is followed, combined with any deflections of the tool, parts/fixture, or machine caused by the cutting forces or vibrations.

The cutting tools' trajectories are subject to the performance of the axis drives and the quality of the control algorithms. One needs to recognize that machining tools wear over time, as does the interfaces between the cutting tool and the tool holder and between the tool holder and the tool frame fixed to the end of a spindle. Eventual repairs and adjustments require recalibration by an expert engineer and theoretically, the risk of wear is inherent in the design of the milling machine. The complexities of how these tribological processes affects performance is discussed in an excellent recent review (60).

Milling machines come in all sizes ranging from desktop size to mammoths weighing several tons. A wide range of milling machines have been reported used in the literature or promoted in advertisements targeted to professionals working in the field of dentistry. Size matters - the more powerful the harder the material that can be machined. Moreover, the accuracy of dental devices are in general better when a fully hardened material is milled compared to a semi-sintered ceramic or alloy that needs to undergo further processing before completion (Figure 6)

In the author's opinion, all dental clinics should invest in a desktop-size milling machine, including a small 3D scanner with a proper designing software. Its use would not primarily be for machining permanent reconstructions, but for a rapid fabrication of semi-permanent temporaries, occlusal splints, surgical templates and other dental devices. Milling machines without automated change of multiple cutters should be avoided, as time spent on manually replacing these is non-productive. Once the dental device designed has been stored in memory and the delivered semi-

permanent device observed for a relevant period to record patient-reported outcomes what remains next is a modification or a simple touch of a button to start the milling of something more solid and more accurace achievable by use of a heavy milling machine somewhere else.

Additive manufacturing

A virtual 3D model can be sliced into layers virtually, whereby each layer is exported to an appliance that can solidify the shape of each layer from some material, while simultaneously stack the layers successively to build an exact construct of the virtual 3D model. The amount of energy that is required for the solidification will depend on the choice of material. E.g., some monomers will solidify into polymers by ultraviolet light, while powdered alloys require far more energy, which may be obtained from guiding small but powerful laser beams to cross. The trueness and precision of the construct will depend on how thinly each layer is incrementally built, which a very precise stepping process must regulate. It is not difficult to realize that a construct made from thin layers is more accurate than if built by thick layers. The flip side is that the required time for building the construct is prolonged, hence the need for good software algorithms built for fast computers. Some companies have succeeded better than others to develop products for dental additive manufacturing, but we can expect very rapid changes and principally new resins optimized for dental applications.

There are multiple ambiguous terms that describe additive manufacturing process chains, such as layered manufacturing or rapid prototyping. R*apid prototyping* allude to making prototypes of parts without having to invest time and resources to develop tooling. Within the biomedical field some terms seem to be favored, such as solid freeform fabrication (SFF)*, stereolithography (SLA), powder-fusion printing (PFP) and various types of 3D printing. Solid freeform fabrication is the most common manufacturing method in context with oral rehabilitation. Used somewhat inconsistently in the dental literature synonyms are ”fused deposition modelling”, “laminated object modelling”, “direct metal printing”, “selective laser sintering”, “solid ground curing” or “robocasting”. The use of SLA in dentistry is principally for fabricating surgical models and -templates. PFP has been evaluated for zirconia-oxide slurries, but unsolved clogging-problems led the research to be abandoned. 3D printing is used extensively by dental technicians to fabricate patterns for later investment and casting and its use is increasing in maxillofacial prosthetics for fabricating imitations of soft-tissues. Moreover, one company in USA (URL: dentca.com, Dentca, USA) started recently to manufacture full dentures by 3D

printing a poly-methyl-methacrylate resin named the Dentca Denture Base light-cure resin. Within tissue engineering, anisotropic scaffolds can be made with SFF, precision scaffolds with SLA, rigid scaffolds with PFP and cellularized constructs with 3D bioprinting.

Solid freeform fabrication

There is anecdotal claims that a large portion of partial removable prostheses and an increasing number of fixed prostheses are today being made by laser sintering of metal alloy powder. However, it is very difficult to find any numbers to substantiate the claim. It is in this context remarkable that very little has been published about the merits and challenges with laser sintered prostheses versus fabrication by conventional casting techniques (15). To the authors knowledge, there are no clinical studies comparing prostheses made by SLS versus traditional fabrication methods. SLS is based on a laser that selectively fuses an alloy powder by scanning cross-sections generated from a 3-D digital description of the part on the surface of a powder bed. As each cross-section is scanned, the powder bed is lowered by one layer thickness and a new layer of material is applied on top, and the process is repeated until the part is completed. The machines used for such purposes are sturdy appliances that rely on gas chambers, pistons and strong lasers and are therefore located in large production centres rather than in individual laboratories (Table 9)

Stereolithography in prosthodontics

A solid object can be made by adding an individual thin single layer of a UV-curable material on top of an already existing stack of polymerized layers in succession. UV-light focused onto the surface of a vat filled with a liquid photopolymer will polymerize the top layer. Either a concentrated laser beam is used, or a more recent approach named DLP-SLA printing whereby digital light is applied. Once the intended form of the object is obtained, the structure requires cleaning and post-polymerization, which tend to be a time-consuming process. SLA has been the predominant method for fabricating surgical templates ordered from a central production centre (Figure 7).

Smaller SLA/DLP-SLA appliances have also been developed and found uses e.g., by dental technicians to fabricate patterns for later investment and casting. Envisiontec (Germany) has developed a wide range of smaller SLA appliances for different indications, while other products are the Form 1+ appliance (Formlabs, USA) and the DigitalWax series of printers (DWS, Italy).

A recent innovation patented in 2015 that is labelled Continuous liquid interface production or “Clip” show promises of improving the speed and precision of stereolithography (61), and it will be exciting to see whether any products by use of this new technology will be developed for use in dentistry (URL: carbon3d.com, USA).

3D Printing

3D printing in dentistry has come a long way since 2002 when Cynovad (Canada) launched their product Pro50 and WaxPro, to replace the very time consuming process of fabricating wax models by hand. Two companies located in USA dominate currently the market for 3D printing in dentistry, principally because they own core patents of the technology. The two companies are 3D Systems (URL: toptobottomdental.com / 3DSystems.com) and Stratasys (URL: stratasys.com). The latter owns also two other 3D printer manufacturers who promote their products for use in dentistry, i.e., Object (URL: objet.com) and Solidscape (URL: solid-scape.com). Digital wax models manufactured by other companies are fabricated with SLA appliances and not by use of 3D printers.

3D printing is currently the additive manufacturing method that attracts the most attention from researchers and investors alike because of great strides and potential prospects to hopefully biofabricate body tissues. Consequently, vast investments from both governmental as well as commercial enterprises are currently being directed to rapid ongoing research within 3D printing research. By “blending” SLA and 3D printing, extruded nanocomposites during the deposition process are UV-illuminated to create microstructures (62), and bioprinting skin is no longer fantasy (63). Another promising avenue is to develop artificial functional constructs for drug screening and toxicology research, and 3D bioprinting of slush made from autogenous stem cells that have been harvested and selectively treated in the laboratory is not a science fiction scenario. The indirect benefit for the future practice of dentistry has been recognized within osteology (64) and in craniofacial (65) and maxillofacial (66) reconstructions.

Electroforming technologies

Electroforming technologies has found a few applications in oral rehabilitation. One use for plating surfaces, e.g., gold for esthetic reasons or to improve lost friction of a telescopic superconstruction (URL: galvanoforming.de, Gramm, Germany). Also the company Wol-Dent (Germany) invented in 2007 a procedure for electrolayering

ceramic powder onto abutment dies. The procedure was named the electrophoretic ceramic procedure (ECP) and several different appliances were sold until the company was liquidated in 2015.

Materials for digital manufacturing appliances

More or less all existing materials currently in use in dentistry can be processed by either an additive or a subtractive manufacturing process. New materials specially made for new CAD-CAM technologies will likely differ from direct traditional restorative materials with regard to mechanical and physical properties. A description of materials for milling machines is covered in a separate review by professor Miyazaki and colleagues in this issue of JOR.

The number of manufacturers of blanks to be used in milling machines has seen a rapid increase. The majority of these manufacture partially or fully sintered zirconia blanks, while a few offer only sintered metal powders (Table 10)

Clinicians should be aware that currently there are no ISO standards for CAD-CAM blanks. It would seem prudent to ascertain that their ordered dental devices are made from products from reputable manufacturers.

Full dentures milled from monolithic resin blocks is a fabrication method spearheaded by Avadent (Global Dental Science, USA) (URL: (URL: avadent.com). Two recent digital concepts for fabricating full prostheses have recently been launched in Germany by Merz Dental (URL: baltic-denture-system.com) and Wieland Dental (URL: wieland-dental.de). All concepts mill deep sockets into to the highly polymerized resin acrylic to maximize the extension surface for bonding the prefabricated teeth.

A new group of materials has been developed that is made specifically for laser sintering. Cobolt-chromium powder has been developed by BEGO (Germany), i.e., Wirobond C+, by Dentaurum (Germany), i.e. remanium star CL, and by Scheftner (Germany), i.e., Starbond CoS powder. The manufacturer named SLM solutions (Germany) offers also under the umbrella name of medi-dent other metal alloy powders besides Co-Cr.

It should perhaps be added that the somewhat disappointing lack of progress towards making composite resin materials with better clinical performance has been boosted due to new digital manufacturing technologies. One element is that industrially manufactured composite resin blocks have superior properties compared

to materials that are polymerized intraorally with light. Another consideration is that the alternative combinations of organic and inorganic constituents in the composite resin may potentially be optimized for alternative digital manufacturing appliances (67)

4 Other computer-assisted applications

Computer-assisted training of procedures used in oral rehabilitation

Innovative educators began using computers in undergraduate clinical teaching from early on, including in prosthodontists (68), and even over the Internet (69). The continuous improvements of the computer capacity has today transformed several aspects of clinical teaching, and perhaps one of the most successful novelties is the adoption of simulation training. The Dentsim simulator (denX, Israel), which appeared around 2000 provided students the opportunity to improve psycho-motor skills by preparing teeth in a manikin. By virtue of an opto-electronic concept using IR fiducials and tracking cameras, the software could record deviations from a pre-defined cavity preparations. Fifteen years later, the cutting edge digital educational simulators incorporate also haptic, i.e., sensory, feedback just like a vibrating cell phone. Many dental schools and institutions have developed their own concepts, and even though several were commercialized it is unclear how many have survived in a tough competitive market. Examples of such systems are the HapTEL (King's College London, U.K), the Iowa Dental Surgery Simulator (IDSS) (University of Iowa, USA), PerioSim (University of Illinois at Chicago, USA), the VirDenT system (University of Constanta, Romania) and the Virtual Dental Patient (VDP) (University of Thessaloniki, Greece) and the Virtual Dental Training System (VRDTS) (Harvard University, USA). To the author's knowledge, several institutions have invested in haptic tools, e.g., Phantom (Sensable Technologies, USA) that makes it possible for users to touch and manipulate virtual objects, but experiences from teaching is so far only anecdotal. A commercial product for the pre-clinical training of dental students is Simodont (MOOG, The Netherlands), which appears to have been implemented in several dental schools (70). A final somewhat kinky twist of progress is that quite sophisticated patient robots have become available for teaching dental students, and this is basically a spinoff benefit from innovations developed within the industry of the flesh.

Discussion

The great majority of commercial digital products identified in this review has no clinical documentation at all, while the products from a distinct minority of manufacturers have frequently appeared in more or less scientific reports. An FDI World Dental Federation expert group established some time back to appraise the quality of dental implant products on the global marked (71) reported the same observation. The impact of this report within the field of dental implantology is intangible, but anecdotal data in 2016 imply that the situation has not changed. The lack of evidence of effectiveness and safety of most of the products is of course a major concern, and one should not rule out publication bias. Moreover, the value for money remain obscure for the potential buyers, which creates an ethical challenge when we know that it is our patients in the end that pay for all costs whether the product turns out to be a lemon or excellent.

Obviously, a new digital gadget or tool is not necessarily a predestined improvement compared to an established method or technology. E.g., within craniofacial oral rehabilitation surgery, not all experienced surgeons are overwhelmingly impressed by what the new pre-planning softwares can bring to improve current practice (72). It would seem reasonable that the burden of proof of merits should rest with the manufacturer or distributor. However, it is seldom the research and development (R&D) unit, but rather the marketing division that deal with product sales. Often the documentation is so scant that a clinician is unable to make an educated decision whether to implement an innovation that may directly or indirectly benefit their patients.

Compounding the issue is the “Moore’s law” phenomenon which means that the time span for a return of the R&D costs invested in bringing a new digital product on the market is short and may even fold before the launch because someone else launched a faster and better digital solution. History is replete with examples of digital products that were put onto a market that was not ready yet, or the product in itself was not ready. The former is exemplified by Steve Jobs who left the very successful Apple in 1985 to create the NeXT computer that didn’t sell, while an example of the latter is the Samsung Galaxy Note 7 released with a software glitch that caused the battery to generate excessive heat with risk of fire and explosion.

An often-quoted description of how innovations diffuse in society is attributed to Everett Rogers who in a textbook from 1962 proposed that consumers who adopted

new technologies could be grouped into five categories. The incorrect inference is that somehow, the first group named “innovators” have better foresights or intellects, while the last group labelled “laggards” were a reflection of the elected term. Unfortunately, this explanation is too simplistic. The purchase of digital devices by dental professionals is a largely unknown complex interplay between economical, psychological and scientific mindsets –or lack thereof- of the purchasers. Economical elements in operation are a price elasticity of demand and a price elasticity of supply in combination with an income elasticity of demand.

Dental technicians are acutely aware of medical device regulations established to safeguard patient safety and enable traceability of substandard products and services. E.g., in Europe, it is mandatory to adhere to the EU Council directive 93/42/EEC (URL: eur-lex eur-lex.europa.eu). It is perhaps not recognized by all dentists that by regulation, the doctor is in the end responsible for the coordination of all steps of the CAD-CAM processing chain. The implication is that the same regulatory principles apply to the fabrication of a CAD-CAM dental device for an individual, e.g., a “customized abutment” as for the industrial production of prefabricated abutments. It is essential to recognize that it is always a **responsibility of the doctor** to maintain the control of, and an overview of the chain of materials and methods in the manufacturing process and that materials and parameters of the manufacturing process may be incompatible. Clinicians should stay with validated concepts for fabricating dental devices by use of CAD-CAM , and maintain or upgrade their knowledge about the properties of new materials and about new additive and subtractive manufacturing technologies. One counsel is to remember that in today’s commercial world, company brand-naming have a great value. Beware if a company with a well-established brand-name decides to disconnect itself from a newly acquired product from an original manufacturer by establishing a subsidiary company to sell the newly acquired product.

It may be questioned whether dental professionals have been prepared educationally to make use of new digital appliances within the field of dentistry. A hazard under current circumstances is the development of what may be labelled as a “bundle package industry”, whereby “brokers” take care of all facets of digital dentistry, even including an interpretation of the tomographs from cbCT (!). The many consultants that may be identified on the internet are not listed in this review, but their services are offered within all aspects of digital dentistry. The phenomenon is generated by computer-illiterate clinicians who, for whatever reasons have proceeded with a use of

digital technologies, but can't prioritize their time to learn how to maximally exploit the technologies for their own and their patients good. The more advanced a digital product is, the longer the expected learning curves are required. E.g., for CAD-CAM of a dental device the clinician should have competency in (1) best operation of new appliances for 3D surface and 3D volumetric rendering, (2) mastering designing of dental devices by use of a software (3) choosing the additive or subtractive manufacturing method that is optimal for the planned dental device and (4) deciding on the best biomaterial with respect to properties and technique-sensitivity as a function of the chosen manufacturing method. By regulation, these are not the decisions to be made by the dental technician or by any external "consultants".

Conclusions

Two factors apply, which is that (1) Moore's law still apply, which means that new digital appliances will continue to be faster and with lower cost per performance unit and (2) innovative software programs will harness these improvements in performance. Manufacturers make a calculated risk when setting out to develop a new digital appliance for the dental market, and the product life cycle of past products within the field is short-lived. However, clinicians must request clinically meaningful information about new digital products and not accept only the technological verbiage combined with a promise of an "improved productivity".

Final reflections

The scope and length of this review may be criticized as being too extensive too the average reader, which is acknowledged. However, any dentist who is determined to provide best care for his or her patients is forced to constantly consider the newest technologies that are being developed. The bombardment of information from companies who are eager to capitalize on their R&D costs will be never-ceasing. One needs to be reminded that commercial enterprises do not exist to improve the health of individuals or the public but to generate an income for their stock-owners who otherwise will reallocate their investments. If anything is virtual, it is the prices of the new digital products. High costs are in the end projected to higher expenses for the individual patient or society.

Financial sustainability for the manufacturer means selling as many appliances as possible for the highest possible price within the short period before a better or

cheaper competing product appears on the market. Financial sustainability for the clinician who invest in a high capital cost appliance require a high throughput of qualitatively impeccable dental devices. The worst case scenarios for both parties are left to the readers to consider.

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Legends to figures

Figure 1. The clock rate of the central processing unit in select computers. Clock rate is the frequency of the clock in any synchronous circuit. Note that the clock rate is no longer considered as a reliable benchmark for computers, since today there are different instruction set architectures or microarchitectures in computers. A more common indicator used in today is “MIPS”, i.e., million instructions per second).

Figure 2. Digital tooth shade guides sold on the market over the last 25 years. Products highlighted in yellow are still available, while products in grey shade have disappeared. Two products highlighted in pink are a stand-alone software product that extracts the shade from digital photographs that include a calibrated gray item, rather than actual digital appliances. The year may not apply for some countries due to select market entry strategy decided by the manufacturer, alternatively due to regulatory obstacles.

Figure 3. A digital motion capture system based on reflection of infra-red light from fiducial markers (MacReflex, Qualisys, Gothenburg, Sweden) combined with electromyography (Biopac MPIOOWS, Bio-Research Associates, Milwaukee, WI, USA). used in the author’s university in the mid-nineties for research purposes. The software was run on a Apple Macintosh PowerBook 140 with a clock rate of 25 MHz. The frequency of the registration was 40 frames per second (Hz), while current systems can provide up to 1000 Hertz.

Figure 4. Improvement of technologies used for CAD-CAM of dental devices

Figure 5. Seemingly similar 3D scanners for intraoral use, but with different brand labels

Figure 6. Milling machines described in advertisements for dental professionals or described in the dental research literature. Desk-top size machines can mill softer types of materials, while heavy machines can mill everything. Software algorithms are required for materials that are milled in a pre-sintered state and subsequently undergo shrinkage upon sintering

Figure 7. Surgical templates for implant placement. Made from stereolithography Left, Simplant Surgiguide (Dentsply USA), right Nobelguide (Nobel Biocare, Switzerland).

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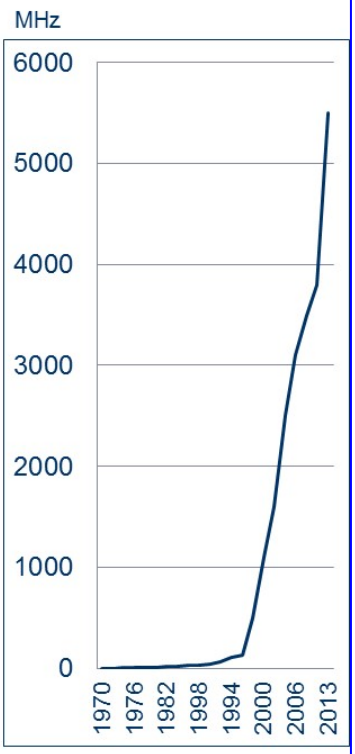
<1	1971	Intel 4004/ Texas Instrument TMS100
1	1974	8bit.Cp/M (Commodore 64, Apple II)
5	1976	16bit; (Compaq, IBM PC); Intel 8088 (IBM (1981))
12	1985	Intel 80386 32bit; Motorola 68040 (Macintosh, Amiga, NeXT))
20	1989	Intel i486; Cyrix, Intel Pentium, Pentium MMX → Pentium Pro
110	1994	IBM PowerPC 601 (Power Macintosh 8100)
.....		
500	1997	IBM PowerPC 750 (iMac)
1400	2002	Intel Pentium III (Celeron/Zeon)
3000	2001	IBM PowerPC950 (PowerPC G5)
3800	2001	Intel Pentium 4 (Pentium M/D)
3000	2003	AMD Athlon 64bit
3200	2005	AMD Athlon 64bit X2
.....		
5500	2013	IBM zEC12



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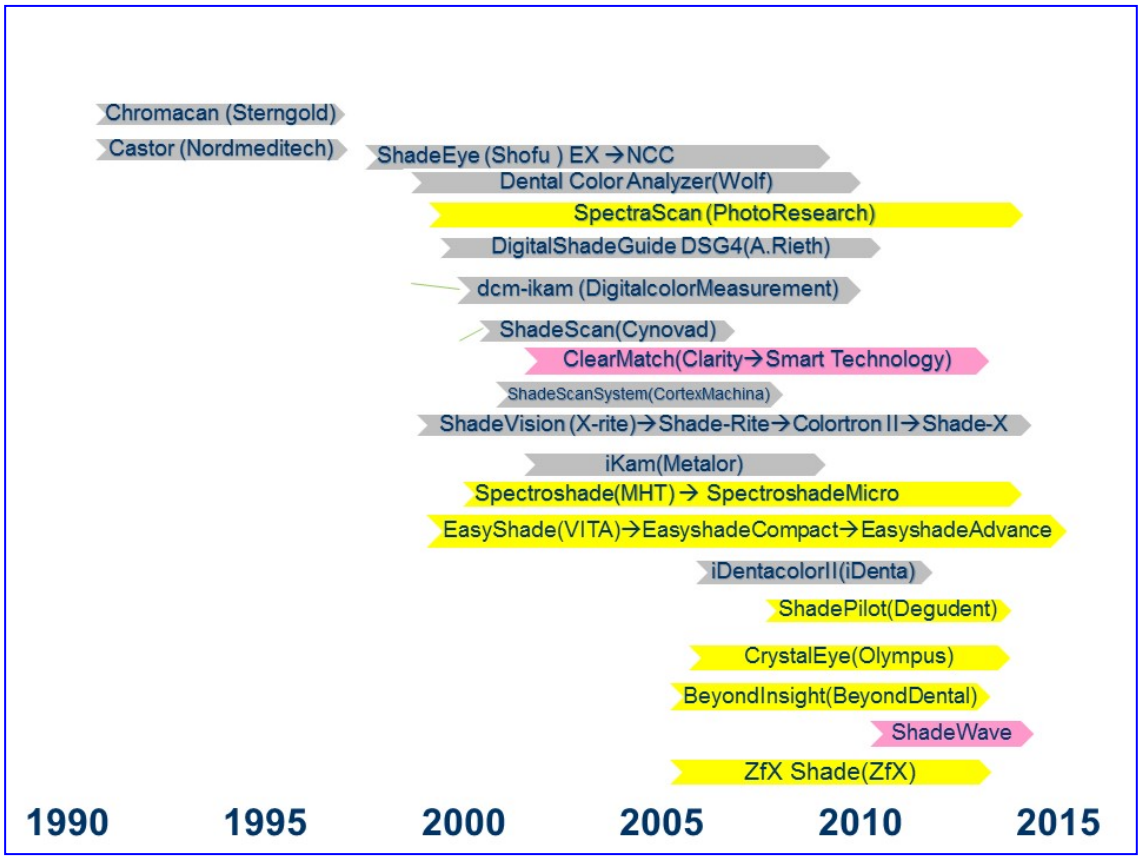

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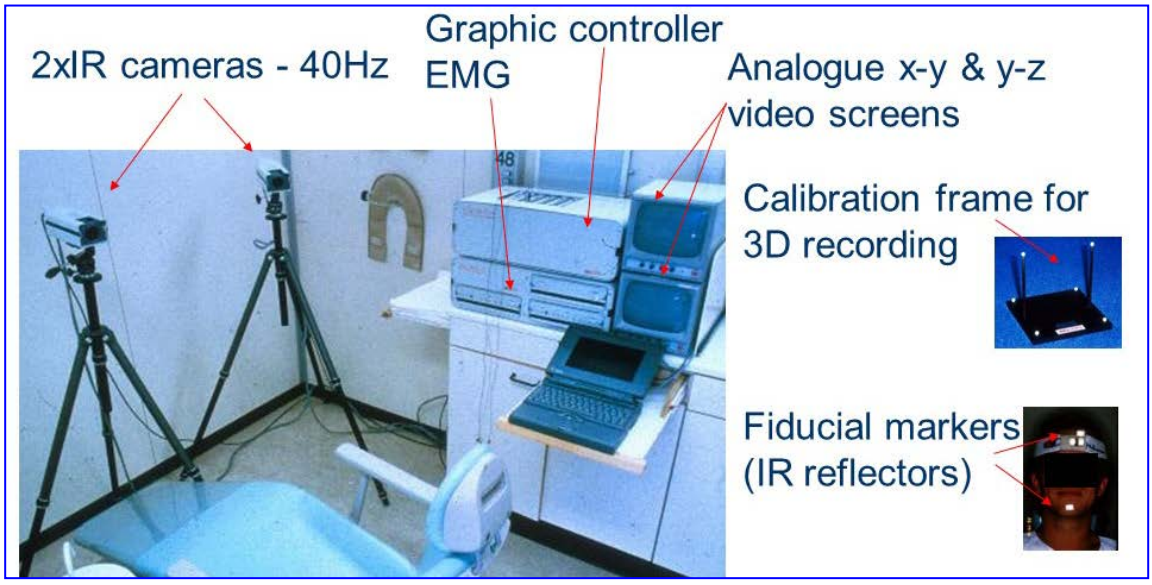

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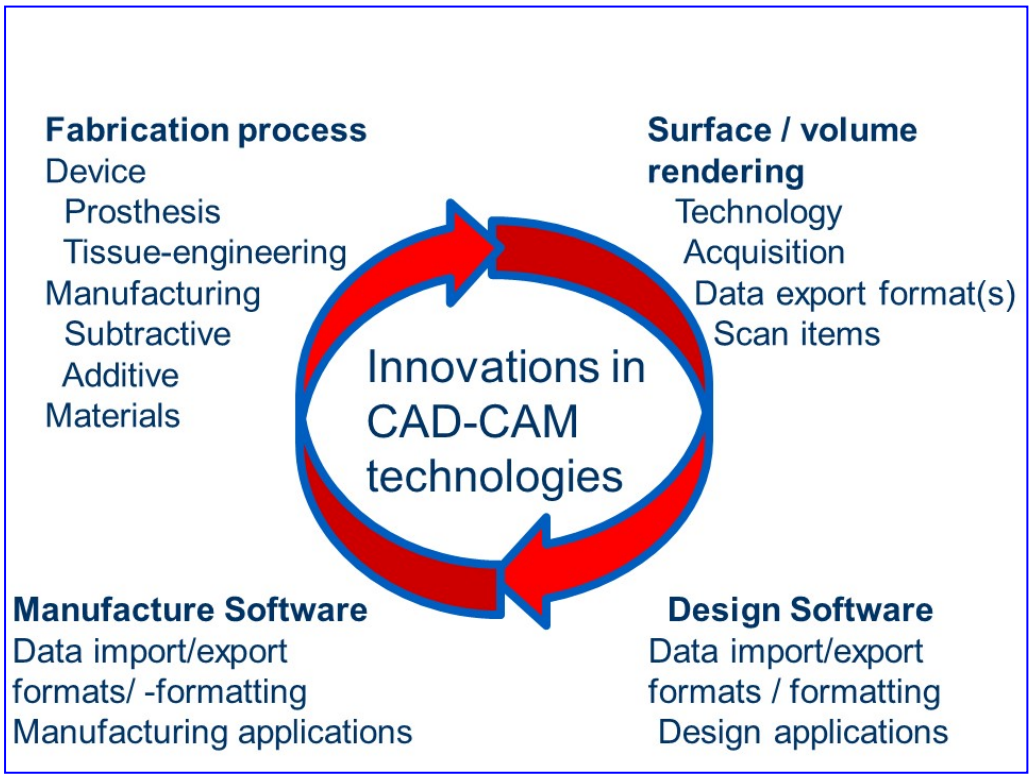

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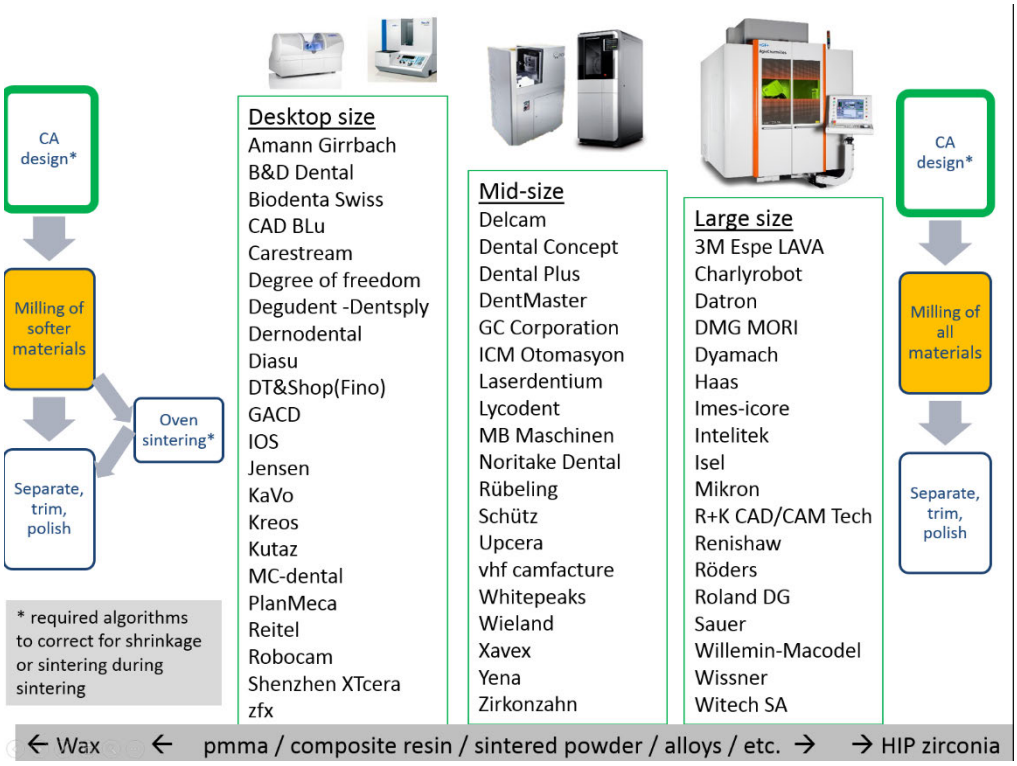

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