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Reproducibility of cephalometric landmarks on conventional film, hardcopy, and monitor-displayed images obtained by the storage phosphor technique

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SUMMARY The aim of the present study was to evaluate and compare the reproducibility of cephalometric landmarks on (1) conventional films, and images acquired by storage phosphor digital radiography both on (2) hardcopy and (3) monitor-displayed versions. The material consisted of 19 cephalograms for each image modality. The phosphor plates were scanned in an image reader and the 10-bit normalized, raw data digital images were converted to 8-bit TIFF images for PC monitor-display. The digital hardcopies were produced in a laser printer. Six observers were asked to record 21 cephalometric landmarks on each conventional film, hardcopy, and monitor-displayed image. For the films and hardcopies, the landmark co-ordinates were recorded via a digitizing tablet. For the monitor-displayed images, the co-ordinates were recorded directly from the monitor using a dedicated Windows-based cephalometric program. Reproducibility was defined as an observer's deviation (in mm) from the mean between all observers. Differences between the image modalities and between the observers were tested by two-way analysis of variance for each landmark.

There was a statistically significant difference between the reproducibility of film, hardcopy and monitor-displayed images in 11 of the 21 landmarks. There was no unequivocal trend that one modality was always the best. For a full cephalometric recording (the sum of all 21 landmarks), the monitor-displayed images (mean = 25.3 mm) had a lower precision than film ($P < 0.005$) and hard-copy ($P < 0.02$). There was no significant difference between film (mean = 21.8 mm) and hardcopy (mean = 22.8 mm). The lower reproducibility seen for the monitor-displayed images is most probably of little clinical significance.

Introduction

During the 1980s and early 1990s research into the application of digital technologies to lateral cephalometric radiography emerged. Conventional lateral cephalometric films were digitized using different detectors, processed by computer and displayed on a monitor. Jackson and co-workers (1985) compared some common cephalometric landmarks sampled by manual point identification on film with those acquired by digital sampling on images displayed on a video monitor. They found the results from the digital image system comparable with those obtained by the traditional method. Other studies (Jäger *et al*., 1989; Döler *et al*., 1991) showed an improvement in image quality of digital cephalograms when using various digital enhancement and filtering techniques. Macrì and Wenzel (1993) concluded, however, that the reliability of landmark location in digital images was inferior to conventional film when a low-cost black-and-white video camera and a spatial resolution of 512 × 512 pixels was used for digitization, and that digital image processing only increased reliability in the digital images when good quality original films were used.

Currently the most promising digital acquisition technology for cephalometric radiography is the photo-stimulable storage phosphor plate (Buckwalter and Braunstein, 1992; Cowen *et al.*, 1993). The storage phosphor plate is a thin (less than 1 mm), flexible re-usable plate of polymer material coated with a photo-stimulable phosphor compound (Sonoda *et al.*, 1983; Seki and Okano, 1993; Barenghi *et al.*, 1995). There are two display possibilities of the digital image, monitor-display and 'hardcopy', where the image is printed photographically onto a film. The storage phosphor plate has a very wide dynamic range (Sonoda *et al.*, 1983; Miyahara, 1987; Borg and Gröndahl, 1996), which in practice means that there is no fixed relationship between exposure dose and image density.

In recent years, cephalometric studies using the hardcopy display of the storage phosphor technique have been published, especially in relation to radiation dose (Murphey *et al.*, 1990; Cowen *et al.*, 1993). No differences in reproducibility of landmark identification have been found with exposure reductions between 50 and 75 per cent of that needed for conventional film (Seki and Okano, 1993; Näslund *et al.*, 1995). It has been demonstrated that for conventional film, soft tissue landmarks could be more reliably localized when small radiation doses were used, but that higher doses were necessary for hard tissue. On the digital hardcopies, however, both soft and hard tissue landmarks were equally well localized, independent of the radiation dose (Eppley, 1991; Ruppenthal *et al.*, 1991). No studies in cephalometry using storage phosphor radiography have evaluated the other method of digital display, i.e. the monitor-displayed image.

The aim of this study was to compare the reproducibility (repeatability) of some commonly used cephalometric landmarks recorded on conventional radiographic film and digital hardcopy and PC monitor-displayed images obtained from storage phosphor radiography. The following null hypothesis was tested. There is no statistically significant difference between landmark reproducibility on conventional film radiography and digital images on hardcopy or monitor-displayed versions.

Subjects and methods

Patient sample

The sample consisted of 20 randomly selected patients attending the Orthodontic Department of the County Council, University Hospital of Lund, Sweden for orthodontic diagnosis. The gender, the type of occlusion, and the skeletal pattern were not taken into consideration in the study design. The subjects were aged between 10 and 17 years (mean age 14.3 years). All patients were exposed to one radiographic lateral head examination.

The radiographic recording methods

The radiographic examination was based upon simultaneous acquisition of a conventional film and a digital image in a single exposure (Oestmann and Greene, 1988). A storage phosphor plate is sandwiched into a standard cassette with the conventional film. The residual radiation available to the storage phosphor plate after passing through the conventional film-screen is adequate as the phosphor plate is more sensitive to radiation than film and is able to create an image even with lower doses (Näslund *et al.*, 1995). A standard 24×30-cm cassette with a film-screen combination (Quanta Detail/Quanta Fast Detail screen, du Pont de Nemours, Wilmington, USA, and Cea RP blue sensitive film, Cea AB, Strängnäs, Sweden) was used as the basis. However, the Quanta fast detail screen was, on one side of the cassette, replaced by the phosphor plate (type STV, Fuji Photo Film Co. Ltd., Tokyo) with the plate facing the film. After exposure, the image plate was removed in a dark room and placed in its usual cassette.

The cephalometric equipment included an X-ray unit (GE Phasix 65, General Electric SA, France), a tube (MSN 742, focus 0.8 mm, 1.0 mm Al filter) together with a cephalostat. The radiographs were taken with the patients in the fixed head position in the cephalostat (Iikubo *et al.*, 1975). The focus-to-film distance was 160 cm.

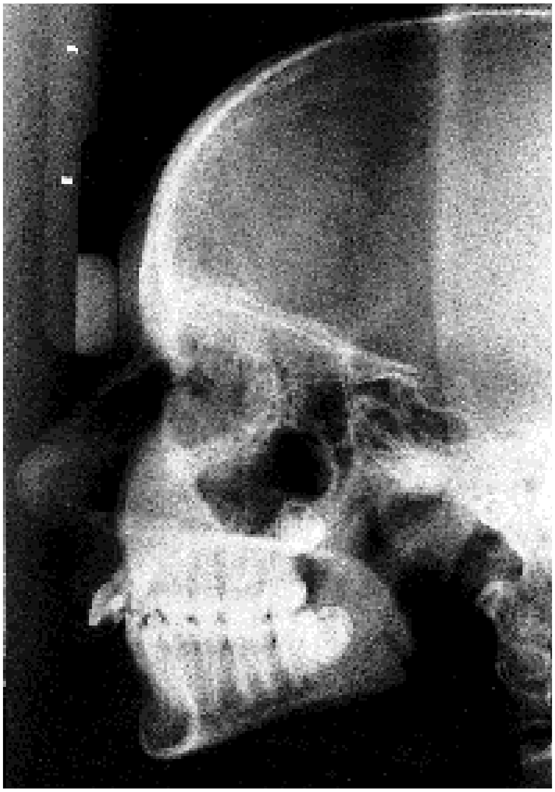

Figure 1 The conventional film radiograph.

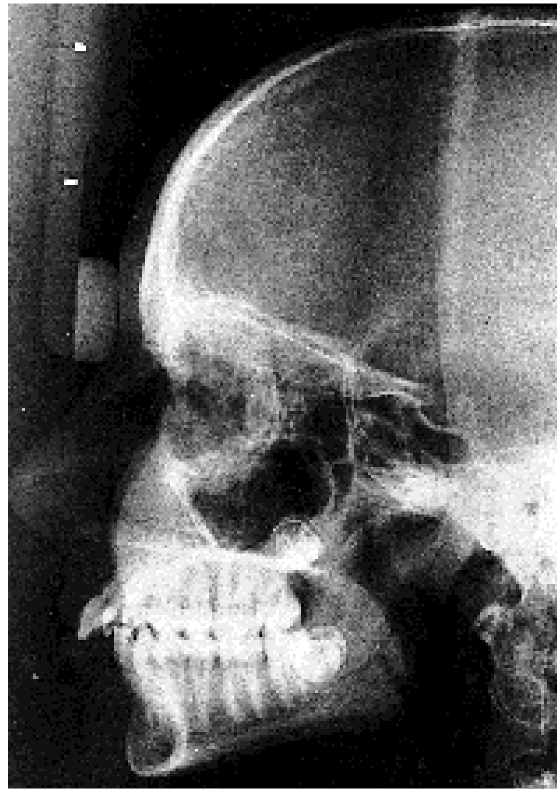

Figure 2 The digitally enhanced hardcopy.

The conventional films (Figure 1) were developed in an automatic film processor (Compact Daylight System II, du Pont de Nemours). The image plate was processed by an image scanner (AC-2, Fuji Photo Film Co. Ltd.) and temporarily saved on a work station (HIC 652B, Fuji Photo Film Co. Ltd.). Subsequently, the images were transferred to an Optical Disc Filing unit (ODF-612) used for permanent storage. Hardcopies (Figure 2) were made after post-processing the raw data with seven default image enhancement algorithms and printed out by a digital laser printer (LP414N Fuji Photo Co. Ltd.) on a single emulsion 36 × 25.5 cm film (CR 780). The digital images for monitor-display (normalized raw data) were transferred from the ODF-612 via a DICOM gateway on a File Transport Protocol (FTP) server and transported from Lund, Sweden to Aarhus, Denmark via the Internet. In Aarhus, the 10-bit DICOM images were transformed to and saved as 8-bit Tagged Image File Format (TIFF) images for use in the Windows platform (Figure 3). The pixel size in the images was 0.15 mm and the matrix resolution 6.7 pixels per mm.

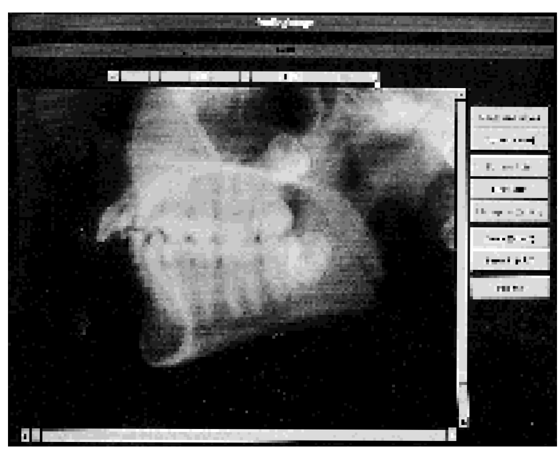

Figure 3 Part of the digital monitor-displayed image.

In this way, one set of images consisting of (1) a conventional film (modality I), (2) a digitally post-processed hardcopy (modality II), and (3) a digital image displayed on PC-monitor (modality III) was acquired for all 20 patients. The digitally acquired image of one patient had not been adequately saved and was lost, so that only the radiographs of 19 patients could be used for this study.

Landmark definition and sampling

Twenty-one commonly used skeletal and dental cephalometric landmarks (Figure 4) were selected and accompanied by the reference plane, if required by definition.

Four co-ordinate points (fiducials) were marked directly on the films and the hardcopies as perforations with a fine sewing needle using an acrylic perforation template (Baumrind and Frantz, 1971). The fiducials 1 and 2 were used to construct a co-ordinate reference grid with fiducial 1 as the origin, and the line connecting fiducial 1 and 2 as the z-axis. In this way, each landmark was related to the y–z co-ordinate system and characterized by a y–z co-ordinate. The other two fiducial points were not used in this study. They can be used as controls when lines and angles are measured in a full cephalometric analysis which was not the aim of the present study. For the monitor-displayed images the construction of such a y–z co-ordinate system was not necessary as the digital image consists of a pattern of rows and columns (the matrix) with an evenly spaced number of pixels in a known reference system. Magnification of the two digital image modalities compared with film was measured by the inclusion of a metallic ruler and found to be 2 per cent for the hardcopies and 11 per cent for the monitor-displayed images (for both axes). This magnification was taken into account when calculating the results.

Six observers recorded the 21 landmarks on the images from the three image modalities in the 19 patients. The observers were four orthodontists, all staff members of the Orthodontic Department, and two postgraduate trainees from the same department. Prior to the registrations, in a special meeting, the observers were calibrated with respect to definition of the landmarks. The 19 films and the 19 hardcopies were coded and presented to the observers in a random order. To prevent recognition of the two modalities, all markings on the two types of films were removed. Landmark identification on both the conventional films and the hardcopies was performed in a dimmed tracing room. Landmarks were recorded on an 8 × 10-inch sheet of 0.003-inch matte, acetate tracing paper before digital sampling. Digital sampling was performed directly on the acetate tracing paper; the tracing paper still present on top of the film/hardcopy. For this procedure, a digitizer (Graphtec KL 43000 light digitzer, Graphtec Corporation, Yokohama) with a cross-haired recording tablet and a computerized cephalometric program for landmark sampling (PorDios, Purpose On Reqest Digital Input Output System, E. Gotfredsen, Aarhus) was used. The digitizer has previously been shown to have a high accuracy in both the z- and y-axis (Macrì and Wenzel, 1993).

For the monitor-displayed images, landmark identification was performed in a dark room, the

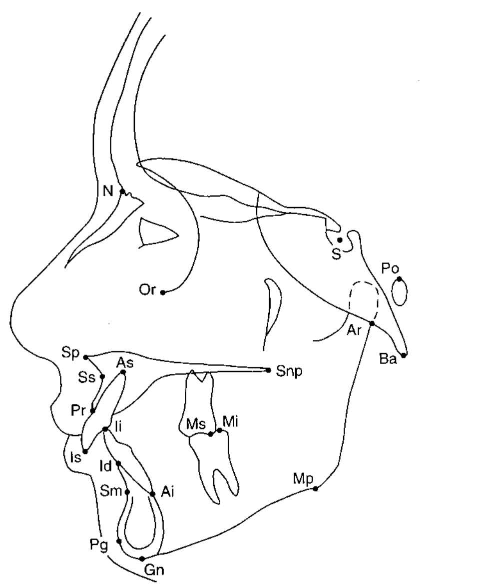

Figure 4 The 21 cephalometric landmarks. Ai = apex incision inferius; Ar = articulare; As = apex incision superius; Ba = basion; Gn = gnathion; Id = infradentale; Ii = incision inferius; Is = incision superius; Mi = molar inferius; Mp = mandibular prominence; Ms = molar superius: N = nasion; Or = orbitale; Pg = pogonion; Po = true porion; Pr = prosthion; S = sella; Sm = supramentale; Sp = spinal point; Spn = spina nasalis posterior; Ss = subspinale.

only illumination being from the PC-monitor. Landmark sampling was performed with a mouse-controlled cursor in combination with a computerized cephalometric Windows-based program for landmark sampling in digital images (pre-release program PorDios for Windows, E. Gotfredsen, Aarhus, DK). The cursor consisted of an arrow, and when a landmark was recorded, a red dot appeared on the screen over the selected pixel. Reference lines and perpendicular lines necessary to help identification appeared automatically afterwards. The observers were allowed digital manipulation of the image by changing the setting of the contrast, brightness and gamma scale. A zoom function allowed enlargement up to ×4. The program scaled the image so that it was always displayed covering the full screen in a vertical dimension. This approximated half of the full image resolution. The full resolution was achieved when the observer zoomed once. The observers started the landmark recording at random on the films and hardcopies. At least 3 weeks later, the recording on the monitor-displayed images was undertaken. The total data material thereafter consisted of 114 recordings for each modality.

Data treatment

Each landmark formed on each conventional film, hardcopy, and monitor-displayed image was thus defined by six recordings as performed by the six observers. For each of the landmarks in each of the three modalities, the mean y- and z-co-ordinates (y, z) between the six obervers were calculated $(\bar{x}y, z)$, leading to the best estimate for that particular landmark in a given image (the arithmetical centre point). The recordings of the six observers were thus spread around their mean. The differences between the mean co-ordinates and the co-ordinates of the observer for each landmark were calculated as the distance in millimetres, named 'the deviation from the mean'. The deviation from the mean was used as the variable determining reproducibility (repeatability) for each landmark. The means and standard deviations, as well as the range for the deviation from the mean were calculated per observer and per modality for each landmark. The smaller the deviation in millimetres, the higher the reproducibility.

Statistical comparisons between the three modalities and the six observers were performed using a two-way analysis of variance (ANOVA) for each landmark. For overall evaluation of the reproducibility of a full cephalometric recording, the sum of the deviations from the mean was calculated for all landmarks combined (Σ landmark 1–21) for each of the three methods (using the means between the observers). Differences between the modalities for the sum of the deviations were tested by Student's t-tests. All differences were considered statistically significant at $P < 0.05$.

Results

In Tables 1 and 2, the results from the ANOVA comparing the modalities and the observers simultaneously are presented. Table 1 describes

Table 1 The deviation from the mean ($\bar{x}$ and SD) in millimetres for each modality as an average between observers for each landmark ($n = 114$).

	Modality					
	M I		M II		M III	
	$\bar{x}$	SD	$\bar{x}$	SD	$\bar{x}$	SD
S*	0.64	0.37	0.67	0.37	0.51	0.34
N	0.58	0.60	0.54	0.69	0.71	0.76
Sp*	1.02	0.89	0.93	0.85	1.40	1.24
Snp	0.87	0.51	1.09	1.50	1.03	0.74
Ss	0.95	0.80	0.90	0.63	1.10	0.76
Pr*	0.56	0.30	0.62	0.35	0.61	0.49
Is*	0.67	0.76	0.56	0.43	0.36	0.44
As*	0.90	0.70	1.03	0.80	1.30	0.96
Ms*	1.04	0.64	1.07	1.06	1.75	1.14
Ii*	0.44	0.24	0.46	0.22	0.32	0.22
Ai*	1.48	1.10	1.50	1.07	1.52	0.82
Gn	1.08	0.68	1.02	0.66	0.93	0.65
Mp*	1.20	0.71	1.37	0.83	1.57	1.23
Mi*	0.77	0.40	1.02	1.00	1.33	1.00
Id*	0.70	0.51	0.75	0.51	0.61	0.47
Sm	1.37	1.11	1.27	1.03	1.23	0.82
Pg	0.75	0.49	0.74	0.48	0.71	0.53
Ar	0.62	0.46	0.55	0.37	0.53	0.47
Ba*	1.28	1.06	1.46	1.54	1.99	1.67
Or	2.18	1.62	2.29	1.81	2.08	1.76
Po*	2.75	1.94	2.96	2.52	3.68	2.70

*$P < 0.05$.

Table 2 The deviation from the mean ($\bar{x}$ and SD) in millimetres for each observer as an average between the modalities for each landmark (n = 57).

	Observers											
	1		2		3		4		5		6	
	$\bar{x}$	SD	$\bar{x}$	SD	$\bar{x}$	SD	$\bar{x}$	SD	$\bar{x}$	SD	$\bar{x}$	SD
S*	0.53	0.28	0.50	0.27	0.93	0.48	0.60	0.31	0.41	0.22	0.67	0.34
N	0.61	0.70	0.48	0.43	0.62	0.57	0.57	0.78	0.56	0.59	0.83	0.92
Sp*	0.93	0.91	1.13	1.33	1.33	1.06	0.97	0.82	0.95	0.64	1.38	1.18
Snp	0.92	0.55	0.72	0.44	1.14	0.71	1.10	0.72	0.87	0.70	1.26	2.00
Ss	0.97	0.64	1.19	1.01	0.99	0.68	0.92	0.68	0.99	0.75	0.85	0.56
Pr*	0.62	0.35	0.71	0.52	0.63	0.38	0.58	0.35	0.46	0.31	0.56	0.37
Is*	0.54	0.44	0.42	0.24	0.44	0.31	0.85	1.08	0.42	0.37	0.51	0.49
As*	1.01	0.75	1.10	0.85	1.41	1.05	1.05	0.85	0.89	0.73	1.02	0.71
Ms*	1.86	1.41	1.73	0.88	0.97	0.63	0.98	0.65	1.24	1.28	0.95	0.57
Ii*	0.46	0.28	0.38	0.23	0.35	0.21	0.41	0.21	0.44	0.26	0.39	0.20
Ai*	1.24	0.78	1.47	0.85	1.40	0.82	1.88	1.49	1.49	0.92	1.52	0.91
Gn	1.18	0.57	1.31	0.60	0.75	0.54	0.57	0.37	1.33	0.91	0.90	0.49
Mp*	1.18	0.74	1.28	0.71	1.96	1.42	1.32	0.90	1.09	0.69	1.46	0.86
Mi*	1.67	1.25	0.95	0.50	0.94	0.50	0.75	0.40	0.99	1.29	0.94	0.53
Id*	0.74	0.38	1.16	0.77	0.52	0.31	0.57	0.37	0.57	0.38	0.57	0.33
Sm	2.17	1.33	1.30	0.75	1.20	0.92	0.90	0.80	1.34	0.81	0.83	0.59
Pg	0.84	0.49	0.74	0.47	0.78	0.61	0.74	0.49	0.67	0.48	0.64	0.44
Ar	0.57	0.38	0.52	0.35	0.45	0.31	0.63	0.40	0.69	0.66	0.55	0.41
Ba*	1.26	0.85	1.14	0.81	2.51	2.36	1.50	1.70	1.75	1.07	1.31	1.00
Or	1.85	1.24	1.87	1.62	2.84	1.88	1.51	1.08	2.35	1.77	2.66	2.19
Po*	2.38	1.24	3.15	2.29	2.62	1.86	2.55	1.75	2.81	2.05	5.27	3.55

*$P < 0.05$.

the deviation from the mean ($\bar{x}$ and SD) in millimetres for each modality as an average between observers for each landmark. Table 2 describes the deviation from the mean ($\bar{x}$ and SD) in millimetres for each observer as an average between the modalities for each landmark.

For 11 of the 21 landmarks (five dental and six skeletal), a statistically significant difference was observed between the modalities (marked with *). For landmarks S, Is, Ii, and Id, the monitor-displayed images showed the highest reproducibility, for landmark Sp the hardcopy had the highest, and for six landmarks (As, Ms, Mp, Mi, Ba, and Po), the conventional film showed the highest reproducibility (Table 2).

There was a large variation in reproducibility between the observers, and for 16 landmarks (five dental and 11 skeletal) the difference between the observers was statistically significant ($P < 0.05$) (Table 2). Observers 1, 2, and 3 (one trainee and two academic staff members) were less precise with the monitor-displayed images compared with the other modalities. For observers 4 and 5 (two clinical staff members), the modality was associated with no significant difference in their performance, while observer 6 (a trainee) showed low reproducibility with both digital techniques.

There was a large variation between the overall reproducibility of the landmarks irrespective of the observers and the modalities. Landmarks Or and Po showed an avarage variation of more than 2 mm. Landmarks Sp, Snp, Ss, As, Ms, Ai, Gn, Mp, Mi, Sm, and Ba were within the limit of 0.75–1.75 mm while landmarks S, N, Pr, Is, Ii, Id, Pg, and Ar varied less than 0.75 mm (Table 3).

The overall reproducibility for a full cephalometric recording (the sum of all 21 landmarks)

Table 3 Average deviation from the mean (all modalities combined) for each landmark

	Deviation from the mean		
	<0.75 mm	0.75–1.5 mm	>2.00 mm
S	X		
N	X		
Sp		X	
Snp		X	
Ss		X	
Pr	X		
Is	X		
As		X	
Ms		X	
Ii	X		
Ai		X	
Gn		X	
Mp		X	
Mi		X	
Id	X		
Sm		X	
Pg	X		
Ar	X		
Ba		X	
Or			X
Po			X

showed that the monitor-displayed images in total (mean 25.3 mm) had a lower precision than the film ($P < 0.005$) and the hardcopy ($P < 0.02$). Between hardcopy (mean 22.8 mm) and film (mean 21.8 mm), there was no statistically significant difference ($P = 0.27$).

Discussion

Digital radiography could revolutionize both clinical and research practice in craniofacial cephalometrics as occurred with the introduction of computer programs, digitizers, and plotters in the 1970s. Storage phosphor imaging plates are becoming the dominant radiographic detector in digital radiography (Kruger, 1995). The potential advantages of digital technology lie in the ability to (1) manipulate the image, (2) reduce patient dose, and (3) improve storage and access of information (Wenzel, 1991; Forsyth *et al.*, 1996).

Several studies have found the main source of error in cephalometry to be the visual identification of the landmarks (Richardson, 1966; Midtgård *et al.*, 1974; Houston *et al.*, 1986) and thus one of the efforts to improve the precision in landmark identification should be directed towards improvement in the image quality (McWilliam and Welander, 1978; Eppley, 1991). In conventional film radiography, the image quality is already determined during exposure and processing of the image. Once the specific film-screen detector has been chosen and the latent image has been obtained, little can be done to improve the quality of the image. In comparison, image processing is an intrinsic part of digital radiography (Oestmann *et al.*, 1992). Image post-processing can be repeatedly performed in a single data set to obtain image optimization of the final display version.

As a radiation detector, the film is extremely inefficient because it absorbs only approximately 2 per cent of the incident beam, thus for all extra-oral radiography, intensifying screens are required to increase sensitivity. However, with storage phosphor radiography, even very small radiation doses can create an acceptable image quality (Borg and Gröndahl, 1995; Näslund *et al.*, 1995; Huismanns *et al.*, 1997).

Although film is quite stable and can retain its information for many years, it is labour-intensive, expensive, and not always a dependable archive medium due to its physical weight, size, and singular nature. Film deterioration or displacement has been a major source of information loss in craniofacial biology (Melsen and Baumrind, 1995). The inability to view the original radiographic image simultaneously in two locations may compromise the delivery of clinically relevant information. In digital radiography, picture archiving, and communication systems (PACS) permits links with other communication networks (Taaffe and Bauman, 1992), the so-called technology of integrated services digital networks (ISDN). Exchange of information, access to consultants and education at a distance will in this way be facilitated (Curtis *et al.*, 1983; Wenzel *et al.*, 1989).

Some cephalometric landmarks can be located with more precision than others, depending on the radiographic complexity of the region (Baumrind and Frantz, 1971; Miethke, 1989). The distribution of errors for many landmarks is systematic and follows a typical pattern (non-circular envelope), making the landmarks more reliable in either the horizontal or vertical plane depending on the topographic orientation of the anatomical structures along which they are defined. The pattern of landmark identification error for the skeletal and dental landmarks irrespective of the modalities was approximately the same in this study as has been previously described (Richardson, 1966; Baumrind and Frantz, 1971), except for the points Or and Po. An explanation could be that all observers were trained in a cephalometric analysis where these two landmarks are traditionally not included and that 'true' instead of 'machine' Po had to be identified.

In the present study, significant differences between three image modalities were found for 11 of the 21 landmarks. Therefore, the null hypothesis has to be rejected, at least for these 11 landmarks. There was, however, no unequivocal trend that one modality was always the most reproducible. For the full cephalometric recording (the sum of the deviations for all 21 landmarks), the monitor-displayed images, however, had a lower precision than film and hardcopies, while there was no significant difference between these two latter modalities.

The hardcopies in the present study were digitally enhanced before print by seven default enhancement routines and the monitor-displayed images were enhanced by the observers during recording. Thus, in both digital modalities, image quality was optimized. It should be noted that post-processing algorithms may cause a systematic error in landmark localization. As this study was only able to evaluate precision and not accuracy of landmark recording, the possibility for this type of error could not be investigated.

The films and the digital hardcopies appeared almost identical, and only individuals with a knowledge of digital imaging would be able to distinguish between these two modalities. The monitor-displayed images could, on the other hand, not be assessed blind. As the observer plays an important role in the precision of landmark identification (Richardson 1966, 1981; Gravely and Benzies, 1974; Houston, 1983), it is important that several observers are included when a new cephalometric technique is evaluated. In this study there was no clear relationship between the observers' education and routine, and their performance. Only one of the observers was, however, acquainted with digital imaging. Working on the PC-monitor was, in some instances, considered uncomfortable and fatiguing for the eyes. Furthermore, the reference planes or construction lines that are needed in order to locate landmarks defined as e.g. 'the lowest point of', appeared only *after* digitization of the landmarks. Thus, landmark identification had to be undertaken without the support of a reference plane first and adjusted afterwards, if the helping line demonstrated that the landmark was mispositioned. Some observers found this time-consuming and disturbing. These factors may partly explain why the full cephalometric recording had a lower reproducibility on the monitor-displayed images than on the films. Technical improvements of the program used for positioning the landmarks on the monitor should take this into account, and familiarity with the medium may increase reproducibility over time. However, it is doubtful whether the higher variation in landmark recording on the monitor-displayed images has a clinically significant influence on the outcome of the cephalometric analysis. This was not evaluated in the present study.

Conclusions

1. The reproducibility of cephalometric landmarks was significantly different on film, hardcopy, and monitor-displayed images for 11 of 21 landmarks. However, there was no unequivocal trend that one of the methods was always more reproducible than the others.
2. Overall reproducibility for a full cephalometric recording (sum of 21 landmarks) was lower (on average 3 mm more variation over the 21 landmarks) for the monitor-displayed image than both film and hardcopy, between which there was no significant difference. This is considered to have little clinical significance.

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