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Evaluation of bone surface registration applying a micro-needle array

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Abstract

Aim: In this study we present and evaluated a new registration technology for the jaw-bone surface. It is based on a micromechatronic device for the generation of a ''mechanical image'' of the bone surface by means of an array of micro-needles that are penetrating the soft tissue until they touch the surface of the bone. This ''mechanical impression image'' is aligned with the CT data set.

Material and Methods: Based on laboratory measurements on 10 specially prepared jawbone models we evaluate the accuracy of this new registration method.

Results: Our measurements of the 10 specimens revealed a maximum overall location error of 0.97 mm (range: 0.35–0.97 mm).

Conclusions: From the technical point of view the presented registration technology has the potential to improve the performance (i.e. accuracy and avoidance of errors) of the registration process for bony structures in selected applications of image-guided surgery.

Key words: accuracy; bone surface registration; image-guided surgery; tactile technologies

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Registration is a central topic in image-guided surgery. From the theoretical point of view the problem of a registration procedure is to find the optimum rotations and translations between structures in different coordinate systems, provided that these structures are corresponding. Most of the established registration methods require a manual input from the user to define the corresponding points (e.g. fiducial markers or anatomical landmarks), using a so-called ''pointer'' (also known as ''stylus'' of ''digitizing probe''), or they work on the base of a surface scan by means of a laser beam (Raabe et al. 2002, Schicho et al. 2007). Several technical solutions have been developed with the common purpose of aligning the radiological data of an anatomical region (acquired by any imaging modality) with the corresponding structures in the patient intra-operatively (Maurer et al. 1998, Caversaccio et al. 2000). The workflow (usability; invasive or not invasive?) of a typical application and the accuracy are crucial criteria for evaluating registration methods. Well-established concepts for registration are based on fiducial markers (e.g. tiny metallic spheres or micro screws attached to the bone; (Maurer et al. 1997, Birkfellner et al. 2001, Ewers et al. 2004, Eggers et al. 2005, Labadie et al. 2005) or skin markers (Wolfsberger et al. 2002, Hoffmann et al. 2005). The main principle of both, fiducials and skin markers, is the point-to-point matching of markers recognizable in the computer tomography (CT) scan and markers visible to some kind of tracking system. The points are correlated pairwise. One way of calculating the transformation is the singular value decomposition. In computer-assisted dental implantology, micro-screws inserted to the bone of the mandible or maxilla as well as teeth-affixed splints carrying the registration markers have proved their worth in clinical routine (Ewers et al. 2004, Brief et al. 2005).

Instead of the above-mentioned method, a laser surface scan can be used for registration (Marmulla et al. 2004). The laser scan measures points in a three-dimensional space of a reflecting surface. It can thus be used to determine the position of a geometrical structure such as a human face. To register this laser

Conflict of interest and source of funding statement

The authors declare that they have no conflict of interests.
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scan to its corresponding CT scan, the segmented surface of the CT has to be aligned to the laser surface scan. Because correlating points are not known before registration, a surface-matching algorithm iterates with changing transformations until minimum distances between both surfaces are found. This is the key idea of the well-known iterated closest points (ICP) algorithm by Besl & McKay (1992) (Fig. 1). The ICP algorithm computes the optimum transformation proceeding on the assumption that closest points within the CT data set and (e.g.) intraoperative data from the patient are corresponding to each other. As illustrated in Fig. 1a, no convergence can be achieved with this algorithm in case of improper starting positions. Provided that the starting positions are sufficiently close, the ICP algorithm converges and the alignment of the two data sets is successful (Fig. 1b).

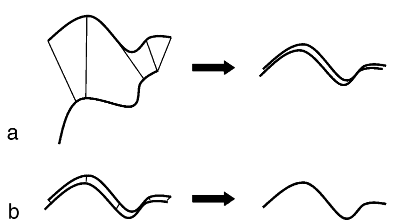

Fig. 1. The optimum transformation is being computed proceeding on the assumption that closest points within the two data sets (CT data and e.g. intra-operative data from the patient) are corresponding to each other. (a) Owing to improper starting positions the procedure fails, convergence is not achieved. (b) The iterated closest points algorithm converges and alignment is achieved, provided that the starting positions are ''close enough''.

Nevertheless, several problems hamper laser scan-aided registration. For example, soft tissues may change their surfaces when slightly swollen, due to varying turgor (pressure caused by blood perfusion of the tissue) or positioning (resting) of the patient on the operating table.

These problems can be overcome by scanning surfaces of bony tissue.

In this study we describe a new technical approach for registration using bony surfaces especially in (but not at all limited to) image-guided dental implantology. The specific potential improvement compared with established point-by-point registration methods is that neither markers (e.g. pre-operatively inserted fiducials or anatomical landmarks) nor bone exposure is required. This fact is expected to result in a time-saving clinical workflow. The technical realization is based on the generation of an image of the bone surface by means of an array of micro-needles that are penetrating the soft tissue until they touch the surface of the bone. This ''mechanical impression image'' is aligned with the CT data set. Based on laboratory measurements we evaluate the accuracy of this new registration method.

Material and Methods

Bone surface imaging needle array (BSINA)

The central part of the registration method presented in this study was an array of micro-needles, generating a ''mechanical image'' of the contour of the bone surface. Figure 2 illustrates its principle in an intuitive example. With our bone surface imaging needle array (BSINA), this principle is used in a micromechatronic device that measures the positioning of each of its needles (Fig. 3). The cartridge contains the needles and position measurement technology for each one. The micro-needles are pushed through the patient's soft tissue until they touch the underlying bone. Measuring the needle displacement at bone contact provides a local surface mapping of the bone. All the needles are pushed together by a piston. An encoder continuously measures the piston displacement. As each needle encounters the jawbone surface, the rigid bone counters push on the needle. The base of each needle touches a thin wire bond. The increased pressure on the wire bond activates it and the momentary displacement is registered as the specific needle–bone displacement. As the piston continues to push the needle, its base penetrates the wire bond; therefore no additional force is transferred to the bone. The wire bond thus acts as a ''mechanical fuse'' that breaks down at a certain force after activation. At the end of the piston motion, all needle–bone displacements are registered and the cartridge can be pulled out. The electrical interface to the cartridge enables separate registration of individual needle–bone contact. The needles are retained in a way that ensures full retraction of all needles after end of measurement.

Each BSINA consists of 22 micro-needles (diameter: 0.3 mm each), which can be moved for a distance of up to 6.0 mm calibrated so they can penetrate soft tissue, but when they come in contact with bone surface, trigger sensors that measure their lengths. Accuracy of these sensors is 0.1 mm. Using the combined data of all the needles, the BSINA generates a ''mechanical'' 3D image of the bone surface. The tips of all 22 needles are in a coplanar starting position (i.e. they are located in the same plane) and the ''mechanical image generation'' remains stable against angular changes of the bone surface. The crucial information is the difference between the coordinates of all the needles' tips. To measure these differences by the BSINA it is not at all necessary that the axis of the needles is perpendicular to the corresponding tangent plane of the bone surface. This is relevant especially in case of a sharp alveolar ridge.

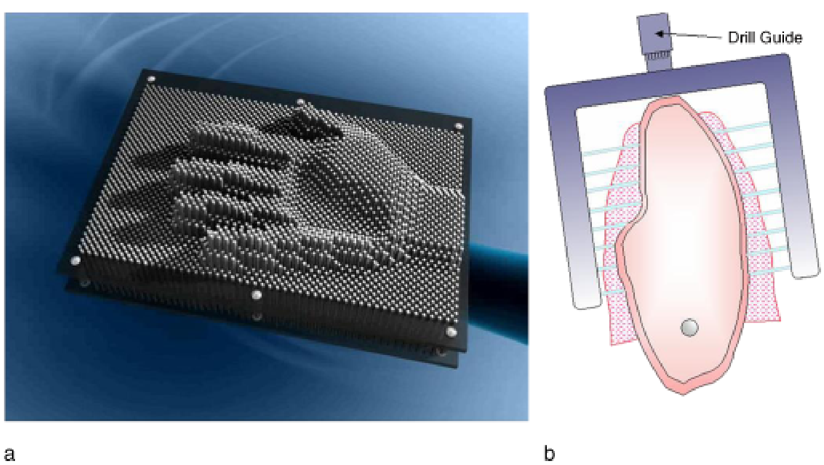

Fig. 2. (a) This simple ''nail board'' illustrates the idea of the micro-needle array for registration of the bone surface. By means of the matrix of needles a three-dimensional image of a surface can be generated. (b) The technical realization of the ''nail board principle'' on the jaw bone is accomplished by means of the bone surface imaging needle array.

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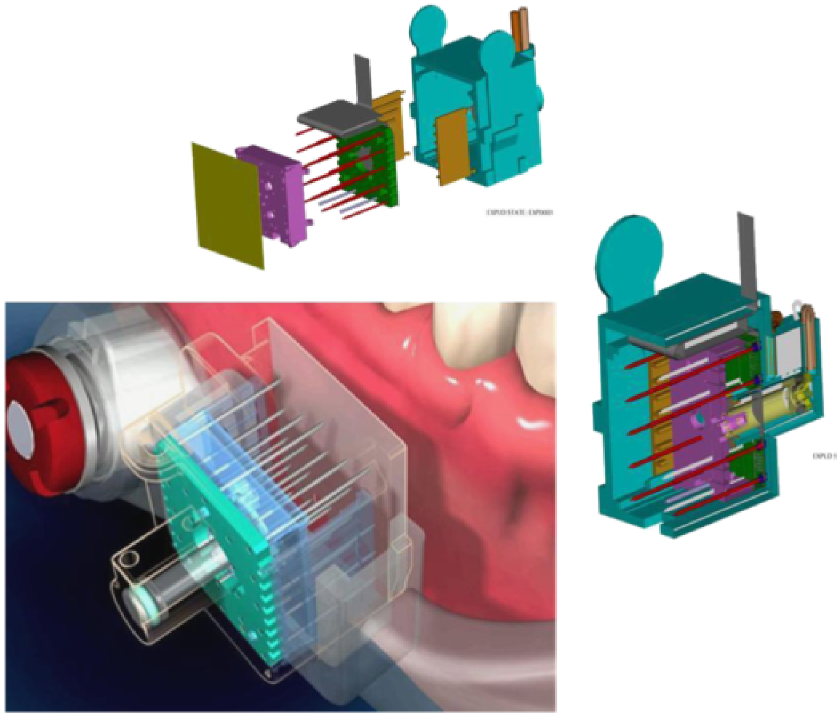

Fig. 3. Exploded drawing of the array of micro-needles, which is embedded in a cartridge.

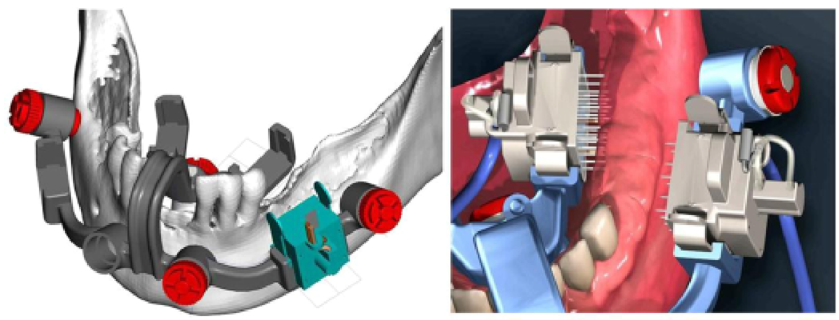

Fig. 4. The cartridges are fixed to the jaw using a special frame.

To achieve the ''mechanical'' image of the bony surface, three BSINAs (embedded in a cartridge) are fixed to the jaw using a specially developed frame as shown in Figs 4 and 5. The 3D information achieved from the three BSINAs combined with the geometrical information of their position relative to each other serve as a specific jaw bone ''fingerprint''.

Registration between this ''fingerprint'' and the 3D image of the jaw's segmented CT is carried out by surface matching using multidimensional minimization process combined with a grid base genetic algorithm. Parts of the specific algorithm (which seems to be most efficient regarding computing time and memory management) are proprietary knowledge of Tactile Technologies Inc. (Tactile Technologies Ltd, Rehovot, Israel), but from the scientific point of view any other optimization method could be used as well for this purpose. Once the registration process is completed, the frame's position over the jaw bone as well as in the CT image is calculated according to BSINAs locations, and from that point, any tool that is related to the frame can be registered over the CT image. Therefore the well-defined geometry of the precisely manufactured frame is the ''key link'' between the patient's anatomy and the corresponding CT-based computer model. The surface areas of the ''mechanical image'' generation (i.e. the needle matrices in the three BSINAs) are small ($<2\,cm^2$, Fig. 4), but due to their defined positions at the frame the combination of the data from the three BSINAs provides sufficient information for calculating the bone surface (according to basic mathematics).

Pre-clinical registration experiments: jaw specimen for the test

To achieve realistic testing conditions for the registration accuracy the device was applied on 10 specially prepared jaw-bone models. The models were manufactured by converting the Dicom data of a scanned jaw into a CAD-model file and using a 3D printer (Eden™ by Objet Geometries Ltd, Rehovot, Israel) in order to create the model from a plastic material which has the expected mechanical properties of a jaw bone (FullCure® by Objet Geometries Ltd), so that needle sensing will be as realistic as possible. To represent the full variety of expected anatomical situations of implant patients, the CT data for the fabrication of these models were selected thoroughly, i.e. scans from persons of different age, gender, anatomical dimensions, etc. were included. The CT scans were taken from an existing database, including only scans of persons who had agreed with the use of their data for scientific purposes. In the course of the manufacturing process the jaw models were supplied with tiny spheres (diameter: 5.0 mm) as precise fiducial markers for the registration verification as described below (Fig. 6). The manufacturing process of the jaw models provided an accuracy of better than 50 μm.

Testing procedure

During the measurements, the frame was attached to the jaw model at different positions (in order to vary the needle array position) before the BSINAs were applied. The BSINAs were operated and the results were used for the registration process in order to calculate frame position over the CT image. The actual placement of the frame relative to the fiducial markers on the model was measured using an optical coordinate measuring machine (CMM; SmartScope® Flash™ 200 by OGP® Inc. Rochester, NY, USA). For this purpose, the spheres on the frame were measured in the same coordinate system, therefore the actual placement of the frame in relation to the model could be extracted. Using the actual position of the frame relative to the model and the calculated

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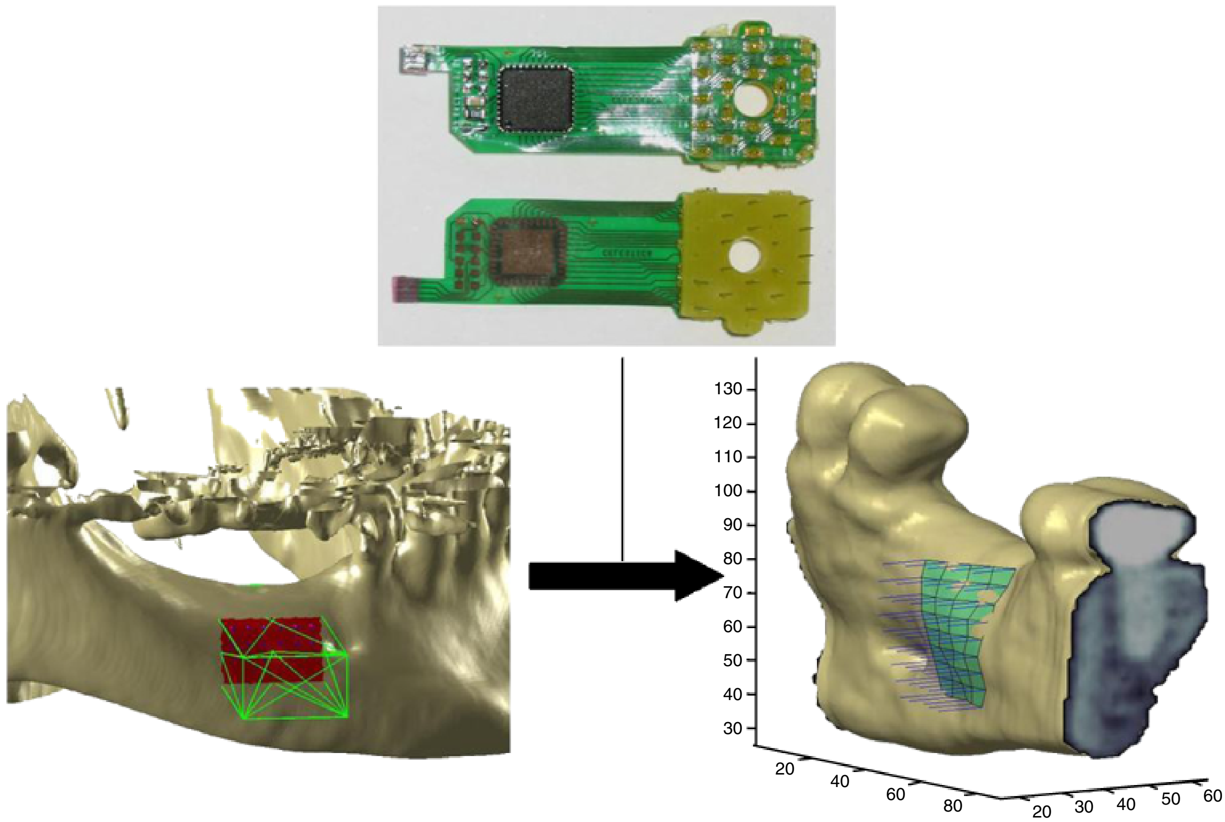

Fig. 5. The needles of the bone surface imaging needle arrays (attached to the jaw using the frame) are driven by push–pull hydraulics to penetrate the soft tissue, stopping when their tips touch the surface of the bone. The electronic device generates the points for the surface matching.

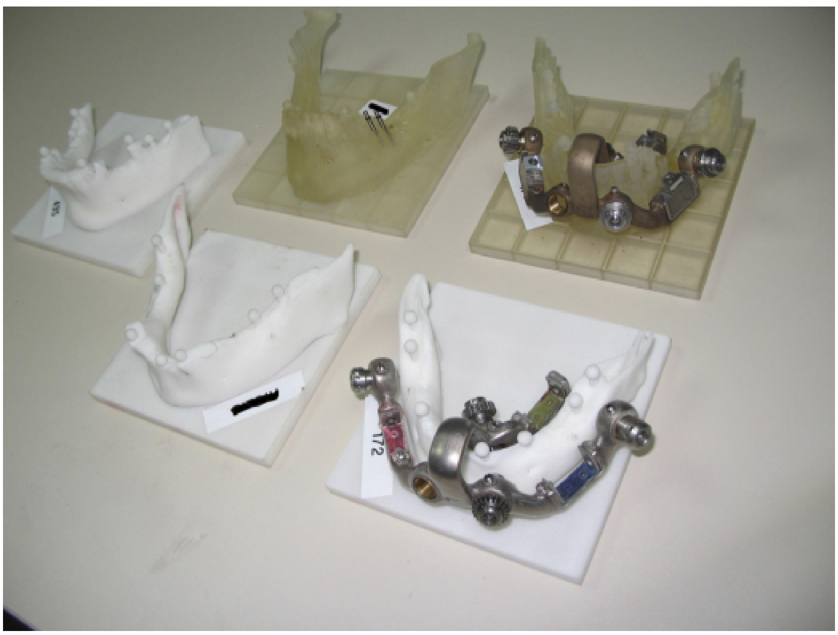

Fig. 6. Figure shows some of the jaw models (two of them already supplied with prototypes of the frame) as used for the registration experiments.

transformation between the model and the CT, a reference (ground truth) transformation could be determined with an error of <0.2 mm (due to CMM, mechanical fabrication and model to CT registration accuracies). Finally, errors were calculated and recorded by comparison of each registration transformation with the corresponding reference transformation.

Evaluation

Central criterion in our evaluation was the difference between the actual measurements and a virtual value for the corresponding needle lengths. For all the achieved valid results the root mean squared error (RMS) of these differences was calculated. When the measurements and the virtual value indicated the maximum step for a specific needle (i.e. a full step of more than 6.0 mm), a compensation to this scoring was calculated.

The actual overall registration error was represented by the registration error with respect to the ground truth, i.e. the comparison of the registered frame location over the CT to the actual location of the applied frame as measured using CMM. The comparison was made on eight probe points that were located roughly in the place of interest (implantation location). If the frame was used for registration at the left side we took the eight left probe point or else the right

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ones. The differences between the two frame locations were represented by both the Euclidean distance and the mean Euclidian distance (i.e. the RMS) between the two probe point sets (Fig. 7).

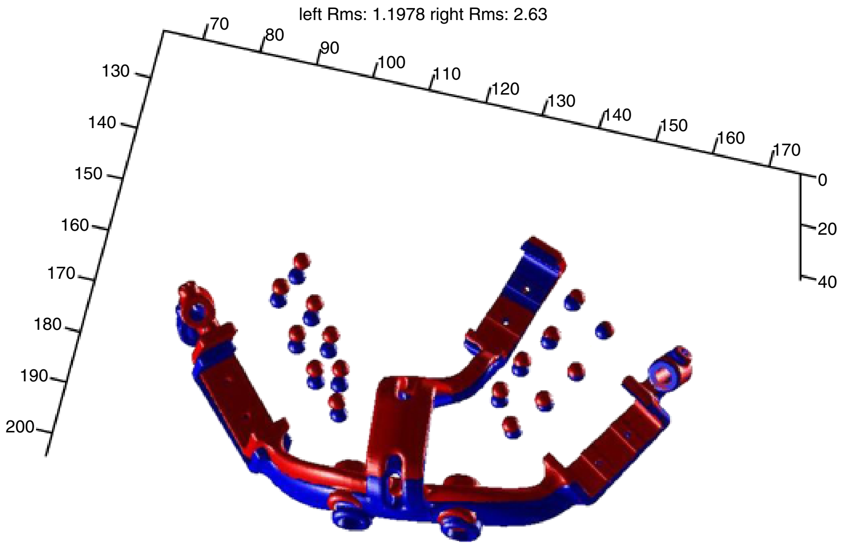

Fig. 7. The frame with the probe points at both sides. Depending on the ''area of interest'' for the evaluation of the registration (i.e. the location of the planned implant insertion) our data for the analysis are based on left or the right set of points. In this example the frame is oriented onto the left side, therefore in this example registration is better on the left side and only these eight points from the left side are considered in the performance analyis.

Results

The measurements of the 10 specimens revealed a maximum overall location error of 0.97 mm (range: 0.35–0.97 mm). The observed differences achieved with the CMM, respectively, the registration by means of the BSINA for the 10 specimens are documented separately in the Boxplots of Fig. 8. The total differences measured using both methods are summarized in Fig. 9. Using the BSINA, smaller errors occurred more frequently as compared with the CMM (Fig. 10). The superiority of the BSINA against the CMM is clearly perceptible. RMS error of probe points location differences for the 10 documented cases were as follows *X*: RMS, 0.25 mm, *Y*: RMS, 0.54 mm and *Z*: RMS, 0.46 mm.

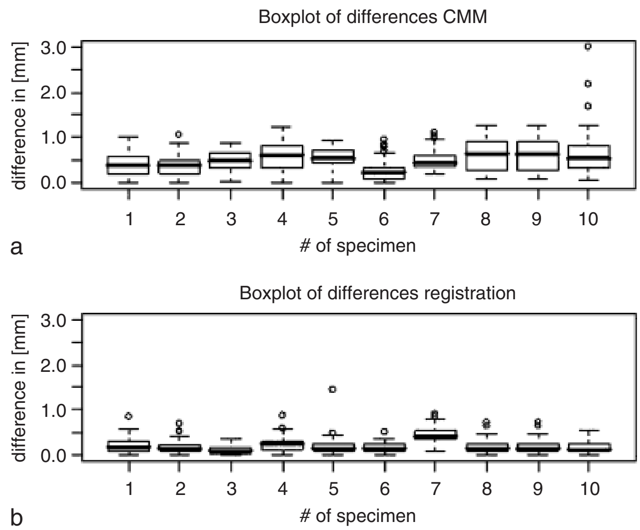

Fig. 8. Boxplots of all results at the 10 specimen for (a) the coordinate measuring machine measurements and (b) the bone surface imaging needle array registration. Boxplots showing first and third quartile (i.e. the box is the interquartile range) and median, the lines (''whiskers'') depict the 1.5 × interquartile range above and below the hinges of the box, circles indicate outliers.

Discussion

The registration method described in the article is in principle a surface-matching registration as known for many years. The innovative part of this method is twofold. First, compared with per-point registration, this method does not require discernable anatomical landmarks that are not available on the jaw-bone surface at a small defined area. Second, compared with surface registration, this method does not require bone exposure and is much less time-consuming because the point-to-point acquirement of anatomical landmarks is carried out simultaneously and not one by one. The exact intra-operative frame-on times have to be investigated in following clinical studies. Our results prove that the BSINA-based registration provides highly accurate registration, also in comparison with the accuracies of well-established registration concepts (e.g. as described in Marmulla et al. 2004, where the authors report on a mean accuracy of 1.2 mm). Considering that some of the errors in the course of this study can be attributed to the experimental setup (e.g. the measurements of the actual frame location), we can expect that the actual performance might be even slightly better than in our results. Our experimental setup actually reflects a ''worst case scenario'' in this context, i.e. the results include all the errors from the production, etc. From the maximum overall location error of 0.97 mm with the BSINA (which is unambiguously in the range of established methods), we can conclude that it meets all clinical demands.

In the development of this new technical approach for registration, Tactile Technologies Inc. (Israel) has initially primarily focused on an application in image-guided dental implantology. Therefore the jaw models were used in our experiments. The principle of the actual application of this technology to support the insertion of dental implants is illustrated in Fig. 11. Special guidance

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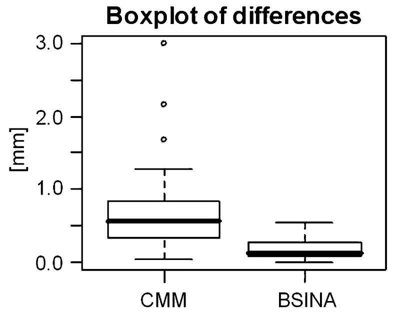

Fig. 9. Boxplots summarize the measurements at the 10 specimen with the bone surface imaging needle array (right Boxplot) and the coordinate measuring machine (left Boxplot).

sheaths are placed into an electromechanical device and automatically formed according to the computer-based plan. Then they are cured by means of ultraviolet (UV) light flashes. After this so-called rapid prototyping process, the guidance sheaths are attached to the frame (as described before) and found as a kind of drilling template. The expected most important advantage of this solution is that all the features of the well-established templates can be used (e.g. safe and easy intra-operative handling) but combined with the benefits of computer-based planning. Furthermore, this kind of ''templates'' can immediately be modified intraoperatively. Preliminary tests did not indicate complications caused by the penetration of the gingival by the needle array. We expect that common local anaesthetic as routinely applied in dental implantology is sufficient, but of course this aspect has to be considered thoroughly and intraoperative safety has to be proven in the clearance process of this device.

The soft tissue penetration process was also crucial in the course of the development of this technology. An essential question focused on the relation between the translation of the needles (i.e. the penetration of the soft tissue and the following stop exactly in the moment of bone contact) *versus* the force at the needles. For this purpose we used special measurement equipment, consisting of a sliding calliper with an electronic force detector unit connected to a personal computer running software for automatic recording of force-*versus*-translation curves. In these curves a strong change in the inclination (i.e. a clear increase of the force) indicates the bone contact of the needles. After the moment of bone contact the force at the needles still increases, but without further translation of the needle tip: this means that the needle does not penetrate (and injure) the bone. By means of these preliminary experiments we could investigate the adequate biomechanical parameters (i.e. forces and dimensions) for the BSINA in dental implantology.

Nevertheless, the technology is not at all limited to this specific application. For example, spine surgery in orthopaedics and the insertion of dental implants are very similar procedures from the ''technical point of view''. both require accurate insertion of a metallic part into the bone without causing damage to adjacent anatomical structures. Consequently, similar methods of computer-assisted surgery are applicable for both fields of medicine. Therefore, especially orthopaedic or spine surgery is likely to allow for the utilization of this registration technique.

A central aspect of this technical solution is the ''implicit'' correction of undetected inaccuracies and shifts within the CT data set, e.g. resulting from slight head motion during the CT scan (Wagner et al. 2003), because (in contrast to established registration concepts) this approach generates a well-defined relation between the bone and the frame (carrying the BSINA) in the course of the intra-operative registration. This relation between the bone and the BSINA (and therefore the

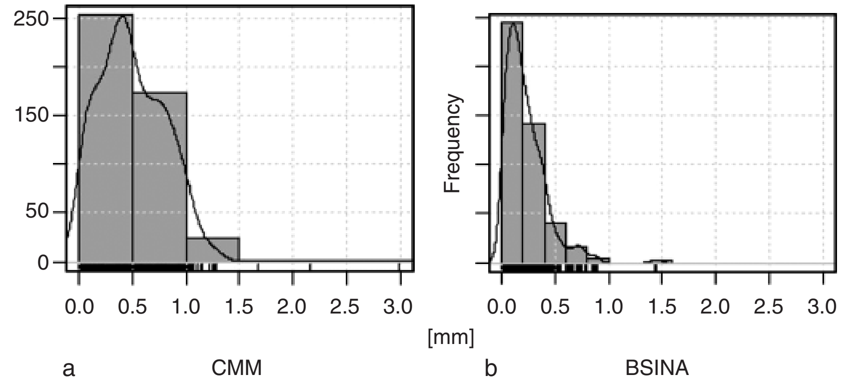

Fig. 10. Histograms illustrate the frequency of the observed errors. With the bone surface imaging needle array (a) smaller errors were measured more frequently as compared with the coordinate measuring machine (b).

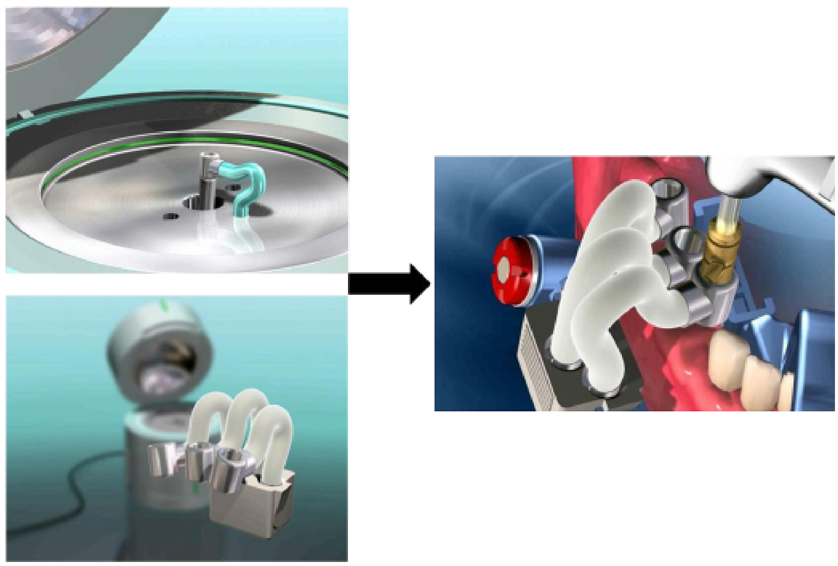

Fig. 11. Left part: Initially the guidance sheaths are flexible. Then they are inserted in a special electro-mechanical device, the so called ''manipulator'', where they are cured according to the computer based surgical plan using ultraviolet light flashes. During the operation the cured sheaths are rigidly attached to the frame at the patient's jaw in order to guide the drill (right part of the illustration).

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frame) cannot be affected by errors in the CT data set. Affection of the performance in image-guided surgery by the chain of errors (such as undetected head motion during the CT scan) is a well-known challenge, e.g. in navigated dental implantology – a fact that might promote the application of our described registration method in the future (Wagner et al. 2003, Ewers et al. 2004).

An assessment of the actual feasibility and potential medical benefit of the presented registration method in the context of certain indications has to be subject of separate studies. The further development and ''impact'' of this technology will crucially depend, e.g. on the way the BSINA is integrated in navigation setups, but the results of our basic research and development clearly revealed that the method works well under laboratory conditions.

From the technical point of view, BSINA-based registration has the potential to improve the performance (i.e. accuracy and avoidance of errors) of the registration process for bony structures in selected applications of computer-assisted surgery.

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Clinical Relevance

Scientific rationale for the study: Registration is the crucial step in every image-guided surgery application, because it essentially determines the accuracy of the whole treatment workflow. In this manuscript we describe and evaluate a completely new technical realization of the theoretically well-established surface registration principle, especially for the jaw bone, in computer-assisted dental implantology. A specific advantage is the fact that in this approach potential inaccuracies, e.g. occurring during the CT scan, do not affect the registration process.

Principal findings: Our preclinical laboratory experiments revealed that this registration method, respectively, the device, in which it is implemented, provides stable performance and high accuracy.

Practical implications: This concept focuses on easy intraoperative handling and avoids an affection of the registration accuracy, e.g. by inaccuracies during the CT scan (e.g. due to undetected movements of the patient).

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