Robot- and computer-assisted craniotomy (CRANIO): from active systems to synergistic man-machine interaction


Abstract (summary)

Computer and robot assistance in craniotomy/craniectomy procedures is intended to increase precision and efficiency of the removal of calvarial tumours, enabling the preoperative design and manufacturing of the corresponding implant. In the framework of the CRANIO project, an active robotic system was developed to automate the milling processes based on a predefined resection planning. This approach allows for a very efficient milling process, but lacks feedback of the intra-operative process to the surgeon. To better integrate the surgeon into the process, a new teleoperated synergistic architecture was designed. This enables the surgeon to realize changes during the procedure and use their human cognitive capabilities. The preoperative planning information is used as guidance for the user interacting with the system through a master-slave architecture. In this article, the CRANIO system is presented together with this new synergistic approach. Experiments have been performed to evaluate the accuracy of the system in active and synergistic modes for the bone milling procedure. The laboratory studies showed the general feasibility of the new concept for the selected medical procedure and determined the accuracy of the system. Although the integration of the surgeon partially reduces the efficiency of the milling process compared with a purely active (automatic) milling, it provides more feedback and flexibility to the user during the intra-operative procedure. [PUBLICATION ABSTRACT]
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Keywords: craniotomy/craniectomy, medical robots, synergistic system

1 INTRODUCTION

Osseous tumours of the calvaria are usually treated by a total or subtotal resection followed by a removal of the tumourous tissue [1]. During the trepanation of calvaria the major concern is the injury of the dura mater underneath the bone. For the occlusion of a bony defect, bone cement, autologous bone as well as customized alloplastic implants can be used [2]. The use of bone cement is adequate in smaller resection areas. For larger surfaces, especially in frontal regions of the skull, cranioplasty is mandatory owing to functional and cosmetic requirements. In cases of meningioma infiltrating the skull bone or large fractures, the original bone cannot be reimplanted, and artificial implants such as titanium implants [3] or polymers [4] are needed.

Computer-assisted planning, navigation, and robotic craniotomy, with optional skull reconstruction using customized implants, are of increasing clinical interest in craniofacial- and neurosurgery [2]. The use of robot systems for drilling tasks on the skull has been shown to be a valuable surgical technique for the insertion of cochlea implants [5, 6] and for the development of a system for craniotomy [7-9].

Particularly in the case of tumour infiltration into the skull bone, stepwise milling of the affected areas is necessary as a craniotome cannot be used in all cases. Robotic guidance of the surgical high-speed micromilling device can provide higher efficiency, safety, and accuracy of the milling process. Furthermore, for the subsequent placement of the individualized implant, the geometric accuracy of the resection is highly important.

In robotic calvarial tumour surgery the protection of the dura mater remains an important issue. To protect the dura and to account for inherent inaccuracies, a safety offset from the inner table of the skull is preoperatively planned by the surgeon.

The main objectives of the CRANIO project (Fig. 1) for computer and robot-assisted cranial surgery are:

(a) semi-automatically assisted segmentation of the bone infiltrated tumour in computed tomography (CT) images;
(b) semi-automatically assisted preoperative design and manufacturing of the customized implant;

(c) precise and efficient robot-assisted removal of calvarial tumours.

Initial project work related to the latter aspect was focused on the autonomous operation of an active robot system, i.e. during the procedure the physician is just an observer of the process. The system relieves a surgeon from the tiring milling process and performs the bone removal with better efficiency and accuracy, enabling the use of prefabricated implants [10]. However, it constrains the procedure to the previous planned path and restricts the surgeon’s flexibility to adapt the intra-operative process.

To reintegrate the physician into the process, thereby allowing them to control and intervene with the previously planned milling path during surgery, a teleoperated synergistic system was proposed, combining the enhanced capabilities provided by a robotic system (efficient milling paths) with the abilities of a human operator for flexible adaptation to the actual intra-operative information and requirements.

Major system components as well as experimental results will be presented in the following sections.

2 PRE-OPERATIVE PROCEDURES

2.1 Tumour segmentation and resection planning

Resection planning is performed preoperatively on the basis of CT data. Modules for preoperative planning and intraoperative user-guidance, navigation, and communication with the robotic system are integrated within the DISOS (desktop image processing system for computer assisted orthopedic surgery) software platform [11], also developed previously in the Helmholtz Institute.

The major issue in resection planning is the segmentation of three-dimensional (3D) grey level images to identify the tumour volume in bone and soft tissue, the appropriate geometric registration and description of the structure [12], and finally the robot path generation.

Image thresholding is a standard procedure for skull bone segmentation in the CT data [13]. However, the segmentation of bone-infiltrated tumour requires further efforts. The current authors' approach towards a computer-aided detection and knowledge-based automatic segmentation based on 3D level sets showed accuracy in the range of interrated variability with a significant improvement of the robustness and efficiency of the segmentation process (see reference [14] for a detailed description) (Fig. 2). However, a final check of the segmentation result by a medical expert remains mandatory.

After the segmentation of the relevant structures, the bone resection volume and its boundary to the healthy tissue has to be defined and geometrically described to be used as a basis for robot path planning and robot-assisted machining of the related bone structures. Based on the segmentation results, the surgeon interactively defines the resection boundary based on a 3D view of the skull with the highlighted tumour. As the theoretical system accuracy is limited by different inherent factors in the process such as, for example, the minimum CT scanner resolution (0.45mm isometric resolution), a safety distance from sensitive structures (dura
mater and brain tissue) is necessary. This safety distance, defining the remaining bone layer, can be determined by the surgeon interactively (typical value accounting for all inaccuracies is in the 0.5-1.0mm range). Owing to the differences of the inner and outer surfaces of skull bone this aspect requires special attention. To achieve good precision concerning safety distance for the milling process, an accurate algorithm for determination of surface normals is needed, both on the outer as well as inner surface, to assess bone thickness profile. Although this topic has been covered by many authors (an overview is given in reference [15]), they have mostly focused on visualization (normal vector assessment) [16] or diagnostic problems [14, 16], which do not require high accuracy. Therefore, a study was performed within the CRANIO project to develop and validate algorithms for an accurate definition of bone thickness and resection volume [14].

2.2 Milling path generation

The milling path generation is a module of the CT-based surgical planning system in the CRANIO project [17]. Apart from the resection boundary and volume definition, an appropriate milling tool (typically a spherical micro milling tool with a diameter of 6mm) has to be selected. The machining of bone is performed with a microsurgical highspeed milling machine (HiLan, Aesculap, Tuttlingen, Germany) with about 40 000 r/min (feed rate 53mm/s; cutting depth 1mm maximum). These technical parameters for robotic machining of bone are selected depending on the average property of bone at the related anatomical location. Standard milling parameters are assumed for the initial milling path generation for the automatic robotic milling of bone (further considerations and optional approaches will be discussed in sections 5 and 6).

For the path planning, an initial milling boundary defined by the surgeon is used to generate a planar path covering the area enclosed by the predefined boundary. The planar path is subsequently projected on the outer skull surface to define the first layer (Fig. 3). Using outer surface normal vectors alongside skull thickness and applying a safety offset S, for each point in the 3D path generated through projection on the outer surface, a corresponding point on the last surface is defined (last layer). The milling path is generated in layers by offsetting the first layer along the perpendicular direction by a predefined offset d (equivalent to the desired cutting depth) until a collision with the lower surface is detected. In the next step, the same procedure is performed using the last layer and inner surface normal vectors. The algorithm stops if all voxels from the reference geometry have been removed. After the milling path generation, a safety check and path optimization is performed in a final step that ensures that the tool would not exceed the lower surface bound and provides an efficient robot motion with defined milling parameters (see also reference [17]).

2.3 Implant design

A craniofacial implant is used to reconstruct large congenital or acquired defects (e.g. after tumour resection or trauma). Careful preoperative planning is required to achieve a good functional and cosmetic result. The defect boundary can be acquired from CT image data (in case of existing defects) and the subsequent planning process (e.g. in case of tumour resections). Design and manufacture of a cosmetically adequate and well-fitting implant often involves cumbersome manual modelling of free-form surfaces of wax implant models on physical models of the skull generated by rapid prototyping methods or complicated computer aided design (CAD)/computer aided manufacture (CAM) processes with iterative
communication of the results and requirements between the CAD technician and the medical expert [18, 19].

To improve the efficiency and effectiveness of the implant design process, a planning module integrating the data processing from the preoperative resection plan to the CAD/CAM data of the implant has been developed in the framework of the CRANIO project. A model-based approach for individual implant design was proposed to support the surgeon performing the implant design task autonomously by using skull geometry data from a case database.

This knowledge-based approach for implant design can be divided into three steps (for more details see reference [2]):

(a) derivation of predefined patient-specific geometric parameters of the defect area of the skull and derivation of a ranked set of similar 3D skull flaps from a structured reference database;

(b) matching of the patient and reference model, analysis of best fit;

(c) final implant design based on semiautomatic deformation and adaptation.

A 3D reference database with 20 skulls was built for the current application. Both unilateral (Fig. 4) and bilateral cases were reconstructed.

Depending on the individual requirements, the final implant model can be directly transferred to a generative manufacturing process (e.g. fused deposition modelling (FDM), selective laser sintering (SLS), or selective laser melting (SLM)), or computer numerical control (CNC) milling process. Further CAD-based refinement and post-processing (e.g. for implant fixation to the bone) will be required before it can be transferred to a technical CAM process. However, the time to generate such an implant is dramatically reduced compared with the conventional design and manufacturing approach and the medical expert is enabled to implement his/her knowledge related to medical constraints and requirements of the implant design autonomously.

3 SURGICAL NAVIGATION

The targeting accuracy is highly dependent on the type of landmarks used (bone screws, skin adhesive markers, or anatomical landmarks) and the registration approach (paired-point or surface-based). Whereas the bone markers offer high accuracy and reproducibility, their invasiveness restricts the use in neurosurgery. Skin adhesive markers and anatomical landmarks are non-invasive and, although established in clinical use, are of limited accuracy. Markerless surface-based registration accuracy strongly depends on the area and structure accessible for direct palpation [20]. The use of amplitude modulated (A-mode) ultrasound for noninvasive transcutaneous surface-based registration using an optically tracked single element transducer represents an alternative to conventional direct palpation of bone [21-23]. In this case the received ultrasound bone echo can be directly used to display and calculate the thickness of the intermediate tissue layer. Because of minimal hardware expenses, Amode ultrasound-based registration systems are very cost-efficient in realization. Within the CRANIO project, a study was performed to assess accuracy of different approaches in neuronavigation and practicability of those approaches for the specific task of robot-aided surgery [22]. As reported by Maurer et al. [24] time efficiency can be a critical issue in A-
mode ultrasound registration since the alignment of the probe can be time consuming. However, based on appropriate signal processing and knowledge-based user guidance algorithms, mean registration time was 0.5 min in phantom studies (accuracy of 0.28-2.78) and 0.7 min in the cadaver (accuracy of 0.63-2.64mm) and patient study respectively [22]. The time efficiency and registration accuracy could be further optimized on the basis of enhanced registration algorithms (time of 0.180 s and accuracy of 1.30-0.49mm) [25].

4 ROBOT DESIGN

Based on the previous experience with the hexapod system CRIGOS [26] and its specific workspace, an optimized intra-operative robot set-up has been developed. In this arrangement the non-sterile robot system is placed under the patient's head, rigidly connected to the Mayfield-clamp and the tool is held by the robot platform with a sterile C-shaped arm. Owing to this tool adapter, the umbrella-shaped characteristic workspace of the Steward-Gough hexapod platform closely matches the required surgical workspace around the skull (Fig. 5).

To identify a reference for the design of a robot-assisted procedure an experimental study was performed to reveal the deficits and complications during manual neurosurgical milling tasks [10]. These results were taken into account for the design parameters of the new hexapod robot [27]. Neurosurgeons defined typical areas on the skull [1] that have to be entirely accessible for the robot to cut without repositioning the system.

Based on the initial concepts, a process-oriented risk analysis for the complete intra-operative system has been performed using the CARAD risk-analysis software (SurgiTAIX, Aachen, Germany) combining both FMEA (failure mode and effect analysis) and FTA (failure tree analysis). The analysis included the navigation system, the robot, additional sensors, the patient, the medical staff, and the environment in the operating room. The results of the risk analysis lead to further safety requirements: apart from redundant position sensors and miniaturized failsafe brake systems, integrated into the hexapod system, further modifications such as a six degrees of freedom (DOF) force-torque sensor and an autonomous robot safety hardware unit have been designed and implemented. This unit communicates with the control system to give information about the status of sensors and other components. The safety hardware is designed to fulfil the safety requirements of a large range of medical robot systems.

Based on these modifications, a speed control was implemented based on information from the force-torque sensor (Fig. 6). A maximum contact force can be defined as an additional safety feature. Moreover, an online control and optimization of milling parameters (e.g. taking into account different qualities of bone) can be realized [10].

5 TELEOPERATED SYNERGISTIC SYSTEM APPROACH

The term 'synergistic system' was introduced in the field of computer-assisted surgery by Troccaz et al. [28] as an extension class of semi-active devices. However, teleoperated systems are included in the active class. This latter can be directly related to the studies of Sheridan [29] about telerobotics and supervisory control. The development of teleoperated systems is motivated by the possibility to match human cognitive and adaptability capabilities with machine accuracy and reliability for the complete realization of the task [29]. So-called 'synergistic' devices are intended to work as a guiding tool for the physician, based on a direct haptic guidance of the surgeon performing an accurate manual transfer of the surgical
planning into the operating site. Depending on the specific application, the synergistic device may allow the physician to control some DOF, while the device controls others. In other words, the system restricts the motions intended by the surgeon to the paths, positions (and velocities) defined by the surgical plan. Human performance is supported by haptic (and partially visual) guidance taking into account limitations of natural hand-eye coordination [30]. Studies have shown that the combination of different senses such as vision and haptics (kinesthesia or proprioception) improves performance of human movements and coordination in general tasks [31, 32].

Different technologies have been used to generate haptic feedback on different types of constraints [28, 33-35]. Ho et al. [36], Harris [37], and Kazerooni and Jenhwa [38] emphasize the cooperative manipulation of the tool by the surgeon moving the endeffector of a robot with programmable constraints. The objective of this approach is to provide direct force feedback for the operators to increase their sense of being 'in the loop'. Moreover, in contrast to teleoperated master-slave systems, the operator has to manipulate the end-effector of the robot directly, which might be disadvantageous in the case of limited work space or exposure to radiation (e.g. in the case of fluoroscopic or CT image controls) [29]. Moreover, the transparency of the haptic feedback is limited owing to milling reaction forces and mass inertia of the robot systems. Some commercial medical robots such as ACROBOT [37] and MAKO [39] are available, which are especially designed for orthopaedic applications. They permit the direct manipulation of the robot by the user, constraining his or her movements within a planned area. The user freely moves the end-effector in a randomized way. However, this random movement of the tool might lead to less efficient milling paths and uncontrolled milling parameters.

In the framework of the CRANIO project, the concept of a teleoperated synergistic approach has been developed and tested. Machining parameters are controlled by the robot and the path-related constraints are designed based on a path generated by the preoperative planning. These constraints are displayed to the user by a separate haptic device. However, the user has the flexibility to make changes intra-operatively. These changes should only be allowed in relation to an enlargement of the resection if there are suspicions that bony borders are harbouring additional tumour. The operator can use the haptic device as a master system to 'push' the robot along the constrained path. In this case, the robot controls position and speed as long as the operator 'keeps in contact' and follows the displayed path, potentially ensuring a higher level of vigilance in human supervisory control. In this case the separate haptic feedback device provides high dynamics for the display of actual milling forces. However, the human operator can interrupt or reduce the speed of the robot-controlled milling process at any time. Optionally, he or she can leave the planned path and perform other micro-/macromanipulations in limited areas (in this case one to five DOF can be freed for manual position control) depending on the intra-operative situation and needs. Synergistic cooperation benefits from the robot providing accurate and precise motion control while the physician feels the constrained forces and torques and modifies them according to his or her expert knowledge if required.

6 MATERIAL AND METHODS

Different modules of the CRANIO system have already been analysed in previous studies (resection planning [11], implant design [40], navigation [22], and active robotics [2]). The following will focus on the evaluation of the overall system and will introduce the present authors' approach for synergistic cooperation together with preliminary results.
For the evaluation of the autonomous milling mode, the craniectomy was conducted on a polyurethane phantom skull. For these laboratory investigations, preoperative CT scans of the phantom skull with implanted ball markers were used. The entire surgical workflow was taken into account. The surgeon performed the computer aided 3D resection planning for two typical cases: one in the frontolateral region (resection volume: 35cm³) and the other in the frontoparietal region (resection volume: 61cm³). A safety offset of 1mm was selected.

The intra-operative set-up of the CRANIO system is shown in Fig. 5. The sterile draped robot was placed under the specimen's head. Then the upper sterile part of the end-effector was mounted and the robot was fixed to the Mayfield clamp. After an initial calibration of the robot and the robot tool (relative position between tool tip and robot) the registration was performed, using the passive optical tracking system Polaris (NDI, Waterloo, Canada). During the milling procedure log files documented the data exchange between the robot system, the controller, and the autonomous safety hardware unit.

The results were evaluated using two measuring techniques: intra-operative optical tracking of the robotic tool and a postoperative CT scan. Whereas the postoperative scan provides the accuracy of the entire system, intra-operative tracking has been used to assess the accuracy of the robotic system and the intra-operative calibration.

Post- and preoperative CT scans were cross-evaluated using original axial two-dimensional (2D) slices and reconstructed sagittal and coronal slices. The pre-/post-op data-sets were matched based on implanted spherical fiducial markers to compare the planned and resected 3D volume.

The speed control module was evaluated in an additional experiment using polyurethane blocks. Cavities of different dimensions in the polyurethane blocks simulated discontinuities of the skull bone. A calibrated six DOF force/torque sensor (ATI Industrial Automotion, Apex, USA) was mounted on the robot end-effector. Forces, torques, robot speed, and task completion time were logged. For comparison the procedure was performed with and without speed control.

For the investigation of the active synergistic control approach, a haptic guidance module has been added in the autonomous set-up (Fig. 1).

The first evaluation of the interactive master-slave mode was performed on polyurethane blocks. The blocks were represented in the graphical interface together with the desired guiding path for milling. Moreover, the haptic device constrained the movements along the desired path such that the user was able to move forwards and backwards on the constrained path only. Registration points were defined on the blocks and used for the interactive as well as for the autonomous mode. Once the registration is made, the actual position of the milling tool could be observed on the graphical interface. The user could define relative movements on the master and those were sent to the slave unit as control commands. The speed control module supervises the milling forces and controls the milling parameters.

For initial analysis two trials were performed to evaluate this whole process. The evaluation was made considering the movement tracking between master and slave. Therefore, the robot path was optically tracked and transformed into the coordinate system of the haptic guidance module in order to compare the robot tool path and the commanded milling path. This difference was defined as an error value. Once the procedure was made, geometry
measurements of the block were realized to evaluate machined area variations and mistakes of the registration procedure.

7 RESULTS

The results of the milling process in autonomous mode are shown in Fig. 7. The optical tracking of the robotic milling tool yielded a mean distance from the planned positions of 0.36mm and 0.38mm, with 95 per cent of all positions under 0.85mm and 0.8mm, respectively. Postoperative CT data showed a remaining bone layer of about 1-2mm thick (planned: 1 mm). The accuracy of the volume matching was approximately 1 voxel (<0.45mm). Spatial overlaps of approximately 95 per cent and 97.5 per cent were achieved, respectively. Less bone than planned was resected in both cases, preserving the enforced aforementioned safety offset.

The evaluation of the speed control module reveals that lower mean values of the speed were observed during the milling of solid areas (reduction of [asymptotically =]22.65 per cent) (Fig. 8). In contrast, higher speed values were also observed in the areas without material ([asymptotically =]7.87 mm/s). Lower variations of the force and torque values were observed in the controlled mode (Force [N]: with control [asymptotically =]SD 4.45; without control [asymptotically =]SD 13.37. Torque [Nm]: with control <SD 0.6; without control [asymptotically =]SD 4.73.) (Fig. 8). The task completion time was increased between 17.78 and 23.26 per cent.

In synergistic mode, a visual and haptic feedback was provided to the user. The movements were constrained along the guiding path. The error distribution between the performed robot path (in the graphical interface) and the guiding path was low, as represented in Fig. 9. However, the geometric measurements of the milled cavities showed a bigger difference between resultant machined area and the expected area (from -20.3 to 7.5 per cent).

8 DISCUSSION AND CONCLUSION

The studies showed results of the milling procedure performed with the CRANIO system using different modes of operation. The results of CT scan comparison between planned and realized safety margins present accuracy limitations owing to the voxel size ([asymptotically =]0.45 mm), which is large considering the planned margins (0.5-1.0 mm). For practical reasons leaving a bony layer of 1mm attached to the outer layer of the dura is perfectly sufficient since this can be removed easily during surgery. In the autonomous mode the most prominent sources of inaccuracies observed are registration and intra-operative robot calibration. Both modules involve an optical tracking system (nominal accuracy: 0.35mm RMS [41]). Furthermore, the safety check and optimization of the milling path might introduce an offset from the dura mater larger than planned. However, for safety reasons, it is important to constrain the tool movement to the reference volume, trading-off uniformity of the remaining layer. This layer could be removed in a synergistic mode with an automatic control of the milling path along the bone surface (with reduced speed) while the user is interactively controlling the milling depth in a macro/micro master-slave mode while the system is providing haptic feedback. This mode is being investigated and will be reported later.

The speed control showed a reduction in the deviation of the level of milling forces accompanied by an increased completion time. Although the speed is increased when the
milling tool is outside the material area, the speed control decelerates the robot during the milling process in order to keep the forces inside the predefined range. The opposed parameters force level and speed can be further optimized for higher efficiency.

In the synergistic mode, the tracking between master device and slave presented good levels of the control architecture implemented. Some inaccuracies owing to the registration process were also identified, requiring revision of the process adopted. The planned path was displayed to the user by visual as well as haptic guidance. Some deviations were observed by the path performed by the robot. These variations were related to human inaccuracy (tremor within the guidance) and deviations between the position tracking of the haptic device and the optical tracking system. Further analyses of the related man- machine interaction are necessary for a better understanding and evaluation of the system characteristics and optimization of system parameters. Apart from the accuracy and efficiency of the process, the transparency of the haptic feedback as well as the analysis of level of vigilance of human operator related to the supervision and control of the milling process in comparison to other modes of operation, will be further aspects of ongoing research.

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