Robot-Assisted Placement of Craniofacial Implants

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Purpose: *The purpose of this study was to improve and accelerate the rehabilitation process for patients with severe ear microtia with an implant-anchored auricular prosthesis. A medically approved robot system was used to place the craniofacial implants and a new process was developed for preoperative fabrication of the prosthesis using a rapid prototyping technique.* ***Materials and Methods:*** *Preoperatively, after computerized tomography, the implant positions were determined in a planning tool according to bone availability and esthetic considerations. Intraoperatively, the robot showed the surgeon the planned implant positions and guided the placement procedure.* ***Results:*** *The accuracy measurements showed that with this robot system, absolute implant position accuracy of approximately −0.5 ± 0.4 mm, a relative accuracy between the implants of approximately 0.2 ± 0.5 mm, and a deviation from the parallel position of approximately 0.6 ± 0.5 degrees were achieved. Thirty implants were placed in 13 patients with robot assistance with no intraoperative injuries.* ***Discussion:*** *This technique made it possible to apply the preoperatively fabricated auricular prosthesis directly after surgery.* ***Conclusion:*** *From this experience it can be concluded that the robot system and the new manufacturing concept for anaplastology can be applied advantageously in other areas of the head as well.* INT J ORAL MAXILLOFAC IMPLANTS 2003;18:712–718

Key words: *auricular prosthesis, craniofacial implant, rapid prototyping, robotics*

Surgical reconstruction of an ear with severe microtia (grade 3 malformation[1,2]) is difficult and usually involves several stages.[3,4] The cosmetic results are not always satisfactory, so alloplastic reconstruction with a silicone auricular prosthesis is an attractive alternative procedure.[5] Craniofacial titanium implants guarantee secure retention of the prosthesis,[6] and if primary stability is sufficient, they can be placed in a 1-stage procedure.[7] For optimal results, implant placement must be carried out with both functional and esthetic considerations in mind[8]; this requires precise preoperative planning.

Computer planning tools that employ computerized tomographic (CT) image data can assist in the planning phase, but the exact realization of the plan in actual surgery is not possible with current routine navigation techniques or drill templates.[9,10] A robot-assisted procedure was conceived to overcome this deficit. In addition, the authors envisioned fabrication of the prosthesis before surgery, rather than (as is current practice) 3 months after implant placement and exposure.

MATERIALS AND METHODS

To realize this new concept of robot-assisted implant placement, every step—from image acquisition, planning, and facial prosthesis fabrication to the robot system itself—had to be developed, tested, and optimized. Training for the procedure was performed initially with models and cadavers. Realization of the concept was only possible through a fusion of medical expertise in implant/anaplastology with innovative engineering.

Robot-assisted surgery with preoperative fabrication of the facial prosthesis was carried out on 13 patients ranging from 14 to 49 years in age. All

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patients had severe congenital microtia and were to be rehabilitated with an implant-anchored silicone auricular prosthesis. The craniofacial Brånemark System implants (Entific Medical Systems Deutschland, Bad Oeynhausen, Germany) were placed in outpatient surgery under general anesthesia. Parallel implant positioning and, given sufficient primary implant stability, a 1-stage procedure, were projected. Two telescoping magnets (Steco-System-Technik, Hamburg, Germany) were to serve as the retaining device.[11]

Image Acquisition, Fixation, and Registration

Unlike navigation systems, robotic systems require that the position of the patient be fixed and stable. To achieve optimal image quality for the preoperative planning and nearly identical conditions for data acquisition and surgery, the patient was secured for the imaging and the operation with the same fixation system at the same operating table. The fixation system for the patient's head consisted of a custom-made polyurethane head rest lined with body latex and a custom maxillomandibular splint (Fig 1). The head was set in a lateral position. A padded headrest assured a large contact area to the patient's skin, thereby avoiding pressure necrosis on the skin and nerves, and provided rigid positioning of the patient. The maxillomandibular splint was made of two 2-mm-thick dental occlusal splints (Erkodur-clear; Erkodent, Pfalzgrafenweiler, Germany) fabricated with a thermoforming technique, 1 each for the maxillary and mandibular teeth. These splints were both attached rigidly with acrylate adhesive onto an enforced torsion metal impression tray. This ensured rigid fixation of the teeth and provided secure contact between the patient's head and a hydraulic, lockable fixing arm, which in turn fixed the patient's head rigidly to the operating table. A reference frame of the navigation system was also attached to the splint.

Registration of the patient was done with markers placed around the operation site. Previous to CT data acquisition, the markers were deposited in a silicone impression made from the congenital ear defect. Because the markers were not placed on the patient's skin, errors related to movement of the markers on the skin could be minimized. After CT scanning with the mobile CT machine (Complete Tomoscan M; Philips, DA Best, The Netherlands; 130 KV, 10 mA, 2-mm slice thickness, 1-mm slice distance, voxel size $0.3 \times 0.3 \times 2$ mm^3), the marker positions were determined relative to the reference frame of the robot's navigation system. The registration matrix was then calculated with a point-matching algorithm. Because of the high repositioning accuracy achieved with the maxillomandibular splint, no further registration was necessary during the operation since the robot controller received the registration matrix from the planning tool.

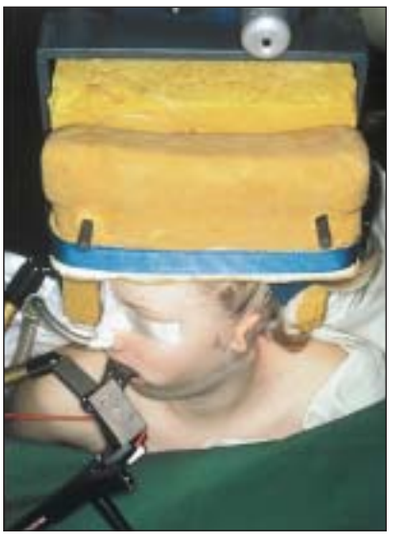

Fig 1 The fixation system for the intervention consists of a custom-made polyurethane head rest and an arm that is rigidly fixed to the patient via a custom-made maxillomandibular splint. The reference frame of the navigation system is also attached to the splint.

Implant Planning

Craniofacial Brånemark System implants (Entific Medical Systems Deutschland) with diameter of 3.75 mm and length of 3 or 4 mm were planned. They were screw-shaped and not self-tapping. In the planning tool, the implant positions and the 3-dimensional alignment were determined with the help of the CT image data, taking into consideration the available bone, soft tissue situation, and esthetic concerns (Fig 2). Location of the optimal positions was difficult, because only the bare minimum number of slides had been taken during the CT scan, and these provided insufficient spatial orientation. The position of the new silicone ear and the most esthetically desirable implant positions were therefore determined on the patient before the scan. Two metal threads—one tracing the outer shape of the ear and one following the best implant positions—were fixed on the patient's skin. These threads, which were visible in the planning tool, helped the surgeon align the implants. Parallel implant axes were planned and 2 special telescoped magnets were projected as the retaining devices.[11]

Model Operation and Auricular Prosthesis Fabrication

To fabricate the prosthesis preoperatively, the anaplastologist required a working cast with implants

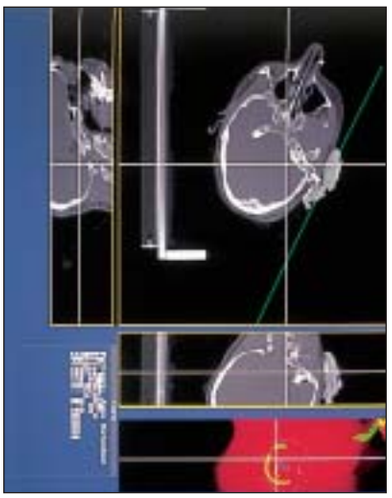

Fig 2 In the implant planning tool, bone availability in the mastoid region is shown in 3 planes. In a reconstructed 3-dimensional view of the skin surface, the position aids are visible; one indicates the preferred implant positions and one *(upper right)* traces the outline of the ear to help orient the surgeon for optimal esthetic results.

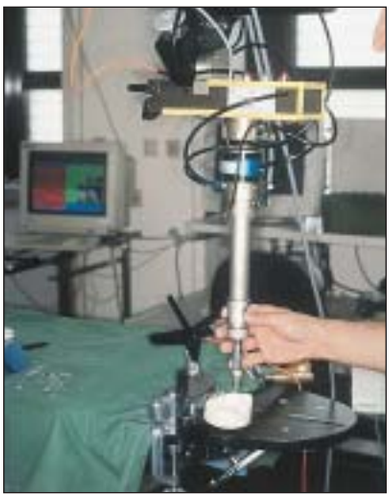

Fig 3 Preoperatively, the surgeon places the implants with robot assistance in a registered cast model. The implant situation required by the anaplastologist for the preoperative fabrication of the magnet-retained auricular prosthesis was reproduced.

Fig 4 A mirror-image replica of the healthy side (seen from the posterior), fabricated in prototyping technique, provided the basis for the anaplastologist's fabrication process.

and magnets attached. A surface skin model of the defect site made with rapid prototyping failed to replicate the preoperative situation with the accuracy and detail required for modeling the fine margins of the silicone prosthesis. This was because of errors in the slice distance of the CT (slice distance of 2 mm could differ by up to 20%[12]), errors during segmentation of the skin, and artifacts introduced by metal in the fixation system and the patients' tooth restorations. Consequently, the decision was made to use a plaster cast of the surface skin of the defect. The silicone impression for this plaster cast was made with the integrated markers mentioned above so that the cast created could be registered in 3-dimensional space. This made it possible to place cast implants in a robot-assisted model operation (Fig 3).

Before this operation, the plaster in the region around the planned implant positions had to be reduced to replicate the patient's bone surface situation. The soft tissue over the projected implant regions was measured in the planning tool and excess plaster was milled off. After the robot-assisted placement of implants, the magnets were screwed on. To replicate the postoperative soft tissue situation as well with the greatest possible accuracy, the malformed ear was removed by the surgeon from the plaster cast. Using the fine lines left by the metal threads on the plaster model as guidelines, the anaplastologist fabricated the auricular prosthesis.

Additionally, with special software and a rapid-prototyping technique (selective laser sintering), the CT image data of the healthy ear was used to create an ear model that was a mirror replica of the healthy ear (Fig 4). After copying this model in wax, the anaplastologist perfected the outer form and relief of the ear, smoothed the surface, and adapted the margins to the plaster skin surface model. The anaplastologist shaped a small, hollowed-out block of polymethylmethacrylate resin (PMMA) and inserted it into the reverse side of the wax ear model opposite the 2 magnets on the plaster model. The countermagnets would later be fixed into this hollow with PMMA autopolymerizing resin. Finally, the form for casting the silicone was produced. All steps were performed without the need for the patient to be present. One day prior to surgery, the patient visited the anaplastologist for an exact color match of the silicone. Then the prosthesis was vulcanized in the

Figs 5a to 5c *Clinical example of the process.*

Fig 5a The auricular prosthesis is fitted intraoperatively directly after implant placement. The sterile draping of the operative site around the ear is visible.

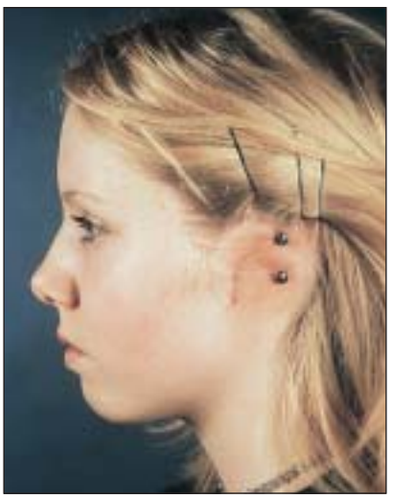

Fig 5b The patient after placement of 2 implants with telescoping magnets screwed on directly after wound healing.

Fig 5c Esthetic rehabilitation with silicone prosthesis fitted.

usual manner, and the finished auricular prosthesis was available prior to surgery.

Robot System and Operation Procedure

The SurgiScope (Elekta IGS, Grenoble, France) was used as the basis for the development of a robot to assist with implant placement in maxillofacial surgery. The original robot system, which was suspended from the ceiling, was constructed to position microscopes in neurosurgery. For implant placement, the controller software and tools were changed, and these have been medically approved.[13,14] The robot consists of a parallel manipulator (Delta-3 cinematic), an infrared navigation system (IGT FP 3000), a control cabinet with the computer for the navigation system, and the control computer of the manipulator. This robot system does not work automatically but rather interactively with the operating surgeon. The robot holds the drill handpiece and moves only when the surgeon applies manual pressure by taking the drill handpiece. However, the movement radius of the handpiece, equipped with the usual drill instruments, is restricted. The robot leads the surgeon to the preoperatively planned implant position and permits handpiece movement only along the selected drilling axis.

Following general anesthesia and nasotracheal intubation, the patient was positioned and fixed on the operating table in the manner described. The operative site was given a sterile washing and covered with surgical draping. The robot was covered with a transparent film. The surgeon removed the malformed ear, taking care to leave a smooth surface so that an esthetic transition from the edges of the prosthesis to the natural skin surface was later possible. The bone in the planned implant region was surgically exposed. The robot, fed with the planning data, guided the handpiece to the planned positions. Preparation of the implant seats and implant placement were carried out by the surgeon with the usual special instruments in the usual manner, drilling and thread cutting. Finally, the implant was screwed into place. Every surgical step appeared on a screen and had to be confirmed by the surgeon on completion via a sterile, covered keyboard. The surgical plan was to screw the magnets onto the implants immediately after their placement in a 1-stage procedure. Subcutaneous tissue and hair follicles around the implants were removed to avoid adverse peri-implant skin reactions.

After wound closure, the surgeon matched the auricular prosthesis. Two counter-magnets were inserted into the hollowed-out PMMA resin block in the reverse side of the auricular prosthesis. At fitting, the hollow was filled with PMMA autopolymerizing resin, enabling the surgeon to manually adjust the final position of the ear, giving careful attention to the distance of the helix from the side of the head and the margin on the cheek. This measure was necessary to compensate for unavoidable discrepancies remaining between the surface of the case model after resection of the malformed ear and the patient's actual postoperative skin surface (Figs 5a to 5c).

RESULTS

Phantom accuracy measurements taken preoperatively to evaluate the robot system for this application showed that it was possible to obtain an absolute position accuracy of approximately –0.5 ± 0.4 mm, a relative position accuracy of approximately 0.2 ± 0.5 mm between the implants, and a deviation of approximately 0.6 ± 0.5 degrees from the parallel axis when CT-generation and reconstruction errors were not taken into account.[15] After these preclinical tests, the robot system now had to furnish proof of its functioning in clinical practice.

In all patients with congenital microtia, the planning CT showed sufficient bone in the esthetically optimal region under the ear to anchor the prosthesis between the helix and antihelix. The primary criteria in choosing positions were bone availability and esthetic appeal. As secondary criteria, regions with less subcutaneous tissue over the planned implants positions were desirable, so as to reduce subcutaneous tissue removal to a minimum. In 86.7% of the sites (total 26 implants), 4-mm implants were planned, and in 13.3% of the sites (total 4 implants), 3-mm implants were planned.

The 30 implants were then placed with robot assistance. Three parallel implants were placed in the first 4 patients, with 1 serving in each case as a reserve. In the following 9 patients, given the positive experience of the first operations, only 2 parallel implants were placed, thus saving costs and reducing operation time. With the exception of 1 patient, whose maxillomandibular splint disconnected because of insufficiently deep anesthesia, all targeted positions were reached. In this 1 patient, new implant positions were determined intraoperatively, but the preoperatively created prosthesis could not be fitted. In total, in the case of 11 patients, the implants were exposed directly after implant placement, and skin-perforating magnets were placed in 1 patient because of the primary stability of the implants. In 10 patients, the preoperatively fabricated prostheses were used, but these patients were advised not to wear the prosthesis constantly for the first 3 months to avoid disturbing osseointegration of the implants. In 2 patients, the implants were not exposed because of inadequate primary stability and were left to allow undisturbed bone healing. No intraoperative injuries with opening of the mastoid cells or damage to the venous sinuses at the base of the cranium or dura mater encephali occurred. The special positioning of the patients caused no damage in the region of the forehead, ear, or zygomatic arch, apart from a temporary skin redness visible immediately after the operation.

An analysis of the duration of the robot-controlled implantation in comparison to 5 conventional operations showed that preparation of the robot and attachments, without the patient being present, required additional time and was relatively constant at approximately 30 minutes. Once the patients were under general anesthesia, the robot-assisted operation required approximately 25 minutes more than the conventional operation. This reflected the time-consuming care and precision required in the positioning and special fixation of the patient and the sterile draping.

The actual operation time differed for the first 4 patients. More time was spent on the patients with 3 implants, and additional time was required in the first 2 operations for the necessary photo and video documentation. The process of gaining initial experience also accounted for lengthened operation time. After the procedure had been optimized, the operation time for the last 9 patients (incision/suture time) was approximately 118 minutes. Without the robot, incision/suture time in the conventional technique was measured at about 115 minutes. These values are comparable. The time lost by using the robot technique was regained when the number of implants was reduced from 3 to 2. With the conventional technique, 3 implants (1 telescoping implant and 2 spherical implants) were needed for the magnetic retention of an auricular prosthesis.

In most cases, the patients' rehabilitation times were shortened; all but 3 patients were able to wear the new prosthesis home after the operation. The new fabrication process with rapid prototyping saved the anaplastologist approximately 1 day of modeling time, and the patient was spared hours in repeated fittings, thus reducing the physical and psychologic burden. Retention with the 2 telescoping magnets proved to be fully adequate. The esthetic quality of the prosthesis achieved with rapid prototyping, particularly the 3-dimensional plasticity and form, surpassed the results attained through manual modeling.

DISCUSSION

Exact planning of the implant positions to anchor an auricular prosthesis is important, especially for patients with congenital malformations. These patients often have abnormal bone and soft tissue morphology around the defective ear and are often missing soft tissue landmarks that are important to orient the surgeon when trying to avoid intraoperative complications.[16] The implant positions were a departure from the typical localizations for auricular

implants described by Tjellstrom and Granstrom[7]: 1:00 and 4:00 positions for a left ear and 11:00 and 8:00 for a right ear. Because no special implant planning tools for craniofacial implants were commercially available, the present planning tool, which works with CT data, was specially developed. In the future, the procedure promises to be more convenient than conventional software tools for planning intraoral implants. The authors also envision improvements, such as a program feature mirroring the healthy ear into the defect area to facilitate orientation for the surgeon during planning.

Robot technologies were used to realize the plan in practice at the operation table. The commercially available surgical robots can be distinguished according to their different control strategies:

- *Automatic systems:* These are used for the automatic performance of a preplanned intervention. An example is the shaping of cavities for total hip replacement.[17,18] Because of the high safety requirements for automatic systems, the application only makes sense for complex interventions where the robot can carry out a part of the operation without any interaction with the surgeon.
- *Telemanipulation systems:* These are used for minimally invasive interventions in which the surgeon has no direct access to the operative site. The systems provide features to dampen down human trembling and scale down movements or forces. Currently, systems are available for positioning cameras and instrument-carrying telemanipulators.[19–21]
- *Interactively controllable systems:* These are a mixture of the 2 system approaches described above. The surgeon is not spatially separated from the patient. Additionally, during the whole intervention, the surgeon can intercept the course of the operation. Until now, only systems for positioning of microscopes have been developed.[22,23] The medically approved robot used in this study belongs to this group because of the interactive communication between the robot and the surgeon.

This robot, the first of its kind for placing craniofacial implants, will launch a new era. A trained team that takes all potential sources of error into consideration in advance can deliver esthetic and functional results. The clinical results presented here were achieved only by careful optimization of each step of the intervention: image acquisition, patient fixation, preoperative planning, model operation, fabrication of the prosthesis, and the actual implant placement surgery. This entirely new process, developed in teamwork by engineers and surgeons, is more complex than manual implant placement and prosthesis fabrication, but only with robot assistance can preoperatively planned implant positions be realized in actual surgery. No other techniques, eg, navigation techniques or drill templates, can do this as precisely.[9,10] The implant site can be located with navigation, but exact freehand positioning of the implants is impossible. Templates or surgical guides are not as exact because they are difficult to keep fixed on the implant spot and do not allow accurate guidance while drilling. Perhaps the future promises the use of new navigation systems developed for intraoral implant dentistry.[24]

The system used to fix and stabilize patient position, which is necessary to obtain the required precision, works only with patients who have teeth. It does not work with edentulous patients or patients with unreproducible dental occlusion. In these cases, temporary dental implants might be used to create a reproducible occlusion.

Formerly, bars were the most frequently used retaining devices for auricular prostheses, but magnets with sufficient retention became available and gained popularity. Advantages of magnets for the patient are easier cleaning of the peri-implant region and more convenient positioning and removal. Compared with magnets, bars require more frequent repair. Fracture and loss of the prosthesis clips have been common. Further, clips must be activated, because the bars' friction force decreased with time. Normally, a prosthesis retained by magnets requires 3 implants: 2 loaded with spherical magnets and 1 loaded with a telescoping magnet to prevent the prosthesis from shifting.[11] Here, 2 implants placed with robot assistance on parallel axes and loaded with screw-on telescoping magnets provided adequate prosthetic retention by combining the effects of parallel implant position and the magnetic and frictional forces involved.

CONCLUSIONS

The clinical accuracy of robot-assisted implant placement is a breakthrough in the rehabilitation of patients with facial prostheses. For example, it allows preoperative prosthesis fabrication and immediate postsurgical prosthesis fitting. Rapid prototyping techniques can also shorten the fabrication process. It should be noted, however, that CT data are not exact enough to replicate soft tissue surfaces for satisfactory rapid prototyping, so that conventional impression techniques are still

required for modeling prostheses. Other imaging data techniques, such as nuclear magnetic resonance or laser scanning, may prove to be more suitable for copying soft tissues.[25]

The positive clinical experience and the accuracy attained in the placement of craniofacial implants to retain auricular prostheses warrant use of the robot for placement of craniofacial implants in other areas of the head as well. The system cannot, however, be easily adjusted to place intraoral implants. Its feasibility, given the high equipment costs involved, depends on the further development of its multifunctional and multidisciplinary potential, with features such as milling and sawing for maxillofacial surgery or tools for other surgical fields such as orthopedic bone surgery.

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