CHAPTER 1
INTRODUCTION

Robotic Assisted Surgery (RAS) has naturally created many new medical opportunities, but also many new technical challenges. One such challenge is the requirement to apply robotic assisted tools in stages of the surgical procedure. As a result, it is often necessary to attach and detach the robotic assisted surgical tool from a single instrument holder during a surgery.

Surgeries which can benefit from robotic systems are diverse; however the chosen surgical case where this thesis was applied is the single jaw surgery with maxillary repositioning.

Approximately 20% of the world's population suffer from some major maxillofacial deformity. Epidemiological studies have shown that in some cases, the severity is so high that it influences their facial proportion and ultimately 5% of these cases can be considered to have a physical disability (135). A recent survey estimated that approximately 13% of the American population suffers from one sort of malocclusion, of which 33% are candidates for orthognathic surgery (62). This enhanced awareness has lead to more and more people seeking treatment from an orthodontist for irregular teeth or obvious jaw deformities.

Although orthodontic treatment can improve tooth alignment, function, and facial aesthetics, severe dentofacial deformities require the combination of surgery and orthodontic treatment. This combination makes it possible to treat dentofacial deformities which could not have been previously corrected (142).

A treatment plan for such patients is made between the surgeon and orthodontist, involving pre-surgical treatment and often postoperative treatment. The pre-surgical orthodontic treatment aligns the dental arch without any attempt to correct the occlusion. This frequently worsens the malocclusion temporarily, but it shapes the dentition to a correct position with regards to the expected result of the subsequent surgery (112).

Shortly before surgery, the surgical planning is performed with a recent cephalometric x-ray and dental cast models. Skeletal movement simulation is carried out on a tracing of the cephalometric analysis, against which contours of the upper and lower jaw are drawn. In this simulation the orthodontist acquires the intended displacements of the jaws. Dental cast simulation is then carried out to reflect these corrections. Markings are made on the bases of the cast models to measure the movements which will be realised on the articulator. The casts are then cut and moved according to the cephalometric calculations, confirming the intended final result of surgery. The simulation of these movements on dental cast models allows the fabrication of dental splints, which are made of an acrylic resin that moulds to the dental impressions of both the upper and lower jaw.

During surgery the jaws are separated from the rest of the skull and repositioned in the correct dental occlusal position predicted by the pre-operative plan. For maxillary repositioning, the correct position of the upper jaw in relation to the base of the skull needs

to be found. The current surgical approach consists of employing the plastic splint which defines the correct occlusal situation and allows placement of the maxilla in the final position in relation to the untouched mandible. This splint is the central piece in transferring the preoperative surgical plan to the operation room (OR).

However this is only true for the horizontal plane. The repositioning, drilling and fixation of the maxilla in the vertical axis remains a difficult task, which is carried out manually by supporting the mandible in a stable position approximating as much as possible to a "normal" situation. Vertical displacement measurements are taken with a compass or ruler and compared with the pre-operative surgical plan.

Orthognathic surgery has evolved to a relative common procedure with a high degree of predictability over the last years (81) (142). Technical advances, such as rigid fixation techniques, bone graft harvesting techniques or bone substitutes, have further enhanced surgical success (12) (94) (140). Despite significant improvements in technique and technology there is still room for improvement (117) (29). Given the known pathology information, the already detailed surgical plan and relatively simple repositioning in relationship to the skull base, it is deemed this surgical problem is an excellent candidate for a systematic robotic approach (141).

1.1 WHY IS IT IMPORTANT TO COUPLE AND DECOUPLE A ROBOT FROM THE PATIENT

Regardless of the type of surgery that is to be performed, if robots are to be used they must comply with specific requirements. Sterility and safety are some of the most important requirements in surgery, and since usually only the tool is sterilizable and the robot not, the surgical tool needs to be separated from the robot to be properly prepared for surgical use. As tools will be removed and replaced repeatedly during many procedures, the tool holder could potentially be exposed to contamination and possible cross contamination between patients. To avoid this hazard an adaptor or coupling device between the tool holder and the tool is necessary.

One example application where different surgical tools are necessary with a single robotic system is with the DaVinci ™ surgical robot. This system employs a multitude of tools, from cameras to scissors and small manipulators. For this reason Intuitive Surgical (Sunnyvale, USA) developed a proprietary solution (173), where the tool changing procedure is executed by the surgeon's assistant. In an attempt to make this procedure automatic a surgical rack system was developed at the University of Washington (65) (69). This rack system is capable of holding, accepting, and dispensing up to 14 tools from a sterilizable carousel to the DaVinci surgical robot.

Another application where such a tool exchange was necessary was presented by Burgner (22). The joint effort of the Universities of Karlsruhe and Heidelberg resulted in a robotic system for orthognathic surgery which intends to support the surgeon intra-operatively and to facilitate the accurate transfer of the pre-surgical plan into the operation theatre.

This system consists of a Stäubli RX90 robot equipped with a force torque sensor (FTS), an optical tracking system and a surgical end-effector attached to the robot. The presence of an FTS enabled the programming of a force control mode which allows the surgeon to move the robot by holding the end effector and pushing in the desired direction. An optical tracking system is used to detect patient movement during surgery. One passive tracking marker is fixed to the patient's eyebrow while another marker is placed on the robots end-effector to register the position of the robot relative to the patient.

The pre-operative plan of the surgical procedure is still performed conventionally, with the added steps of recording the transformation to be performed. This is achieved by coupling the dental cast model of the pre-operative situation with the robot; sequentially the cast model of the expected post-operative situation is also coupled. The difference between the two spatial positions is the required target transformation.

Before surgery begins the patient's position has to be registered. The conventional workflow remains unchanged until the osteotomy of the maxilla is performed, at which point the robot moves to the target position. The surgeon then couples the mobile maxilla with the robot and the correct target position is transferred.

This new robotic approach interacts with the patient and surgeon in specific steps of the single jaw surgery with maxillary repositioning, as shown in more detail on Table 3.

Table 3 - Comparison between the conventional orthognathic surgery and the proposed robotic assisted surgery (short form).

CONVENTIONAL ORTHOGNATHIC SURGICAL WORKFLOW	ROBOTIC ASSISTED ORTHOGNATHIC SURGERY WORKFLOW
Placement of patient under anaesthetics	Placement of patient under anaesthetics
	Fixing the surgical tool to the patient's maxilla
	Coupling the robot arm with the patient
	Perform registration regarding to the preoperative dentition
Incising of the gingiva from first molar to first molar	Incising of the gingiva from first molar to first molar
Subperiosteal dissection and maxillary bone exposure	Subperiosteal dissection and maxillary bone exposure
Placement of reference marks	Placement of reference marks
Anterior and posterior buccal osteotomization	Anterior and posterior buccal osteotomization
Connection of both osteotomizations	Connection of both osteotomizations
Placement of holes for interosseous wires	Placement of holes for interosseous wires
Separation of the tuberosity from the pterygoid plates	Separation of the tuberosity from the pterygoid plates
Completion of the posterior Osteotomy	Completion of the posterior osteotomy and osteotomization of the lateral nasal wall
Procedure repeated on the opposite side	Procedure repeated on the opposite side

Completion of the nasal mucosa dissection	Completion of the nasal spine subperiosteal and mucosa dissection
Downfracturing of the maxilla	Downfracturing of the maxilla
Placement of maxillary positioning wire and exposure of the posterior maxilla	Placement of maxillary positioning wire and exposure of the posterior maxilla
Trimming and redefining of maxillary wall	Trimming and redefining of nasal and maxillary walls
Insertion of wires through the interosseous holes	Insertion of wires through the interosseous holes
Placement of plastic splint between upper and lower jaw	**Wiring the surgical tool with the patients brackets**
Maxillomandibular wire fixation	**Robotic system identifies the target position of the maxilla**
Positioning of the maxillomandibular complex with reference to the condyle	**Fixating the mouth-piece with the target identified by the robotic system**
Checking the position of nasal septum	Checking the position of nasal septum
Measurement of maxillary repositioning using a caliper	Measurement of maxillary repositioning using a caliper
Final fixation of the maxilla with titanium plates	Final fixation of the maxilla with titanium plates
Removal of the maxillomandibular fixation	**Removal or mouth-piece fixation**
Removal of plastic splint	**Removal of the mouth-piece**
Verification of the occlusion	Verification of the occlusion
Suturing and closing the procedure	Suturing and closing the procedure

This new workflow intercepts the conventional procedure in three steps:

- Registration with the patient before the maxilla is osteotomized.
- Present a stable, accurate target position of the maxilla.
- Removal of the surgical tool after fixation of the maxilla.

Analysing the intersections of the system with the conventional workflow it was primarily acknowledged a requirement to place the robot away from the surgical site during most of the surgery and only seldom bring the robot to the patient. Meaning that there is the necessity to couple and decouple the robot arm from the patient-bound tool at least three times per surgery, and two additional times to record the pre-operative plan.

However, difficulties lay in accomplishing a coupling situation in a simple, intuitive way that minimises any hazard to the patient, while maintaining the sterile conditions required in an OR.

Solutions researched so far assume a previously known exact position of surgical tools, in relationship to the robot frame. In such circumstances the system is able to guide the robot arm blindly and couple with the tool. In a situation where the position of the tool is unclear, either a human partner will manually attach the tool to the robot or a tracking system is required.

Burgner (23) described as well a solution for this problem where both robot and patient-bound tool are tracked externally with passive optical markers. The navigation system monitors the markers on both tool and robot, determines a coupling axis, and then guides the robot arm automatically towards the tool. The claimed 1mm accuracy depends on the several components of the system, being the larger error source the external optical tracking system using multiple markers and a large depth for small translations (186). Due to this tracking inaccuracy adaptations on the system had to be made. Finally at the end phase of coupling the robot is moved automatically and the applied forces on the end effector are constantly measured. The sensed contact forces detected during the end phase help to guide the robot arm automatically to the final coupled position. If the forces overshoot a certain threshold a collision is detected and the system comes to a halt.

Effectively, these contact forces are also applied to the patient, increasing therefore the hazard of patient trauma especially when the maxilla is mobile.

1.2 PROPOSED WORK AND PROBLEM STATEMENT

As acknowledged by previous developments in the RAS area, there is a necessity to couple and decouple the surgical tool from the robot at any given time. To achieve a solution that answers the raised issues, a survey over existing coupling devices and solutions was carried out. This survey revealed that tool changers, grippers, connectors and coupling devices are common in industrial robotics (193). Most robot manufacturers already supply their solution for tool changers, as well as a multitude of specialized companies[1]. They are designed for their working industrial environments, however, surgical applications present different restrictions and conditions. In particular the surgical tools, and possibly the end effectors as well, need to be **sterilizable**. Any part of the robot that can come into contact with the patient or which may contaminate the surgical field must be sterilized or covered with a sterile drape / plastic cover. The surgical tool itself does not pose a sterilization problem since it is usually built from steel or aluminium with biocompatible coating, however, the end effector that holds the tool does requires sterilization, and this can be a problem if this end-effector contains non-sterilizable items such as electronics.

Industrial solutions for tool changers depend highly on a constricted, closed and predictable environment where the exact position of the tools is known. In such situation the robot is able to blindly guide itself to the correct tool, couple / decouple and continue its task (180). In a situation where the position of the tool is unclear, either a human partner will manually attach the tool or a tracking system is required. Robotic systems to date employ almost exclusively global maps for navigation purposes, if any. This knowledge is grounded in information from external tracking sensors, which collect data from a large area containing the robot arm and return it with associated position information (the data is embedded into a coordinate system, e.g. in optical tracking). Additional local information can also be collected from the immediate surroundings and help to cope with uncertainty, measurement errors, and incompleteness of data (169).

1 Such as ATI Industrial Automation (Apex, USA), Maxbar Inc. (Houston, USA), SAS Automation (Xenia, USA), GRIP GmbH (Dortmund, Germany), etc.

Optical tracking systems pose another inconvenience which is the non-constant tracking error within the tracking volume. This tracking error increases with the distance between the camera and optical markers (186). Moreover, these inaccuracies in optical tracking technologies have lead to contact forces being applied to the tool, and therefore to the patient, raising serious **safety** concerns especially when the maxilla is mobile (23) (24). Under such circumstances, uncontrolled and unexpected forces are naturally undesirable.

A camera placed on the robot arm closer to the optical markers allows a higher tracking accuracy, which in turn enables a safer coupling without the application of forces on the patient. Additionally, **intuitive handling** is hindered with the usage of these external tracking devices which drive a constant line-of-sight to the tracking markers, and require relatively large sized markers. The **intrinsic camera** approach enables the construction of an efficient automatic / semi-automatic tool exchange procedure. With a single camera it is necessary to detect and extract 3D position and orientation information from the 2D markers, regardless of the lighting conditions found at the OR.

Furthermore, the proposed RAS solution to orthognatic surgery requires an **exact matching** of the interfaces between tool and end effector. The tool may not be connected to the robot arm in an erroneous position otherwise it incurs the error of wrong registration and incorrect maxilla repositioning.

For these reasons a new approach to the coupling problem needs to be researched and the question is raised:

Can a medically safe interface or coupling mechanism be developed that permits **fixation with the maxilla** for **accurate** transfer the pre-surgical plan to the OR with **minimum impact on the surgical workflow** and **improving the risk levels** to previous designs?

1.2.1 SUMMARY OF GOALS

There is a need in RAS solutions for an interface between the robot and patient that minimises collision hazards and intuitive to use by the surgeon. Such an interface or coupling device is subject to the following criteria:

- The ability to completely separate the sterile area from the non-sterile.
- Ensure patient safety by minimizing any applied force to the patient-bound tool.
- Simple to operate, sterilize and customizable to individual patients.
- Robot system with coupling device must sustain the presented RAS approach for orthognathic surgery.

The fixation of the maxilla and accurate transfer of the pre-surgical plan to the OR requires:

- Maxilla supporter tool with individual patient fixation possibility.
- A clear fixation of the surgical tool with the robot’s end effector.

1.2.2 MAIN CHALLENGES

The challenges to reach the proposed objectives can be summarized in to:

- Embed the system with a force control mode for intuitive usage of the robotic system.
- Design an integrated camera-based prototype to track the surgical tool, minimizing therefore a major source of positioning errors and enhancing the simplicity of the coupling mechanism.
- The mechanical prototype must provide an exact, unique position to couple the surgical tool and secure the device.
- Design a mechanical prototype that answers the sterilization problem, while maintaining the camera safe.
- Integration of image processing algorithms to enable continuous target tracking.
- Detect and extract 3D position and orientation information from the 2D markers, regardless of the lighting conditions of the OR.
- Correlate the camera sensor frame with the robot frame.
- Program a graphics user interface that allows the user to control the robot system efficiently.
- Maintain the design as simple and cost effective as possible without sacrificing safety and reliability.
- Analyse the efficiency of the coupling mechanism, and ensure that the designed solution does not transmit forces to the patient during coupling.
- Assert that the solution and robotic system is able to follow the proposed modifications to the conventional surgical workflow.

Zero force coupling is achieved when the robot is able to attach the end effector without colliding with the surgical tool. To assert patient safety, measurements of forces at the tool side were carried out. The single camera tracking approach informs the robot controller of the correct coupling axis, orientation and depth of target. In this way, the surgical tool coupling and decoupling procedure can be made safer, more accurate, less time-consuming, and lower risk of injury to the patient.

The developed prototype was tested in laboratory, simulating OR conditions, with a phantom patient as well as with a swine skull. Additional tests have been made with a light-weight robot, the LBR3 from KUKA Roboter (Augsburg, Germany). These tests are intended to assert the usage of such a robot in assistance procedures under realistic surgical conditions. In particular it is intended to determine the stability of holding the maxilla in the target position during the single jaw surgery with maxillary repositioning.

1.2.3 SCOPE

This study is conducted in the field of robot-aided orthognathic surgery; however the design should be flexible enough to accommodate future changes for other medical fields. Tests will be conducted to evaluate the usability of the proposed solution under realistic conditions.

1.3 DEFINITION OF TERMS

As used herein, the term "tool" means a subset of specific tools for surgery which includes "surgical instruments" or "surgical tools". In this context, the term “end effector” is also constrained in meaning to the final stage manipulator at the end of a robot's arm. This expression is usually understood to already contain a specific tool for a specific end-purpose task, such as a drill, a gripper, a laser cutter, etc. However, here we define the "end effector" solely as the mechanical component that holds the tool. The ability to interchange tools using the same end effector is provided by the “coupling mechanism” or as it is known in industry, “tool changer”.

1.4 THESIS OUTLINE

Materials and methods:

The first part of this chapter reviews the current practice in corrective jaw surgery, detailing the conventional method for preparing a surgical plan, as well as the surgical technique used to carry out single jaw surgery with maxillary repositioning. A short orientation on surgical planning transfer methods is described, and additionally different technical approaches to the problem in question, particularly Robot Assisted Surgery. An outline of existing solutions on medical robot coupling is then presented.

The subsequent section contains a detailed presentation of the mechanical aspect of the developed prototype that answers the raised issues. It explains the original approach to solve the proposed problem with technical drawings, photos of the prototype and explanations of the hardware connections. The prototype was designed with the help of the CAD program, Inventor professional 11 (Autodesk, San Rafael, USA). The manufacturing of the pieces was carried out at the mechanical workshop of the Medical University of Heidelberg.

A thorough explanation of the image processing and interpretation necessary for the development of the presented prototype is presented next. It explains the methods employed to track the 2D markers and perform the position and orientation calculations, as well as camera calibration issues, matching of coordinate systems, FTS interpretation and graphics user interface. The system was implemented under Linux Ubuntu 8.04, employing the open source-image processing libraries OpenCV supported by Willow Garage (Menlo Park, USA).

The final section of this chapter illustrates how the experimental setup was designed to determine the coupling efficiency, forces applied to the patient, stability of the robot arm position during drilling, and screw fixation on a phantom patient as well as on a swine skull.

Results:

This chapter presents the results of the coupling method, in terms of tracking accuracy, applied forces to the patient when coupling and drilling, robot stiffness and its influence in

the surgical procedure. The experiments were performed using the LBR3 on a phantom patient as well as a swine skull.

Discussion:

This chapter discusses technical solutions in the Cranio-Maxillofacial (CMF) surgery, in particular with orthognathic surgery, followed by the discussion of the obtained results with this particular coupling method. It provides the closing conclusions of this work and topics for future work.