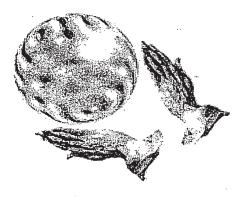
Exhibit 1012

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Robot Controlled Osteotomy in Craniofacial Surgery

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Abstract. Interventions in craniofacial surgery are a great challenge to the operating surgeon, as high precision and long practise are required to perform optimal bone repositionings and to achieve and aesthetic and satisfactory result. Although methods and devices for the preoperative planning of bone repositionings do already exist, the accurate intraoperative transposition of a surgical plan still is a problem. For this solution a joint procject to develop a computer aided method using a surgical robot to control the surgeon's movements while cutting bone was conceived by the surgeons of the Clinic of Maxillofacial Surgery of the University of Heidelberg and the engineers at the Intitute of Process Control and Robotics (IPR), which we present in this paper.

1 Introduction

Up to now the outcome of a craniofacial surgical intervention mainly depends on the experience of the operating surgeon. Due to the complexity of the anatomic structures involved bone repositionings are quite difficult to perform without hazards. In clinical routine the surgeon is already supported by various computer aided devices such as surgical planning systems, intraoperative navigation systems and stereolitographic modelling of the patient's skull. Still, the difficulty is an accurate transposition of the preplanned bone osteotomies during surgery. In order to overcome these difficulties our surgical partners at the Clinic of Maxillofacial Surgery of the University of Heidelberg alnced the idea to be supported by a computer aided devices restricting their hand motions while cutting bone. The surgeons especially favoured a surgical robot which allows them to manually perfom the bone cuts by guiding a surgical saw attached to a robot while the robot constraints their cutting movements.

Several approaches for semi-active surgical devices do already exist. Davies uses a robot with four degrees of freedom, called ACROBOT, which restricts the surgeon's movements within a dissecting plane for total knee replacement by force control [I determine the dir wheel with a hand movements of a pa three degrees of fr

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The surgical pl bone cut includin Then a security ze segments and arou of the inner cylind support points spl the surgeon is allo of the saw is restr surgeon moves th an increasing for the boundary of the

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The presented Various bone cut by measuring the ranged between 0 tolerance. Thus the preoperatively de trajectory of the 1 robot arm can als

2 System A

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by force control [1]. The Cobot by Peshkin offers the surgeon the possibility to determine the direction of a device which can be best described as a spinning wheel with a handle [2]. Troccaz controls the clutches of a joint to restrict the movements of a passive arm with two degrees of freedom [3]. A new model with three degrees of freedom is under construction.

In contrast to the three devices mentioned above we use an industrial robot with six degrees of freedom and a force-torque sensor to constrain the motions of a surgeon manually guiding a surgical saw attached to the robot's flange. In craniofacial surgery cutting paths are not restricted to two dimensions, thus the conception of a method constraining cutting movements along a three dimensional cutting trajectory was necessary.

The surgical planning system of the IPR sends the trajectory of the intended bone cut including the required orientation of the saw to the robot control. Then a security zone is modelled in the following manner: the path is split into segments and around each segment two cylinders are constructed. The diameter of the inner cylinder is 3mm, the diameter of the outer cylinder is 5mm. At the support points spheres are used instead of cylinders. Whithin the inner cylinder the surgeon is allowed to guide the saw without constraints. Only the orientation of the saw is restricted to 10° deviation of the given orientation. As soon as the surgeon moves the blade of the saw into the outer cylinder he has to apply an increasing force to continue into the desired direction. Finally, as soon as the boundary of the outer cylinder is reached the robot prohibits any further movement of the surgical saw into the forbidden zone.

The velocity, direction and orientation which the robot applies in order to control the surgeon's guiding of the saw are computed as follows: the force-torque sensor registers the desired orientation and position to which the surgeon wants to guide the robot arm within a basic cycle. An evaluation function analyzes the desired aim and computes the velocity and direction of the robot's movement.

The presented method has already been satisfactorily tested on pig cadavers. Various bone cuts were performed and evaluated by infrared navigation and by measuring the skeletized skulls. The accuracy of the performed bone cuts ranged between 0.5 mm and 3 mm, which is just within the limits of the defined tolerance. Thus the developed method can support the surgeon to transpose a preoperatively designed plan, while he can still take the liberty to change the trajectory of the bone cut, if suitable. The force controlled manual guiding of a robot arm can also be used for the training of future surgeons.

2 System Architecture

A first experimental set up was created to develop a new method for the required robot assisted sawing of bones with constraints (Fig. 1). We use a RX-90 robot with six degrees of freedom, which can be used for surgery, as the robot itself suffices the guidlines for medical devices.

The position of both robot tool and patient can be detected by an integrated infrared navigation system for automatical registration (Fig. 1 and 2).

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