INTRODUCTION

Although conventional surgical instruments for the alignment and placement of screws and prostheses are widely used, there is still much room for improvement with regard to safety and placement accuracy [1][5]. As an alternative to conventional surgical instruments and camera-based navigation systems, personalized templates have been promoted for accurate placement of dental implants, surgery of the pelvis [3][6], total knee arthroplasty [6] and for placing pedicle screws for spinal fixation [2][6][7]. The template obtains a correct fit to the application area by incorporating the 3D surface information of the bone and provides guidance according to a pre-operative planning. The presence of soft tissue gives a particular problem for templates to find a stable, unique and correct position on anatomical structures of the human body. The occurrence of soft tissue on the bony surface introduces position errors and even can make the positioning of the tool on the bone impossible. Therefore, special 2D-knife-edge support structures have been developed based on the 3D-surface description of the bone. Using this technique, template designs have been developed for pedicle screw insertion, atlanto-axial fixation and the placement of glenoid components for total shoulder arthroplasty.

METHODS

Parametric template designs have been developed for the spine and the shoulder using a Computer Aided Design (CAD) environment. To adapt the parametric design to the anatomical characteristics of the patient, 3D anatomical information is obtained by spiral CT and transferred to the CAD environment. In the 3D representation of the anatomy the surgeon is able to plan the optimal per-operative drill path. The function of the personalized template is to guide a drill according to this pre-operatively planned path. Therefore, the template should provide a correct, stable and unique fit on the bony structures. A mechanical analysis of the template/bone interface resulted in the development of wedge-shaped support structures based on the 3D-surface description of the bone. The support structures are implemented as triangular sections that are extruded along a curve of the bony surface. To obtain a support that is mechanically equivalent to a classical 3D-surface support, a stable combination of knife-edge contacts is made. Figure 1 illustrates the use of knife-edge support in templates for the lumbar and cervical spine and for the glenoid of the shoulder.

The templates are manufactured using rapid prototyping (RP) techniques such as stereolithography and selective laser sintering. Depending on the RP technique the templates are manufactured in polycarbonate or polylactide that are both medical grade (USP Class VI) materials. To validate the template designs post-operative CT-scans are taken. By means of a least-square registration algorithm, pre-operative and post-operative CT-data are merged to a reference coordinate system and registered. The post-operative position and orientation of the drill guide is then compared to the pre-operatively planned position and orientation.

RESULTS

The lumbar and cervical template designs are optimized by 3 series of cadaver studies comprising 18 cadaver spines altogether. A total of 15 lumbar and 4 cervical templates are successfully applied in-vivo. For total shoulder arthroplasty the template is being optimized and validated through 3 series of cadaver experiments. The first in-vivo shoulder replacement will be carried out in the first half of June 2004. In the spine high template stability was observed during application in vitro as well as in vivo. Soft tissue remained on the surfaces of the templates and a unique position was found in all of the cases.

Due to the limited accessibility of L5 during surgery, the general lumbar template design proved to be inadequate for successfully guiding a drill through the pedicle of L5. No stable position could be found in none of the L5 cases. For the segment L1 to L4 the template design showed to be successful. All the screws that had been placed using the spinal templates were clinically successful. None of the screw positions in the lumbar spine deviated more than 2 mm from the planned position at the screw ends. In the cervical spine all screws were placed with sub-millimeter accuracy. No results are available yet for the shoulder interventions as the cadaver experiments are still being performed.

DISCUSSION

Early cadaver studies showed that soft tissue remainders significantly obstruct a stable and correct fit of a large 3D-surface contact. When knife-edges are used no significant influence is observed on the quality of the fit. This means that the concept of minimizing the global contact area is suitable for templates fitting surfaces that are not completely free of soft tissue. This is a major advantage in the operation theatre where every additional action different from the standard surgical procedure (e.g. excessive soft tissue removal), must be avoided as much as possible. The accuracy measurements prove that not only a stable but also a unique and correct position is obtained using knife-edge support. In the lumbar L1-L4 segment and in the atlanto-axial joint this technique provides a clinically accurate tool for guiding the drill along a pre-operatively planned path and hence for the correct placement of screws in the spine. The cadaver studies will reveal to what extent this technique is suitable for template-based drill guidance in total shoulder arthroplasty.

REFERENCES

1. Valstar ER et al., ISPRS J Photogram and Rem Sensing. 2002;[2]

Figure 1: The use of knife-edge support in the lumbar spine, the cervical spine and on the shoulder glenoid.