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Evaluation of a synergistic handheld instrument for resternotomy controlled by an integrated optical sensor

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Abstract— **Re-Sternotomy is an important part of many interventions in cardiac or thoracic surgery. It is performed close to critical structures such as the ascending aorta or the heart with an inherent high risk of serious damage. In this paper, a system for improving the safety of this surgical procedure is presented. A soft tissue preserving saw is combined with automatic depth regulation. The depth is controlled on the basis of the optical characteristics (visible light) of the tissue aligned to the saw blade, which is analyzed using a color sensor. Detection of the blades' position in the bone during the cutting process is possible through the integration of an optical fiber into the tip of the saw blade. The automatic depth control is realized using a hysteresis controller running on a real time system. To show the feasibility of this approach, the sensor technology was integrated into a prototypal sternal saw and evaluated on artificial bone. As part of the experiments the influence of water for cooling and dust particles from the process on the systems control stability were analyzed. The system performed stable and accurate. Future research will focus on the control algorithm and cadaver trials.**

I. Introduction

STERNOTOMY was first described by H. Milton in the year 1897 and reintroduced in 1957 by Julian [1] and replaced the former used thoracotomy in most cases. Today, it is a standard procedure for many interventions in heart and thorax surgery to gain access to the visceral organs covered by the rip cage (heart, lung, aorta ascendes) [2]. During the first sternotomy complications are unusual, whereas the risk for the patient increases with each additional resternotomy applied [3], due to the adhesion of bone and underlying structures.

A. Anatomy of the sternum

The sternum consists of three parts, the *manubrium sterni*, the *corpus sterni* and the *processus xiphoideus*. The thickness of the bone is between 8 mm to 14.5 mm, and in most cases the *manubrium* is a bit thicker than the *corpus sterni*. The length of the sternum is for women 182.9±17.4 mm and for men 208.6±14.6 mm. In summary, the sternum is a plain, slightly curved bone [4]. Directly underneath the sternum, the thorax is enclosed by a dermal layer which consists of loose connective and adipose tissue.

B. Sternotomy and Resternotomy

When conducting a sternotomy, a sternal saw is used to cut the sternum in longitudinal direction. To avoid contact between the saw blade and the underlying soft tissues, the end of the blade is protected by a protective shoe. This shoe is pulled against the sternum and only displaces the underlying soft tissue. The cutting direction is not uniform and is determined by the surgeon. Alternative to a complete longitudinal cut, in some cases a partial sternotomy can be conducted with the advantage of higher preoperative stability and a smaller incision [5], [6]. In contrast to the almost complication-free first sternotomy, problems occur during the repeated opening of the sternum – the resternotomy. Due to the pericardium or other retrosternal structures adhering to the sternum in consequence of the first operation, hemorrhage or even worse an injury of the right ventricle, a prior drafted bypass, the atrium of the heart, the aorta or the internal mammary artery can occur. Follis et al. describe the risk for complications with 8.2% after the first operation, 14,6% after the second operation, and 33,3% after the third operation [3]. To reduce these problems, several approaches are described in literature. Prior to the intervention the patient can be connected to a cardiopulmonary bypass (CPB). This results in a deflation of the heart which indirectly reduces risk of injury [7], [8]. Another option is a preoperative computed tomography (CT) which can help to detect possible retrosternal adhesions and their location, and thus improves safety of the procedure [9], [10]. The retrosternal tissue can be visualized with an endoscope, and can then be removed step by step from the sternum. However, this procedure takes between 6 to 22 minutes [11], [12], [13]. To protect the soft tissue, Temeck et al. describe a technique where the upper layer of the sternum is cut using an oscillating saw, and the rest is incised using scissors [14].

II. State of the art

The most important constraint to be resolved is the limited possibility to get optical and haptic feedback from the instrument inside the bone. This signifies the difficulty to

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the surgeons to determine the type of matter they are cutting, and how deep they may cut. Even though this problem is partially addressed by oscillating saws with soft tissue preserving capabilities by providing a safety margin, a further improvement could be the automatic control of the instrument on the basis of anatomical data of the sternum. In literature, several systems which control surgical tools on the basis of medical imaging data for different medical interventions are described.

Brisson et al. [15] introduced the Precision Freehand Sculptor (PFS) which is utilized for milling of cavities for unicondylar knee replacement prosthesis. The infeed of a milling tool is restricted by additional computer-controlled degrees of freedom on the basis of a pre-planned safe zone. Optical tracking is used to determine the instrument's position relative to the situs.

In the Navigated Control concept, the power of a milling tool is controlled [16]. The power is adjusted according to the tools position relative to a preoperatively defined workspace on the basis of CT data. Position of the tool is allocated using optical tracking. The system has been evaluated for many different applications like spine surgery, oral and maxillofacial surgery, and dental implantology. Stopp et al. [17] use a laser instead of a milling tool which is controlled in the same way to remove bone.

In [18], the Semiautomatic Trepanation System (STS) for opening of the skull in neurosurgery is described. The instrument integrates a handheld soft tissue preserving saw which is controlled in one degree of freedom (depth). The depth is automatically regulated on the basis of preoperatively acquired CT data and optical tracking information from the actual tool's position relative to the skull.

Another system, which is also intended for the use in neurosurgery is the Craniostar [19]. A handheld craniotome is mounted on a two wheeled platform. This allows the system to perform a craniotomy along a pre-planned resection path. To control the speed of the instrument on the pre-planned trajectory, the angle of the instrument is analyzed relative to the skull surface using an optical tracking system (OTS).

III. Concept

The concept of the synergistic controlled tools described in literature has the advantage that the surgeon is supported especially in situations of insufficient perception of the situs. For the purpose of compensation, the synergistic or robotic systems use CT/MRI data for acquisition of the real anatomical landmarks or the virtual safe zones.

The use of optical tracking, combined with this data, to locate an instrument relative to the patient is obvious in neurosurgery, orthopedic and ENT surgery due to the broad use of surgical navigation systems in these disciplines.

In contrary, in heart and thorax surgery use of optical tracking and navigation is uncommon. Thus, the use of an optical tracking system combined with CT/MRI data would not be desirable for sternotomy. In this workflow additional error sources, such as registration, segmentation, optical tracking including the loss of the line of sight exist.

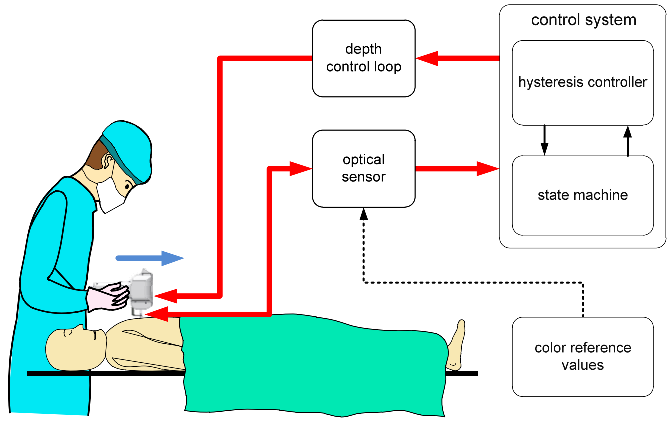

Fig. 1: Instrument concept and integration of the surgeon

When controlling the instrument with information acquired at the point of operation (tip of the saw blade), localization of the instrument with e.g. OTS is not necessary and the amount of possible errors can be reduced. In this case and in contrast to the applications with virtual safe zones, a real anatomical landmark exists with the detectable boundary between bone and soft tissue.

By integrating a sensor into the tip of the saw blade with the objective to detect the kind of matter aligned to it (bone, soft tissue), an automatic depth control can be realized using a hysteresis controller (fig. 1).

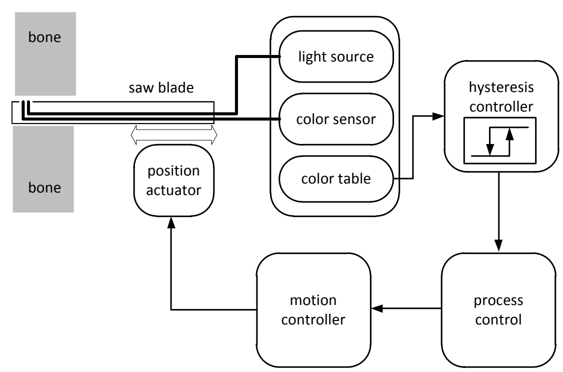

Fig. 2: Detection of the boundary and hysteresis controller

One approach for detecting material characteristics in situ is the use of optical coherence tomography (OCT). The advantage of OCT is that it can penetrate soft tissue up to a certain level and has a high axial resolution. Wickaksono et al. [20] propose a system where OCT is integrated into a dental drilling probe, to monitor the process.

In [21] we proposed a concept for detecting the bone-boundary and controlling a drive on the basis of this information using a colorimeter with visible light (fig. 2).

For the application in sternotomy, the information about the surface should be sufficient, which implies the use of a colorimeter. Even in the case of an optimal depth control, it is practically impossible to completely avoid contact between the saw blade and soft tissue, when cutting through the bone. Follmann et al. showed that a circular oscillating saw (±0.75 mm stroke) has good soft tissue preserving properties with amplitudes up to 2 mm while maintaining a high feed rate [22]. Therefore, an oscillating soft tissue preserving saw is recommendable for this instrument.

IV. Materials and Methods

The system consists of five main elements, which are a specially adapted saw blade with integrated optical fiber, a color sensor, the oscillating saw kinematics, the depth control drive and the process control system (see fig. 2).

The optical fiber is embedded in the saw blade with a 90° bending at the end (see fig. 3) and is connected to the colorimeter on the other side. The optical fibers for the light source as well as the ones for the sensor are integrated into one bundle to optimize illumination of the material and absorption of the backscattered light.

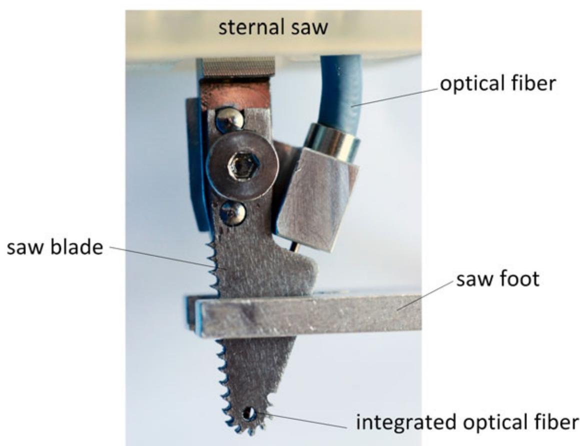

Fig. 3: Integration of optical fiber into saw blade

A SPECTRO-3-FIO (Sensorinstruments, Germany) sensor is used as colorimeter, which includes a color sensor and a white light source. The sensor uses the s, I, M color space which is mathematically similar to the L*a*b* color space. s and i (a*,b*) represent the color, whereas M (L*) represents the intensity. To detect a color and intensity combination, a virtual barrel can be defined in the color space, where the radius represents the color range and the height the acceptable intensity variation.

The process control task evaluates the output from the color sensor and activation switch, integrates the hysteresis control and is able to send set points to the motion controller responsible for the depth adjustment of the saw blade (fig. 4). Turning-on sets the system to the preoperational state. After placing the instrument on the sternum, the surgeon can switch to the operational state by pressing and holding the activation button. In doing so, the saw blade is extended until it reaches the bone followed by activation of the hysteresis controller. It can be deactivated by releasing the activation switch. To guarantee a secure operation, movement of the saw blade is only allowed in a predefined safe range.

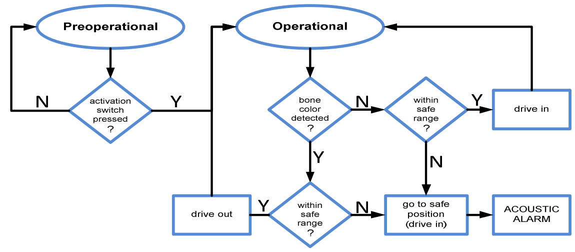

Fig. 4: State machine integrating hysteresis control and safety mechanism

In case the cutting procedure exceeds the safe range, operation is suspended and a warning is issued.

V. Evaluation

Evaluation of the system was conducted with two different setups. First, the impact of different coolants (water, air, no coolant) during the saw process was determined, by analyzing the variations in color and intensity. To be able to examine only the influence of the coolant, the hysteresis controller (depth control) was deactivated and a predefined depth was adjusted. The measurement was performed with four artificial sternums (Sawbones AB, Sweden) and a feed rate between 1 to 3 mm/s with a saw oscillation frequency of 167 Hz. For each of the following situations (1-4, tab. 1), 100 measurements were recorded, then their median and the standard deviation were calculated. During the first measurement (1) the saw was not moved, to acquire reference data, which shows e.g. the noise of the sensor.

TABLE I

Measurements of Color/Intensity for the different setups, median including standard deviation – 1) reference measurement, 2) no cooling, 3) cooling with pressurized air, 4) cooling with water

	R	G	B	s	i	M
1	1218±42	1083±37	604±35	5127±4	2227±7	743±9
2	1795±61	1612±54	1109±47	5135±4	2171±3	849±9
3	1703±79	1525±72	1012±66	5134±3	2184±6	834±13
4	1241±70	1105±63	630±60	5127±4	2222±11	749±14

In the next step, stability and accuracy of the hysteresis controller during the sawing process was evaluated. For this purpose, two synthetic sternums (Sawbones AB, Sweden) were used. The process was continuously cooled with water. During this procedure the position of the tool and the depth information were recorded using an optical tracking system (Polaris Spectra, NDI, Canada) and the control system (DS1006, dSPACE, Germany). Subsequently, two reference measurements were made for each sternum (see fig. 5). The differences between the reference measurements were 0.30±0.21 mm. For the first sternum, the mean error was 0.38±0.31 mm and for the second 0.39±0.38 mm. The respective maximal errors were 1.84 mm and 2.64 mm.

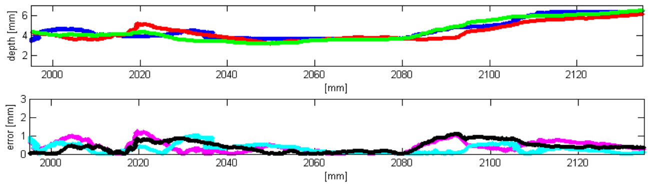

Fig. 5: Measurement conducted on the second sternum with optically controlled depth (blue), reference measurement (red, green) and the error (Ref1, magenta), (Ref2, cyan) and Ref1 to Ref2 (black)

VI. DISCUSSION AND CONCLUSION

The results of the evaluation showed the successful performance of an optical sensor as control device for the cutting depth of a saw blade (fig. 5). The use of different coolants showed no significant variations (see tab. 1). Moreover, the use of water as coolant indicated a slightly positive effect, potentially due to the different transport characteristics of material by the saw tooth in the front and on the sides of the blade. Here, the remaining particles might be removed by the water irrigation. Although the maximal errors of 1.84 mm and 2.64 mm are in a critical range, the control of the depth was stable. The maximal error values in this case probably occurred due to a tilting of the saw, which could not be corrected in time. Most likely, the remaining positioning error during the sawing process has two different sources: The control loop rate and the aperture of the optical fiber. With 1000 Hz, the control loop rate is high compared to the feed rate, indicating that the optical fiber with a radius of 0.6 mm primarily contributes to the error. Moreover, a constant offset of around 3.5 mm is present in all experiments due to current technical limitations in positionning the actual sensor in the saw blade (2 mm) and its oscillation of ±0.75 mm (see fig. 3). This offset could be reduced by further optimizing the geometry of the saw blade and combining the position information of the oscillatory movement with the point in time, when the measurement of the colorimeter is evaluated. Future research will focus on the reduction of the radius of the optical fiber and thinner saw blades, the optimization of the control loop in order to enhance resolution and control accuracy by reorganization of intermediate states at the boundary. However, our initial results suggest that this system is suitable to perform the task. The current in vitro model is limited to the analysis of the sawing process, influences of soft tissue and blood are neglected and will be further investigated with fresh bone in cadaver trials. Even though the proposed workflow is adapted to the standard workflow, the usability of the overall process has to be evaluated in future research in cooperation with surgeons.

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