Sensory Guided Surgical Micro-drill

R. Taylor, X. Du, D. Proops, A. Reid, C. Coulson, and P.N. Brett
Clinical Engineering Research Centre, Birmingham

Abstract: In this paper a surgical robotic device is described that is able to discriminate tissue interfaces and other controlling parameters ahead of the drill tip. The advantage in surgery is that tissues at interfaces can be preserved. The smart tool detects ahead of the tool point and is able to control interaction with respect to the flexing tissue to avoid penetration or to control the extent of protrusion with respect to the position of the tissue. For surgical procedures where precision is required the tool offers significant benefit. To interpret drilling conditions, and conditions leading up to breakthrough at a tissue interface, a sensing scheme is used that discriminates between the variety of conditions posed in the drilling environment. The result is a fully autonomous system able to respond to tissue type, behaviour and deflection in real-time. The system is also robust in terms of disturbances encountered in the operating theatre. The device is pragmatic. It is intuitive to use, efficient to set up and uses standard drill bits. The micro-drill has been used to prepare cochleostomies in theatre and was used to remove bone tissue leaving the endosteal membrane intact. This has enabled preservation of sterility and the drilling debris to be removed prior to insertion of the electrode. It is expected that this technique will promote preservation of hearing and reduce the possibility of complications. The paper describes the device (including simulated drill progress and hardware setup) and the stages leading up to use in theatre.

Keywords: surgical, robotics, sensory, guided, flexible tissue

1. Introduction

Robotic surgery has made its mark as a precise means of tool deployment in surgical procedures since the late 1980s [1, 2, 3]. The majority of applications have focused on the control of tools on trajectories defined using pre-operative scan data. Pre-determined trajectories are appropriate where tissue movement between scanning and surgical therapy processes can be considered insignificant, or within acceptable limits. In a few cases real-time sensory data has been used for guidance of robotic devices in surgery [4, 5]. This level of assistance has its value in many procedures. However more complex tool paths and variations in strategy are required to accomplish assistance in many challenging procedures.

To an extent the increasing complexity of tool trajectories and real-time strategies has been accommodated by introducing the surgeon operator into the control loop. Master-slave systems have attempted to harness the decision functions by the surgeon to interpret the state of tissue-tool interaction, the formulation of strategy by the surgeon and the response to tissue movement [6, 7, 8]. Unfortunately there is always a dilemma associated with the perception of interaction with the tissue at the tool point. This is particularly true in minimal access procedures or in procedures requiring microscopic tool interaction, where information based on visual perception is compromised and the sense of tactile information is lost.

Moving on from automatic and master-slave robotic systems in surgery, there is a need for sensor-guided devices that interpret or react to tissues in order to control the state of interaction between the tool-point and tissues. This is a complex process for a machine as perception requires automated interpretation of data, consideration of information derived and the selection of strategies. Such systems could be fully automatic, or automatic as part of a master-slave system to enable precise operation of tool points with respect to tissue targets and interfaces. At the micro-surgical scale there is the need to control exact penetration through flexible tissues and to control relative motion with respect to moving or deforming tissue targets and interfaces. Precision would otherwise be compromised by the deflection of tissues in response to patient movement or tool forces. Automated tissue discrimination, and the discrimination of behaviour, will be important especially in automated assistive navigation through or around tissues and structures to access a target point. To enable the field to move forward innovative actuation and sensing schemes are key components. Additionally, consideration needs to be given on the means to deploy smart systems in surgery. Pragmatic user interfaces and practical sizes for deployment of devices are essential to enable widespread use. The question of size and registration with respect to the tissues of the patient are being addressed for specific applications. Examples include the MARS robot of Mazor Ltd based in Israel for inserting pedical screws, the MBARS robot of Carnegie Mellon University, Pittsburgh for joint arthroplasty [8] and a research group in Grenoble have devised a system for abdominal surgery [9].

In this paper, a sensory guided smart tool point for surgery is described that controls interaction with tissues through information derived on the state of the process. The micro-drilling tool point is able to discriminate tissue and tool-point interaction to automatically identify the state and to control the surgical process through sensing its own working environment as information rather than data values. This example has been deployed recently in the operating room as the first surgical robotic device of its kind.

2. Micro-drilling tool point

The micro-drilling system is the first surgical robot deployed as an autonomous device that senses its own working environment as information rather than data values in order to discriminate states and conditions in the process, and the automatic selection of actuation strategies. Tactile information is derived from tissue-tool point interaction and used to select control strategies. The strategy enables precise cutting of flexible tissues and to identify the state of the tissue during this process. This paper covers a brief description of the cochleostomy procedure in which the system has been demonstrated in theatre, the design of elements of the micro-drilling system, the sensing technique and a description of the clinical trials.

2.1 Background

Cochlear implantation has become the standard treatment for severe to profoundly deaf patients over the last 20 years [10]. This implant is within the inner ear hearing organ. Creation of a cochleostomy is one of the key steps in the procedure for installing an implant. This is the hole through which the electrode implant is inserted into the cochlea and its location with regard to the anatomy of the ear is shown in Fig.1. Usually the cochleostomy is produced at the base turn of the cochlea working through a deep and narrow access behind the ear.

When drilling through the bone tissue of the cochlea, the inadvertent protrusion of the drill through the delicate internal structures of the cochlea can lead to complications. Protrusion together with contaminating the internal fluids with bone debris is expected to lead to a reduction in residual hearing and increase the risk of post operative infection. Using the new robotic micro-drilling system, it is possible to drill through the bone tissue wall of the cochlea and to complete the hole without penetrating the membrane at the inner medial interface. This minimises trauma to the hearing organ and increases the likelihood of retaining residual hearing. It also maintains a high level of sterility as the endosteal membrane immediately at the medial interface remains intact and there is no invasion of the fluid space of the cochlea during the drilling process. Access to the surface of the cochlea is prepared by the surgeon, and typically results in a hole 30mm in diameter, 30mm deep and narrowing to a 2mm by 3mm hole towards the drilling site. Of importance to the surgeon, who remains in control, is to maintain visual focus at the working site using a binocular surgical microscope, and access to the drilling point while avoiding contact with various anatomical structures. This is reflected in the design of the mechanical elements of the drill.

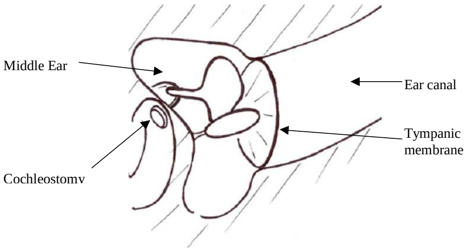

Fig. 1 Diagram illustrating the anatomy of the ear and location of a cochleostomy

The critical stage of preparing the cochleostomy is achieved using the robotic micro-drill, and then the implant is inserted through a pool of antiseptic gel at the cochleostomy. This maintains sterile conditions. As the micro-drill avoids penetration of the endosteal membrane, debris can be removed before the antiseptic gel is applied and the electrode inserted.

2.2 Simulation

Drilling force transients are key sensing parameters in the control scheme employed. To illustrate how these reflect drilling conditions a simulation model produces clear evidence. Distinct stages in the drilling process are:-

1. The start of drilling,
2. Hole depth is equal to the radius of the burr,
3. The stage of equilibrium drilling.
4. The start of breakthrough.

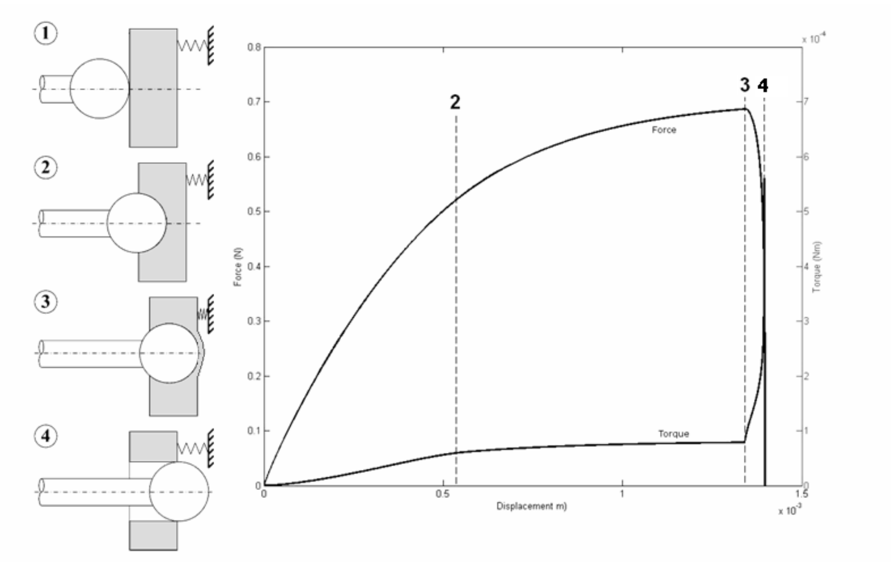

Fig. 2: Key stages in the drilling process.

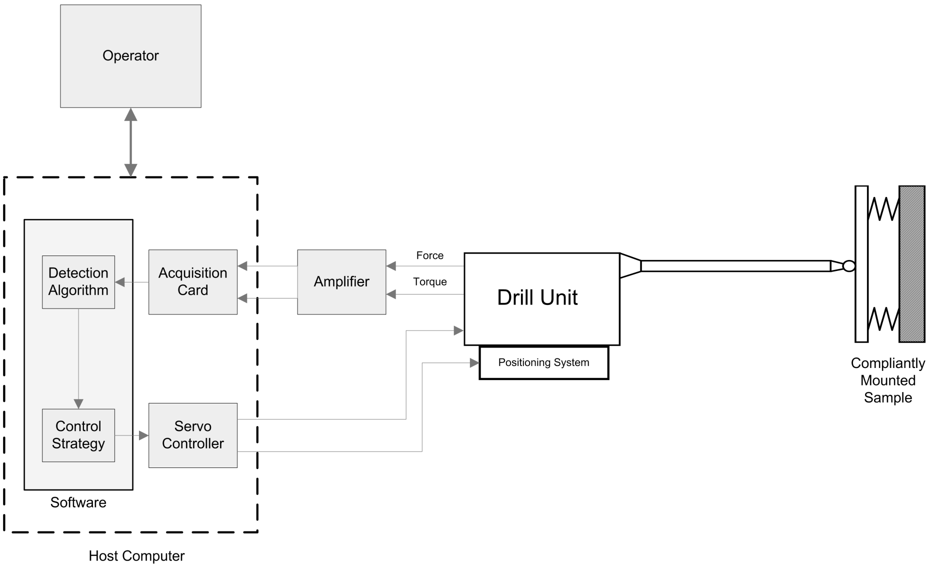

Fig. 3 System function diagram

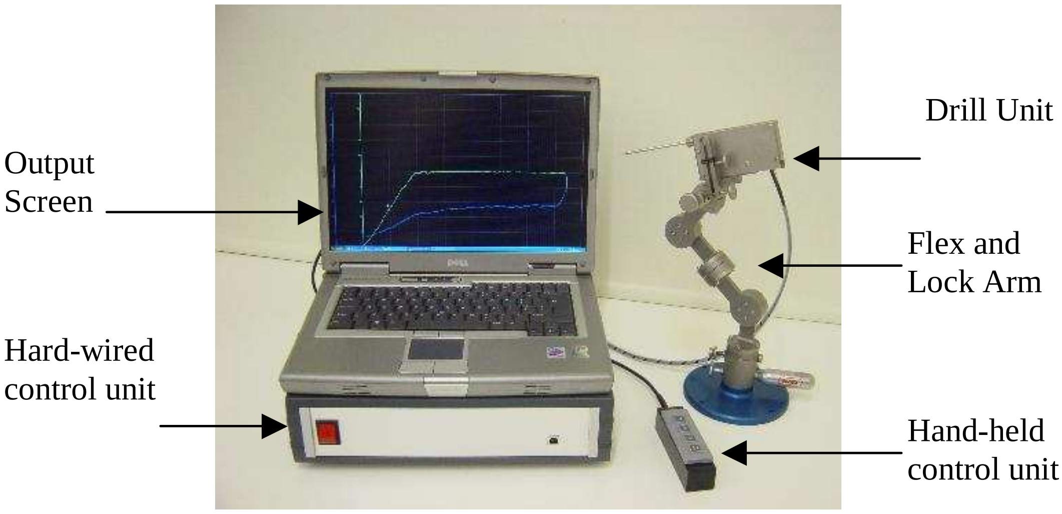

Fig. 4 The micro-drilling surgical robot system

The description of the mathematical model has previously been published [11, 12]. The results in figure 2 show the characteristics of drill bit feed force and torque plotted as a function of displacement. In this simulation feed rate is assumed constant.

The force and torque transients clearly show the key stages in the drilling process discussed previously. The point at which the hole depth is equal to the burr radius can be seen at position 2 (stage 2) at approximately 0.55 mm and is indicated by an observable change in gradient of the torque transient. The onset of breakthrough occurs at position 3 (stage 4) at approximately 1.35 mm resulting in the sharp increase and subsequent roll off of the force signal. The hole was completed at position 4 (stage 5) at approximately 1.40 mm, shown by the force and torque dropping to zero. If drilling is stopped instantly as the force and torque reach zero (position 4), the tip of the drill bit would have penetrated approximately 0.05 mm further beyond the far surface than is necessary to complete the hole due to compliance.

The start of breakthrough and its identification is the key to controlling completion of the drilling process. The start of breakthrough determines location of the far surface of the drilled material. This is an important reference point as the drill is otherwise advancing towards a position that is not known in terms of coordinates. Furthermore, it is breakthrough that presents the challenge in terms of controlling the drilling process and drill bit penetration up to the flexible tissue interface. In contrast, using conventional tools detection does not occur until breakthrough has taken place and the flexible tissue resumes its normal position with the tip of the drill bit positioned well into the next medium.

Experimental measurements have shown that the features in the force and torque data relating to the process of the drill bit breaking through are always present when drilling a stapes footplate [11]. The values and prominence of the peaks in force and torque vary according to the stiffness of the tissue, drill feed velocity and sharpness of the drill bit. The adopted detection process uses the coupled characteristics of the force transients to recognise states in the drilling process as different states. Using this information rather than data values the drill is able to recognise discriminate the important stages and behaviours of drilling associated with tissue interaction from other external disturbances. As breakthrough is approached the simultaneous character of the transients change with persistently increasing torque and persistently decreasing feed force. This ‘pattern’ is a unique and persistence feature of the breakthrough process.

2.3 Hardware setup

The drill point is interacting with flexible bone tissue. Sensory force and torque transients are interpreted to infer the movement of tissue and the patient, and the state of cutting conditions, drill bit and tissues. Using these states as information, the system is able to discriminate different tissue behaviour and, most important, to identify the tissue breakthrough process immediately before it occurs. To achieve precise results, the system automatically selects and implements control strategies based on this information.

Fig. 3 shows the principal functions of the drilling system. The drill unit comprises precision linear feed actuator, drill drive system and sensing elements. The controller consisted of a two tier hierarchy, a high level and a servo level controller. The high level controller responds to key stages of the drilling process by selecting pre-defined strategies based on the interpreted state of the drilling process. In particular, the high level controller searches for the characteristics in the sensory transients indicating the onset of breakthrough. In addition, factors such as tissue stiffness and cutting coefficients are evaluated to reflect how the system needs to respond on approach to breakthrough. Progress of the procedure is relayed to the clinician who is able to override the process. The servo controller controls the mechanical components of the drill. The servo controller is configured as a velocity servo from which position is determined by integration.

The control system and sensory functions operate in hardware. The computer is used to relay information to the surgeon on the state of the tool tip and tissue interaction. The drilling process is controlled through the hard-wired unit either by using the computer or by using the hand held remote unit.

3. Micro-Drilling In Practice

A micro-drill system has been constructed (Fig. 4) and comprises four units. The drill unit with precision linear feed actuator, drill drive system and sensing elements. The flex and lock arm incorporates fine and coarse adjustment. The hard-wired unit integrates sensing and control functions. The user interface is via the hand held remote unit and the computer display screen.

The controller implements drill feed and drill bit rotation in response to interaction between tissue and tool point and the state of the drilling process. Working under a surgical microscope, the drill unit is aligned by the surgeon in close proximity with the drilling site on the correct trajectory by using the flex arm, fine adjustment mechanism and the hand-held remote unit (Fig. 5 and 6). It is then locked in position. Automatic operation of the system is then triggered by using the hand-held remote unit.

Drilling feed is controlled at a constant rate, typically 0.5mm/min with the drill bit rotating at 10rev/s until a limiting force level is reached. Detection of the approach to the medial surface is by automatically identifying drilling force characteristics that occur simultaneously as this point is reached. Drilling then stops with the drill bit retracted such that feed force reduces to zero. Under this condition the drill tip is in contact with the base of the drilled aperture. The surgeon then chooses either to penetrate with minimum displacement to achieve a fully formed hole or to re-tract leaving the minimum thickness of bone tissue at the tool point. At any point the drill bit can be retracted for visual inspection and drilling can then recommence at the same point relative to the tissue.

4. Preparation for Research Clinical Trials

A series of clinical trials on porcine and cadaver specimen tested the system in tissues of similar properties to those of live patients and confirmed suitability of the configuration of the flex arm and micro-drill unit in a set-up similar to that of the operating room. Further preparation trials examined sterility, draping and protocol in use.

In the operating room, with the patient and equipment prepared the surgeon first creates the access to the middle ear. This is usually achieved through post aural incision followed by creation of a complete mastoidectomy and posterior tympanotomy, figure 5. The micro-drill is then assembled, figure 6.

The drill is aligned by the surgeon, working under the binocular microscope, and the support arm locked. The drilling trajectory is then confirmed and drilling commences. Figure 7 shows the micro-drill in use and controlled by the hand-held unit.. Upon completion the drill is removed, the cochleostomy inspected and debris removed.

The completed cochleostomy is shown in figure 8 and shows the intact endosteal membrane. The membrane is then opened gently using a scalpel and subsequently the electrode is inserted through a droplet of antiseptic gel.

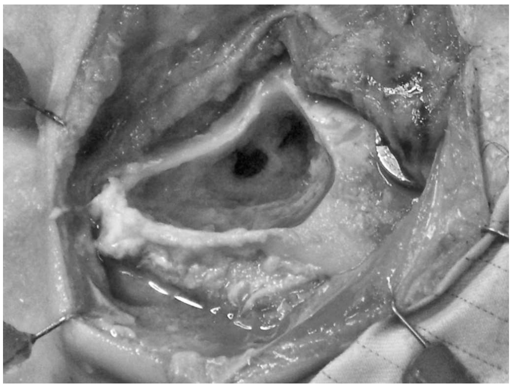

Fig. 5 Prepared access to the middle ear

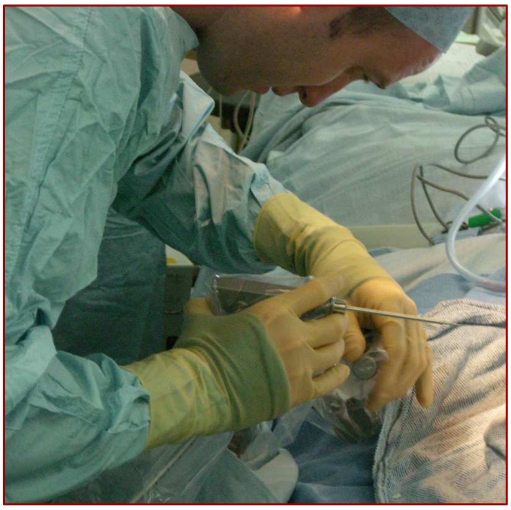

Fig. 6 Assembling the drill

Fig. 7 Controlling the drill using the hand-held unit.

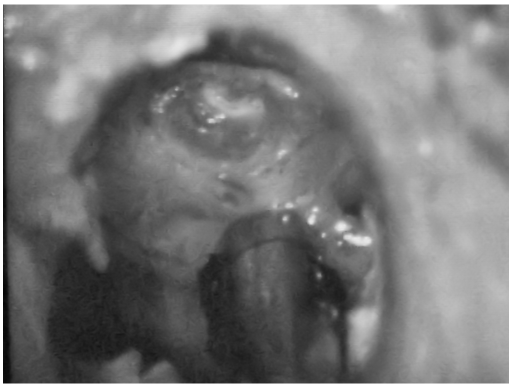

Fig. 8 The cochleostomy with the drill bit retracted and endosteal membrane intact

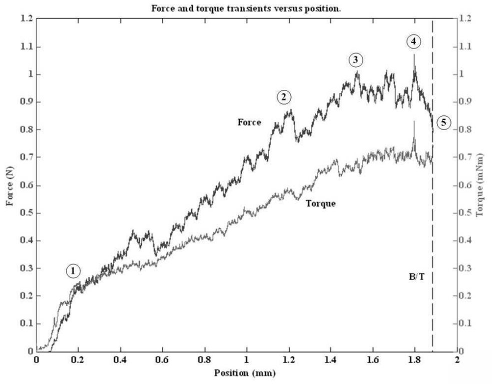

Fig. 9 Force and torque transients from a research clinical trial

Following insertion the procedure can be completed normally by closing the incision and testing the implanted device.

5. Force Transients in Theatre

Fig. 9 shows example force and torque transients from successful clinical trials. The total drilling time was approximately three minutes over a total displacement of 1.89 mm. Looking at the drilling transients the most striking feature is the prominence of fluctuations induced by patient respiration, heart beat and other disturbances at the operating table. These transients are superimposed on the base signal of the drilling force transients. The steep gradient at the beginning of the transient indicates that the initial cutting rate was low, and is due to low feed force. The burr beds in and the cutting rate increases at point 1 and normal drilling commences. The thickness of the bone tissue wall of the cochlea is insufficient for equilibrium drilling to occur so force transients are approximately linear between points 1 and 3. At point 3, movement of the patient results in the feed force reaching the pre-set force limitation threshold. This results in reduced linear feed rate to maintain the force at the threshold. At point 4 the system experiences an external disturbance which is detected and logged by the system. This was caused by a disturbance applied to the operating table. The onset of breakthrough is detected at point 5.

6. Conclusion

This paper has described the need for smart robotic tools to enable precise surgery in tissues. Future robotic surgery systems will need the capability to discriminate tissues and tissue behavior in order to operate relative to tissue position in real-time, and to feedback the description on the state of the process to surgeons. This is particularly relevant at the micro-scale and in procedures working through difficult access. Innovations in actuation and sensory technologies are needed to achieve these aims.

The sensory guided micro-drilling system described in this paper references the tool point to a deflecting tissue interface using information to discriminate the state of the drilling process derived from coupled drilling force transients. As a result it is able to work with the precision required to remove bone tissue material to leave an underlying delicate membrane intact. In the operating theatre the micro-drill has been used successfully to prepare cochleostomies and has shown benefit through consistent results, and in preserving sterility prior to the insertion of electrodes. A lower complication rate is expected. This is the first surgical robotic device to be deployed by a discriminatory approach to sensing. The approach could lead to the greater autonomy needed in future surgical tools as it enables the control of precise interaction between the tool-point and deflecting tissues.

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