Microtechnologies in Cochlear Implantation

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PhD philosophy

Hearing preservation cochlear implantation requires the placement of an electrode array into the cochlea whilst minimizing the trauma sustained during the procedure. Disturbances to the cochlea are intrinsic to the operative steps performed; however, they can be amplified by both human and technical factors. In this thesis I will assess human performance during operations, analyze the effect of drilling techniques on disturbances within the cochlea and suggest a robotic solution to minimize the trauma during cochleostomy formation.

General Introduction

Chapter 1

Introduction

Aims of Thesis

Hearing preservation cochlear implantation requires the insertion of an electrode array into the cochlea whilst minimizing the loss of hearing inherent in this process. The aim of this thesis is to assess the traumatic factors responsible for this hearing loss and propose potential solutions. Initially the performance of the surgeon will be analysed, and the effect of operating time on their tremor and fatigue. The disturbances within the cochlea caused by different steps of the cochlea implant procedure are then explored, with methods of minimizing trauma suggested. Finally, the use of an autonomous drilling robot, capable of controlling some of the key factors causing trauma is presented.

How the Ear Works

For man to perceive sound, sound waves from the external environment are converted into action potentials within the eighth cranial nerve (cochlear nerve), which stimulates the primary auditory cortex within the temporal lobe of the brain.

The pinna acts as a collecting system for sound, channelling it down the ear canal to the tympanic membrane (see figure 1). The middle ear, consisting of the tympanic membrane and ossicles, acts as a coupling device, converting movement of air molecules within the external canal, to movement of fluid within the cochlea. To achieve this, the middle ear acts as an impedance transformer, changing the incoming sound vibrations from the relatively large, low impedance tympanic membrane to the much smaller, higher impedance, oval window[1]. There are two components in the middle ear which make this possible:

- The tympanic membrane 18.75 times larger[2] than the oval window, increasing the pressure delivered to the oval window.
- The ossicles have a lever action, with the malleus being 2.1 times longer than the incus[3], again increasing pressure at the oval window.

These 2 factors work in synchrony to permit sound movement within air to be sufficiently amplified to create movement of fluid within the cochlea. If sound waves were directly incident on a cochlea membrane, the transfer of energy, and therefore sound, into the cochlea would be markedly reduced.

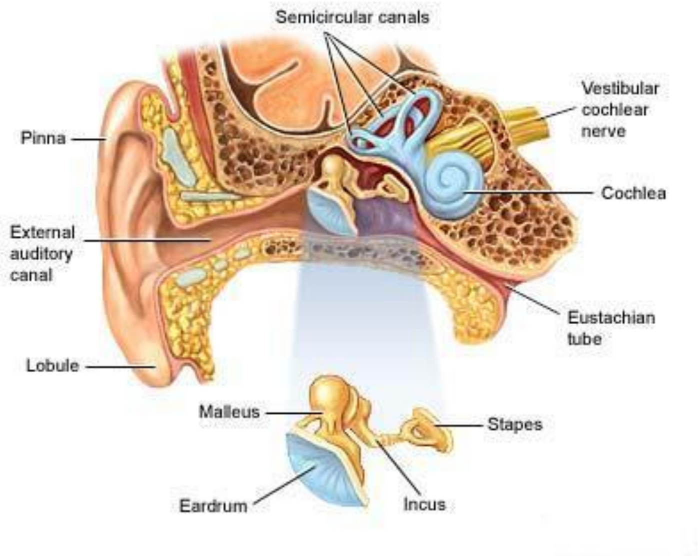

Figure 1: Diagram of gross ear-anatomy of the auditory system

The cochlea is a coiled spiral split into 3 fluid components, the scala tympani, scala media and scala vestibuli (see figure 1 & 2). The scala media sits between the scala tympani and vestibuli and is filled with endolymph, a potassium rich fluid created by the ionic pumps within the stria vascularis. Above and below the scala media lie the scala tympani and scala vestibuli; these are filled with a sodium rich, potassium replete fluid, similar to extracellular fluid. Sitting on the basilar membrane in the scala media is the organ of corti, containing the auditory receptor cells, hair cells, which are responsible for converting pressure waves within the cochlea into action potentials in the cochlear nerve.

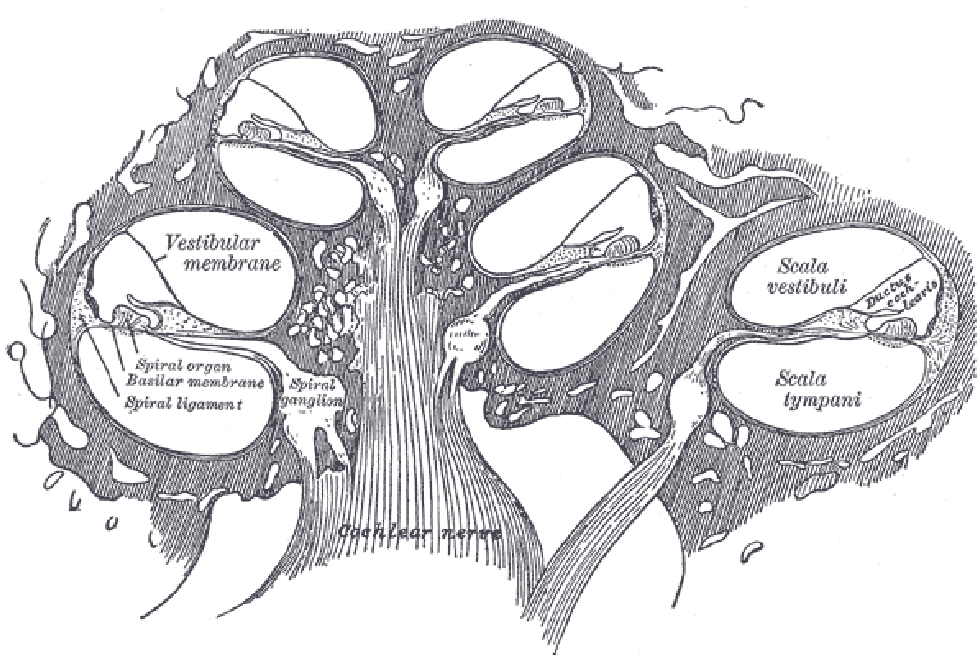

Figure 2: Cross sectional diagram of the cochlea, demonstrating the 3 scala (reproduced from Gray's Anatomy 1918)

The movement of the tympanic membrane in response to sound vibrates the ossicular chain, creating movement of the footplate of the stapes, which sits in the oval window, transmitting the vibration into the scala vestibuli. This creates a travelling wave within the cochlea[4], causing movement of fluid in all compartments and the dividing membranes. Movement of the basilar membrane creates shearing forces splaying apart the hair cells, causing an opening of ion channels and creating action potentials within the cochlea nerve (see figure 3). The action potentials are transmitted by the cochlea nerve to the auditory cortex.

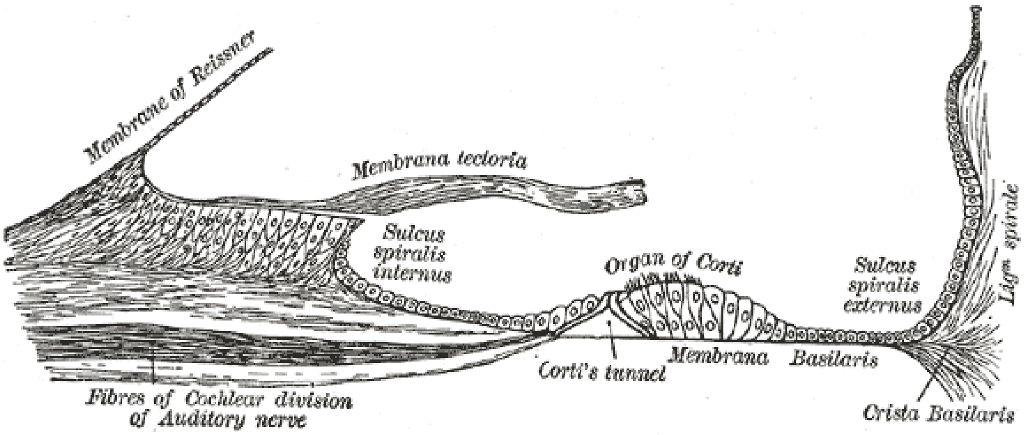

Figure 3: Magnified view of the basilar membrane (reproduced from Gray's Anatomy 1918)

The cochlea (Latin: snail) is spiral shaped and tonotopically arranged, with high frequency sounds detected at the base and low frequency sounds at the apex. The scala run throughout the length of the cochlea. The tonotopic arrangement of frequency recognition within the cochlea is achieved through changes in basilar membrane mass and stiffness. The stiffness of the membrane is maximum and lightest at the base with a gradual progressive change to least stiff and heaviest at the apex. Low frequency sounds therefore exert their greatest effect when the membrane is heaviest and least stiff, i.e. the apex of the cochlea, with high frequency sounds being best detected at the base where the membrane is most stiff and lightest.

History of Cochlear Implantation

Alessandro Volta was the first to discover that a perception of sound can be created by electrical stimulation of the auditory system. In 1800 he placed 2 metal rods into his ear canal and connected them to a 50 volt circuit, creating a sensation of "une rcousse dans la tete" (a boom within the head) followed by a sound similar to that of boiling, thick soup.[5]

The subsequent 150 years produced great interest in auditory nerve stimulation, although there was little success and even scepticism over whether electrical stimulation was achievable[5]. In 1957 Djourno and Eyries[6] presented the first human attempt at correcting a hearing loss by placing a single electrode near the auditory nerve. The patient was undergoing a revision mastoid procedure following a facial nerve palsy sustained during a recent operation to remove a cholesteatoma. An electrode was placed onto the auditory nerve and stimulation of this generated a high frequency sound "like a cricket". Remarkably, the patient developed limited recognition of common words, although the main use of the implant was as an aid to lip reading[5].

During the 1960s various researchers implanted single electrodes in patients[7,8]. House described approaching the auditory nerve via the scala tympani approach. Whilst his 2 test patients experienced successful implantation and electrical stimulation of hearing, they unfortunately needed to be explanted due to hardware problems. Both test subjects' experienced increasing amplification of sound as the voltage was increased[7].

The House 3M single electrode implant was introduced in 1972 following the addition of a speech processor to the electrode. The speech processor modulated the sound signal which was presented to the cochlea via the electrode. As single channel implants do not exploit the tonotopic arrangement of the cochlea, the frequencies stimulatable through a point site within the cochlea are limited, although some variability form 300-500Hz was possible. The lack of frequency resolution meant the implants were primarily an aid to lip reading although some speech recognition was possible.

In the early 1980s a single channel cochlear implant (CI) was designed at the Technical University of Vienna, Austria[9]. This implant differed from the House implant in that it preserved the analogue features of the sound signal and, without modulation, this signal was presented to the cochlea at a single point. This stimulation strategy enabled frequency resolution from 1,000Hz to 4,000Hz. In high performing users exceptional speech recognition scores of 86% were achievable[10], although most users did not achieve this level of success[11].

The late 1970s saw the introduction of multi channel electrodes[8]. These promised the ability to stimulate the cochlea at multiple points, and frequencies.

How a Cochlear Implant works

The vast majority of cases of severe to profound sensorineural hearing loss are caused by damage to the hair cells within the cochlea. Despite the production of a normal travelling wave, the hair cells do not create action potentials either because they are absent, damaged or malfunctioning. The cochlea nerve is invariably intact and working normally. A normal auditory nerve has 35,000 nerve fibres and it is thought that 10,000 of these are needed for speech recognition[12], however it is not known how may nerves fibres are needed for cochlear implantation to be successful. The aim of a cochlear implant is to bypass the damaged / absent hair cells and directly stimulate the auditory nerve in the appropriate location of the cochlea for the frequency of sound that is being delivered.

Cochlear implants are composed of 2 main components: external and internal (see figure 4).

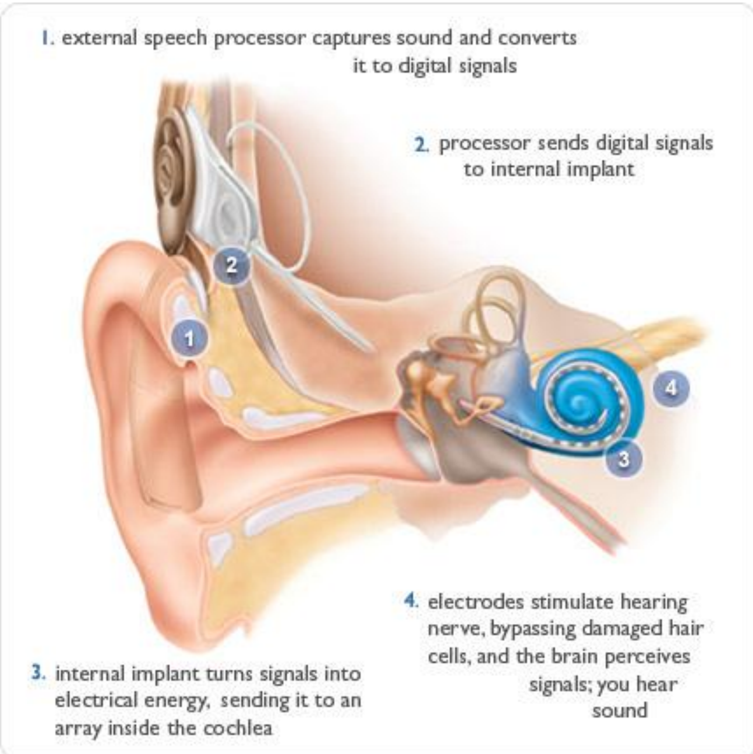

Figure 4: Components of a cochlear implant (reproduced with kind permission from Cochlear Europe Ltd)

The external component consists of a microphone, speech processor and transmitter coil. The microphone unit is hooked behind the ear and senses pressure variations within a sound field and converts this to an electrical variation[13]. Amplification of the signal is performed prior to undergoing speech processing, which selects the necessary components of the signal to be used by the different electrodes - this is known as the programme or map. These signals are sent to the transmitter coil, which is held on the scalp via a magnet in the implanted component creating a transcutaneous link to the internal component.

Once the processed signal arrives at the receiver coil, the internal electronics in the receiver package, direct the appropriate stimulus to the appropriate length electrode. The array of implanted electrodes are placed within the scala tympani of the cochlea, sitting just inferior to the organ of corti and, on activation directly stimulate the auditory nerve fibres. Three main manufacturers of cochlear implants have different numbers of electrodes in their arrays, ranging from 12-22 electrodes. Stimulation of the cochlea location appropriate to the frequency range of human hearing is then achieved by the different lengths of electrodes. The number of electrodes needed to maximize speech recognition remains under debate[14,15].

Operatively, the cochlear implant procedure can be broadly separated into three sections: (a) the approach; (b) the cochleostomy; and (c) the insertion of the electrode array. The approach is performed by drilling a cortical mastoidectomy followed by a posterior tympanotomy. A cortical mastoidectomy is an inverted truncated cone drilled into the mastoid bone. The mastoid bone is located immediately behind the ear and comprises numerous air cells, which are in continuity with the middle ear. It is bounded superiorly by the dura of the middle cranial fossa, inferiorly by the sigmoid sinus, anteriorly by the external auditory canal wall, and at the apex by the lateral semicircular canal (see figure 5). A posterior tympanotomy is a hole drilled from the mastoidectomy into the middle ear; it is approximately 4 mm in the superior-inferior direction and 2 mm medial to lateral. Medially lies the facial nerve, supplying the muscles of facial expression; laterally lies the chorda tympani (responsible for taste in the anterior two-thirds of the tongue) and the tympanic membrane. The objective of the cortical mastoid and posterior tympanotomy is to provide the surgeon with access to the middle ear to make a cochleostomy (a hole through the outer bony wall of the cochlea) and enable insertion of the electrode array into the cochlea. An electrode array can then be routed through the mastoid to the receiver, which is placed above and behind the ear.

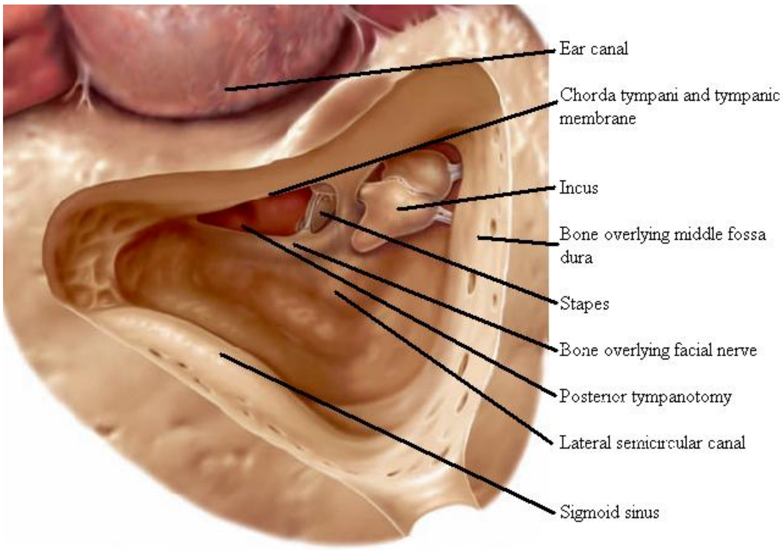

Figure 5: Cortical mastoidectomy and posterior tympanotomy in left ear (reproduced with kind permission from H. Hildmann, H. Sudhoff. Middle Ear Surgery, Springer-Verlag Berlin, Heidelberg, New York)

History of Hearing Preservation Cochlear Implantation (HPCI)

Whilst cochlear implantation is extremely successful in achieving the primary goal of improving speech perception in patients with severe to profound sensorineural hearing loss, the procedure is not without its limitations; hearing in background noise and enjoyment of music remain a challenge to the cochlear implantation community.

Analysis of the factors determining the success for both speech in quiet and noise reveals that frequency resolution is critical. Fishman[16] demonstrated that in a quiet background, top performing CI users only required 3-4 channels of stimulation for speech perception, but once background noise was added, their requirement greatly increased. Henry[17] compared the frequency resolution of cochlear implantees, patients with sensorineural hearing loss and normal hearing volunteers. The normal hearing listeners were found to have excellent frequency resolution of sound, patients with sensorineural hearing loss, and hence damage to hair cells, had moderate frequency resolution. However the implantee had very poor frequency resolution. This demonstrated that even when a patient has sensorineural hearing loss, acoustic reception of sound enables better frequency resolution, and hence better speech reception, than electrically stimulated hearing. Rubenstein[18] determined that residual hearing post implantation is one of the few variables that predict the success of the implantation in terms of speech perception results.

These studies support the concept that if residual hearing is present, then its preservation would lead to a better functional result for the implant recipient. Von Ilberg et al in 1999 was the first to demonstrate that simultaneous ipsilateral hearing aid and cochlear implant for patients with severe hightone hearing loss and preserved residual hearing in the low frequencies post implantation, resulted in a significant increase in speech understanding, compared with a cochlear implant or hearing aid alone[19].

This presents surgeons with a problem: how do you insert an electrode array into the cochlea, whilst maintaining its normal function, when during routine cochlear implantation, a patients' residual hearing is invariably destroyed. The challenge to preserve (or at least not destroy) residual hearing, whilst inserting a cochlear implant begins with determining the factors that cause hearing loss during implantation.

The cochlea sustains trauma during all the steps of the implantation procedure. Accessing the middle ear and preparing the implant bed will subject the cochlea to a combination of noise induced trauma from drill noise and the cochlea will further sustain a mechanical/vibrational trauma during this process which may lead to hair cell loss. Zou demonstrated that a temporary threshold shift, measured by ECoG, was inducible in guinea pigs by applying vibrations to the external canal[20]. Performing a bony cochleostomy will again subject the cochlea to noise and vibrational trauma, protrusion of a running burr into the scala tympani will lead to pressure shifts within the cochlea and inadvertent protrusion of the burr may directly damage the basilar membrane. Suction of perilymph has been shown to be associated with further sensorineural hearing loss (SNHL) [21]. Insertion of the electrode may cause trauma either by pressure fluctuations within the scala tympani during introduction of the electrode array into a closed system, or more likely by damage to the spiral ligament or penetration of the basilar membrane even if the electrode originally passed into the scala tympani, or the electrode may be directly passed into the scala vestibuli[22]. Insertional trauma can lead to new bone formation and fibrosis within scala tympani[23].

Current strategies used to preserve hearing during cochlear implantation

With these challenges in mind, Lehnhardt proposed the concept of soft surgery to minimize the trauma sustained to the cochlea during implantation[24]. This entails performing a cochleostomy with a slow turning burr (<10,000 revs/min), to reduce the acoustic trauma, and preserving the endosteal membrane of the scala tympani. Preservation of the endosteal membrane stops the scala tympani from sustaining pressure surges caused by a rotating drill within it, secondarily; it prevents contamination of the perilymph with bone dust, and finally stops inadvertent damage of the basilar membrane by the drill. The endosteal membrane would then be opened with a knife prior to electrode insertion. Despite there being no accepted drill speed for performing a cochleostomy it is assumed that the acoustic trauma decreases as the burr speed decreases.

Residual hearing in severe to profoundly deafened patients is invariably in the low frequencies – reflecting the cause, presbyacusis. These patients may have normal, or near normal thresholds in the low frequencies, but severe to profound hearing losses in the high frequencies. As the site of high frequency hearing reception is in the base of cochlea, Gantz introduced the concept of a short electrode, inserting a 10mm electrode (as opposed to the normal 25mm length) into the cochlea and electrically stimulating high frequency hearing, whilst the low frequencies are stimulated by acoustic means.

Rebscher demonstrated that the scala tympani tapers in cross sectional area from the base towards the apex, and varies in size in different individuals[26], as the scala decreases in size the risk the electrode traumatizing the basilar membrane or the stria vasacularis increases, putting residual hearing at risk. Use of a short electrode has led to excellent rates of hearing preservation, 100% in Gantz series of 21 patients with an average low frequency loss of 9dB[25]. Whilst a short electrode can successfully rehabilitate patients with very good hearing in the low frequencies, the majority of patients have moderate to severe hearing losses in the low frequencies with severe to profound hearing loss in the high frequencies. These patients are likely to require a longer electrode than Gantz's 10mm. Ideally, a full length electrode would be inserted, whilst maintaining the low frequency residual hearing.

There is no current evidence to suggest which factors predominate as the cause of loss of residual hearing, although it is likely that they all are involved to varying degrees. Soft surgery and inserting a full length cochlear implant has been utilised with some success in preserving residual hearing, however currently hearing preservation is achieved in only 60%-90% of patients[27,28]. The term ‘preservation of residual hearing’ appears to encompass a wide array of entities ranging from preservation within 15dB of preoperative level[25] to hearing that is serviceable by an acoustic aid (regardless of hearing level)[27]. Within the group of the patients who have successful preservation of hearing, some undergo a 0-5dB change in thresholds[29], whilst others sustain a 40dB drop[30]. The cause of loss of residual hearing, and maybe the discrepancies between ‘successful preservation’ results, is thought to be due to an inability to perform the soft surgery technique correctly – i.e. accidental protrusion of the drill through the endosteal membrane into the scala tympani[31], or diameter, stiffness, and length of standard intracochlea electrodes may induce substantial intracochlea damage to the basilar membrane and cochlear hair cells as they advance around the upper basilar turn during insertion[25].

Ideally patients undergoing HPCI would have all their residual hearing preserved, despite insertion of a full length electrode, maximizing their post operative result. This situation is not currently achievable, although it is hoped that mechanising key steps of the implant procedure may permit the surgeon to operate beyond the capabilities of humans and minimize the trauma during implantation.

The history of robotic surgery and implications in otology

The word Robot is derived from the Czech noun "robota" meaning "forced labour" and was first used in Karel Capek’s play *Rossum’s Universal Robots* in 1920. Initially robots were used to perform monotonous tasks in production lines. Compared to humans they could perform these faster, more accurately and without tiring. Robots have since evolved into complex entities that, although unintelligent, can perform highly specialized tasks – collecting dust from the surface of mars, producing microchips etc.

Surgical robots can be split into 2 broad categories, active and passive. An active robot is capable of performing a fully automated step of a procedure independent of the surgeon. The use of this category of robot is generally to work beyond the boundaries of human perception, usually in an attempt to create a more accurate result that a surgeon is capable of. Passive robots operate under the complete control of the surgeon, perform no independent movements, and work in a master-slave fashion. They are more commonly called telemanipulators.

Telemanipulators able to perform complete operations, such as the Da Vinci® robot, were initially the concept of the US army. 90% of combat deaths occur on the battlefield prior extraction of the injured soldier to hospital, with haemorrhage from injuries to extremities accounting for the majority of the salvageable mortal wounds[32]. The US army hoped to invent a robot that could operate on injured patients in the field whilst the surgeon was in the safety of a remote location.

Figure 6: Da Vinci Robot (c)2010 Intuitive Surgical, Inc

Telemanipulators can perform no automated tasks and are fully reliant on the surgeon in a master/slave relationship. This technology was initially used for open operations but it was soon realized that the true benefit of a telemanipulator was to overcome some of the fundamental limitations of laparoscopic surgery, these technical shortcomings could be eliminated by electronically controlling and articulating the tip of the instrument, thus improving range of motion and dexterity. The Da Vinci® surgical system, designed by the Intuitive Surgical company, consists of a surgeons console and a patient side cart, containing the robotic arms and binocular vision system (see figure 6). Once the binocular vision arm and operative, endowrist®, arms have been introduced into the patient through ports, the surgeon sits at the console and is presented with a 3 dimensional image of the inside of the cavity he is operating on. The surgeon perceives the abdominal or thoracic walls as surrounding him. He is inside the patient. The surgeon's arms are placed on arm rests with his hands acting as the tips of the instruments. The endowrist® tool attached to the operating arm allows the surgeon to move the tip almost as freely as if his hand was inside the body cavity. Foot pedals are used for electrocautery, ultrasonic instruments activation, adjustment of focal point of the camera, toggle between robotic arms and clutch to move the machine.

Telemanipulator robotics first impacted on medicine after the invention of the laparoscope. The first laparoscopic cholecystectomy was performed in 1985[33] and since then many abdominal, thoracic, cardiac, orthopaedic, urological, ENT and plastics procedures have been performed using minimal invasive surgery. Endoscopic minimal invasive surgery allows a smaller incision, better cosmesis and faster recovery time for the patient[33]. However, it necessitates surgeons working from a 2 dimensional screen, without the flexibility or touch sensation of the human hand, natural tremor is amplified by the fulcrum effect of the ports, which also lead to reduced hand eye co-ordination.

The advantages of these machines are that the surgeon has a far greater view of the inside of the body cavity in which he/she is working. The Endowrist® appliances have 6 degrees of freedom, compared to 7 for the human hand and 4 for conventional laparoscopic tools, enabling the surgeon to have greater control over the tools than in conventional laparoscopy. The console is usually in the theatre but can be a long distance away. A Zeus robot telemanipulator, a similar design of robot to the Da Vinci® system and subsequently taken over by Intuitive Surgical, was used to perform a laparoscopic cholecystectomy in France with the surgeon in the console in New York[34]. Integrated computer software can permit the reduction of surgical tremor alter motion scaling. Motion scaling can be set so the surgical instrument moves only a proportion of the surgeons hand movement, thus, improving precision. The disadvantage is the lack of haptic feedback and the machine is very large and very expensive.

Active robots are machines that are capable of performing a fully automated procedure or step of an operation, without external input from the surgeon. The first example of this category of robot was PROBOT in 1988. Designed by Davies et al, to perform a transurethral resection of the prostate based on a surgeon predetermined volume of prostate to be resected[35]. In 1992 ROBODOC Surgical Assistant System was created for use in patients requiring primary cementless total hip replacement surgery[36]. It was hypothesized that greater accuracy in reaming out the femur would lead to an improved fit of prosthesis and therefore a superior clinical result. To achieve this, the patient had 3 titanium pins implanted into the femur, prior to undergoing a CT scan. Manipulation of the scan data allowed the surgeon to determine the ideal placement of the prosthesis, this location relative to the implanted pins could then be calculated. These data from the pre-operative planning process are then transferred to the ROBODOC Surgical Assistant which consists of a robotic arm with a distal high-speed milling burr. After incision, exposure and removal of the femoral head, and fixation of the femur, the device mills the femoral canal to create a cavity of the appropriate size and shape for the selected femoral prosthesis. This device offers the surgeon a method of ensuring an accurate reaming of the femoral component of a hip replacement, and obviates the need for the surgeon to guess the correct size, and angle of the stem. In initial trials the Robodoc was found to have 96% accuracy in contrast with 75% accuracy when a conventional hand broach was used, resulting in a better prosthesis fit and contact[37].

The challenge when using robotics in otology is related to the size of the operative field and the accuracy needed for a successful result. Telemanipulators are currently too large to be useful in mastoid surgery, and still rely on vision to predict the limits of resection. Image based robotic solutions rely on the resolution of scanning technology. Whilst accuracy in millimetres is acceptable in joint replacement operations, it is not sufficiently accurate for otological procedures. A cochleostomy is typically 1mm deep, and preserving the endosteal membrane (0.1mm thick) is not possible image based systems. The ideal otological robot would be able to sense its own way through bone and be able to stop on bone – soft tissue interfaces, without relying on the surgeons vision.

Robots used in ENT

The great benefit of minimal access surgery is to decrease the morbidity associated with accessing the operative site. Whilst this makes a large impact in abdominal procedures, its effect in ENT is significantly reduced. Accessing the ear leads to minimal morbidity, however avoiding incisions on the neck does confer a cosmetic advantage. Telemanipulators, therefore, are finding an increasing role in soft tissue operations in head and neck surgery. Oral, laryngeal and para-pharyngeal space lesions have been removed with the Da Vinci® robot[38,39,40]. Thyroidectomy[41] utilising a far lateral, or axillary approach to the neck, avoiding the need to place scars in a central location has been described.

Telemanipulators have yet to prove useful in otology due both to the lack of problem with access and the need for the surgeon to ‘feel’ the forces being used on critical structures. Telemanipulators are extremely expensive to purchase and run, necessitating a substantial advantage from its use to make it commercially worthwhile.

Robots have been used in the otological field. Federspil designed a fully automated robot capable of performing a cortical mastoidectomy[42]. A force torque sensor was placed between the end of the robotic arm and the coupling device for the burr. They used a force sensing programme to ensure only bone was drilled and soft tissue structures preserved. The robot was registered to the specimen by defining 3 points in space at which the robot was positioned. The force was measured throughout the programmed drilling activity and the force decreased to 0N when the drill came into contact with the dura. This enabled the drilling to be stopped before dural penetration. This process has been used on cadaveric temporal bones and further work is underway.

There has been increasing interest in the use of a device during cochlear implantation both to drill the path to the middle ear and to insert a cochlear implant electrode array. These systems are currently being used in temporal bone studies and show promising results[43,44].

It seems that large commercial robotic systems capable of procedures in many fields are not likely to prove useful in otology, their size, lack of haptic feedback and cost will likely preclude their use. However, small, cheap, custom made robots able to perform a set task where accuracy beyond human capabilities is required, may well enable surgeons to improve their patients operative results.

Conclusion

Preservation of residual hearing during cochlear implantation produces an improved clinical result for selected recipients. The surgical challenge is to preserve hearing during the implant procedure. HPCI appears possible if attempts are made to reduce the operative trauma. The variability in clinical results from HPCI indicates not only the complexity of performing this procedure, but also the lack of knowledge of the cause of hearing loss.

This thesis will assess key factors involved in the implantation procedure. An analysis of both human operative performance and the effect of operative technique on critical steps of the implantation procedure are made. We hypothesize that the required accuracy to minimize surgical trauma will require operating beyond the limits of human perception and ability. If this is the case, then a novel robotic solution is required.

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Human frailties and its relevance

Chapter 2

Introduction to chapter 2

Chapter 2 will analyze the effect of operating on surgical performance. If the goal of minimizing trauma sustained by the cochlea is to be achieved, then optimal surgical performance is required. The 3 papers presented determine the effect of operating time on both tremor and fatigue of the operating surgeon, and assess the impact of resting the surgeons' wrist on hand tremor. As the critical part of many operations, and in particular cochlear implantation, takes place at the end of the procedure, then it is necessary to ensure the best possible performance at this time. If surgical performance is reduced, then surgical aids may alleviate some of these problems, or mechanisation of the task may be required to produce an optimal outcome.

The effect of operating time on surgeon's hand tremor

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Chapter 2.1

Abstract

Objectives:

To determine if operating has an effect on a surgeon's baseline tremor.

Design:

Prospective study.

Setting:

2 tertiary referral centers in the West Midlands.

Participants:

10 Head and Neck surgery consultants, 2 ENT registrars, 19 normal controls

Interventions:

Preoperative and post operative tremor measurements for surgeons and pre and post days' desk work for controls.

Main outcomes measures:

Percentage change in tremor.

Results:

No difference in baseline tremor between consultants and registrars. Operating led to an increase in hand tremor in all subjects. Tremor increases in all subjects directly proportional to the length of time spent operating. Operating compared to a normal days desk work increases tremor by a factor of 8.4.

Conclusions:

Surgeons should be aware that their tremor will increase as an operation progresses. More complex parts should be performed as early in the day as possible, or, in the case of a very long operation, a change in surgeons may occasionally be necessary.

Introduction

The outcome of a surgical procedure is influenced by many factors; the most important of which is surgical decision making. However, once a decision has been made the performance of the surgeon comes into play. One factor that could have a potentially detrimental impact on a surgeon's performance is their hand tremor. An increase in tremor will reduce the precision of the surgeons hand movement.

Tremor is a manifestation of the rhythmic involuntary movements resulting from regular oscillatory contractions of corresponding agonistic and antagonistic muscles[1]. Tremor experienced during a surgical procedure can be divided into postural, isometric, and physiologic components[2]. Postural tremor refers to the tremor exhibited by an individual attempting to maintain a body part's position against the effects of gravity. Isometric tremor refers to the tremor induced by muscle contractions against stationary objects. Physiologic tremor refers to a high frequency, low amplitude postural tremor that all normal persons exhibit. There are numerous factors which have been studied and that are thought to affect tremor such as caffeine, fasting, and fatigue through physical and mental activity[3-5]. This paper will examine the development of tremor induced from fatigue caused by operating.

The normal operating day may involve one long operation or many short procedures. These can have differing levels of complexity requiring differing degrees of accuracy. Throughout a day of surgery, a surgeon's tremor can play an important role when completing several difficult tasks, such as performing a vascularized reconstruction after a cancer resection. These tasks tend to be performed at the end of a long surgery and require the surgeon's utmost precision. The same can be said for multiple short surgeries performed throughout the same day. The repetitive and stressful natures of the physically challenging conditions the surgeons are exposed to, can potentially affect the accuracy of the procedure. Many of the shorter operations require a high degree of accuracy to achieve a successful result. For example a stapedectomy requires the creation of a 0.6mm stapedotomy through which is 0.4mm piston is inserted[6]. Excessive hand tremor would therefore decrease the surgeon's accuracy and potentially the outcome of the operation.

Our aim is to try to determine whether or not a surgeon's hand tremor increases, decreases, or remains the same throughout a day of surgery.

Methods

Twelve healthy surgeons, ten male consultants, one male registrar, and one female registrar volunteered to participate in the surgical arm of the study. Nineteen non-surgical measurements were taken during the control arm of the study. The surgeon's ages varied between 31 and 62, with a mean age of 42.17. The non-surgeon's ages varied between 27 and 35, with a mean age of 34.16. All surgeons were right handed, however one of the non-surgical volunteers was left handed. The surgical arm of the study consisted of acquiring tremor measurements before and after performing an operation. The length of the operations varied from one hour to 10 hours as shown in Table 1. The control arm of the study consisted of acquiring tremor measurements before and after several hours of routine desk work.

The tremor measurements were acquired using two triaxial Delatron piezoelectric accelerometers (Bruel and Kjaer Type 4524) as shown in (Fig. 1a). These were attached to a mounting mechanism, which was then attached to the back of the dominant hand with some elastic bands. Two accelerometers were chosen so that the data from them could be averaged and a more accurate tremor measurement achieved. The mounting mechanism was manufactured from DSM 1770 plastic using a rapid prototype machine, and was positioned on the hand in such a way as to not impede the grip of the volunteers. This allowed for tremor measurements to be acquired directly above the hand. The first accelerometer had sensitivities of 95.72 mV/g in the X direction, 98.18 mV/g in the Y, and 95.26 mV/g in the Z (g – acceleration of gravity). The second accelerometer had sensitivities of 97.92 mV/g in the X direction, 100.7 mV/g in the Y, and 97.72 mV/g in the Z. The accelerometers were attached to an Endevco Isotron power supply (Model 2793). The signals from the signal conditioning unit were in turn attached to a Delsys Inc. Universal Input Unit, and finally to National instruments Data Acquisition card (DAQCard 6036E). The acquisition software used was the Delsys EMGWorks Acquisition 3.1.0.5. The data was acquired at a sampling rate of 1 kHz and 16-bit precision.

Table 1: Surgery description and length

Surgeon	Surgery Description	Length (hrs)
#1	• Panendoscopy • Excision biopsy (right brachial cyst)	2
#2	• Tracheostomy • Left selective neck dissection • Mandibulotomy • Resection of tumor left tonsil • Left palate reconstruction with radial forearm flap • Abdominal skin graft	8
#3	• Left modified radical neck dissection	3
#4	• Excision left submandibular gland	1
#5	• Left mastoid obliteration • Bone anchor hearing aid	4
#6	• Right combined approach tympanoplasty (stage 2)	3.5
#7	• Tracheostomy • Left selective neck dissection • Mandibulotomy • Resection of tumor left tonsil • Left palate reconstruction with radial forearm flap	10
#8	• Tracheostomy • Left selective neck dissection • Mandibulotomy • Resection of tumor left tonsil	3.5
#9	• Tracheostomy • Left selective neck dissection • Mandibulotomy • Resection of tumor left tonsil	4.5
#10	• Cochlear implantation	3
#11	• Tracheostomy • Left selective neck dissection • Mandibulotomy • Resection of tumor left tonsil • Left palate reconstruction with radial forearm flap	7
#12	• Tracheostomy • Left selective neck dissection • Mandibulotomy • Resection of tumor left tonsil • Left palate reconstruction with radial forearm flap	7

Each of the tremor readings were measured over a period of 60 seconds. The volunteers were asked to perform a standing, dominant handed, micro-manipulation task by holding a 2 mm diameter pin between tweezers and attempting to hold it steady within a 4 mm diameter hole as shown in (Fig. 1b). Most surgical instruments are stabilized in the hand. The tremor exhibited at the instrument tip is related to the length of the instrument and will be proportional to the hand tremor. We have therefore used hand tremor as a measure of instrument tip tremor. The volunteers were also asked not to rest their arms at any time during the readings and remain standing.

A baseline measurement was taken for each of the volunteers at the beginning of the day. The surgical operations were all different lengths as shown in Table 1. Tremor readings were conducted before and after each of the operations. The non-surgical volunteer's tremor measurements were taken on separate working days at a variety of times.

The raw piezoelectric accelerometer signals were first detrended by using an empirical mode decomposition method, which removed the lowest mode, or the trend from the signal. The new signal was then integrated to give the velocity, detrended again, and finally integrated one last time to provide the position. Once the positions were obtained for all three directions from each of the accelerometers, the maximum amplitude's direction was obtained using Singular Value Decomposition (SVD). The maximum amplitude of the tremor was determined by projecting all tremor positions onto an orthonormal line and measuring it's length. This method was duplicated for each of the accelerometers, and the mean of these amplitudes was used as the volunteer's tremor.

Figure 1: Accelerometer Placement and demonstration of micro-manipulation task of holding within a 4 mm hold a 2mm pin grasped between tweezers. The surgeons were asked to remain standing during this operation.

Statistical comparisons were performed on the tremor data from all of the volunteers. All statistical and other analysis were performed using the Matlab

R2006a Statistical and Frequency Analysis Toolboxes. Any significant differences were defined at ($p > 0.05$).

Results

There was no statistically significant difference between the pre-operative tremor level of the consultants (#1, #2, #3, #4, #7, #8, #9, #10, #11 and #12) and registrars (#5 and #6), (ANOVA, $p = 0.982$). Figure 2 demonstrates the pre and post-operative tremor readings from the specified surgeons in Table 1.

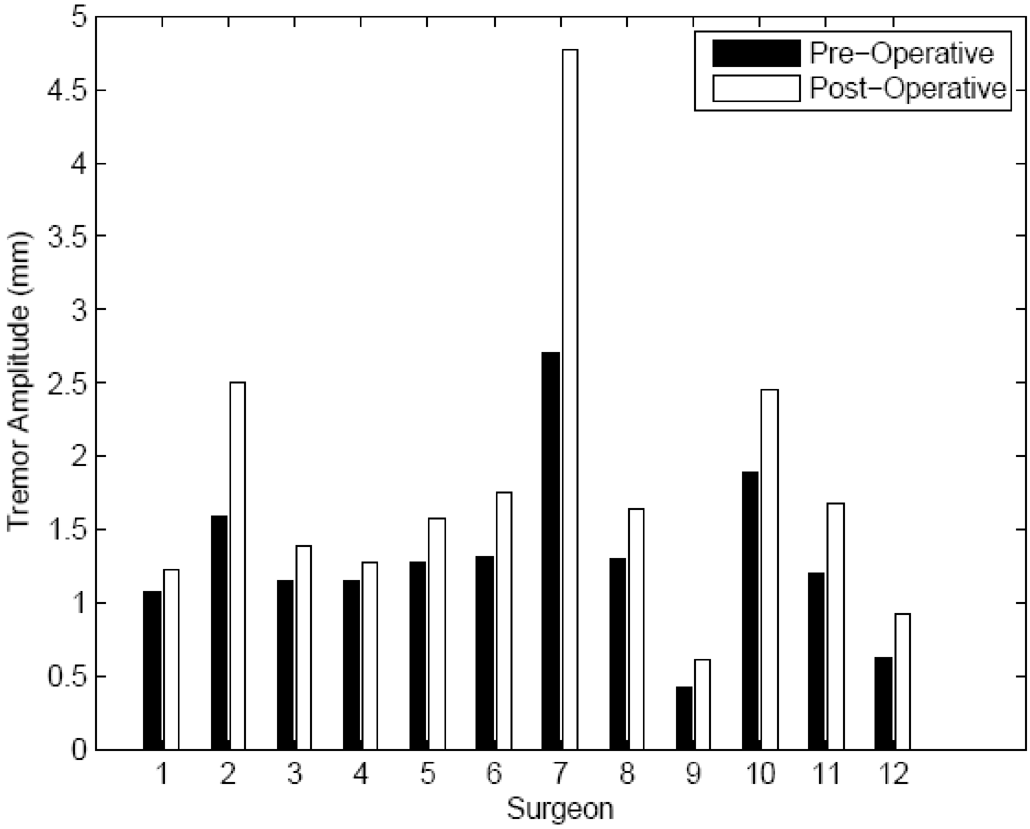

Figure 2: Pre and post-operative tremor readings from each of the surgeons.

The results from the surgical tremor readings indicate an increase over the length of an operation at a rate of 0.111% per minute (Fig 2). Irrespective of experience level, there is a tremor increase in all surgical cases, with surgeons #1, #3, #4, #5, #6, #8, #9, #11 and #12 being the lowest, and surgeons #2, #7 and #10 being the highest. The large variations between the tremors for the latter are indicative of the length of the operations. By examining the percent change of the tremor versus the length of the operations, we notice that increase in tremor is irrespective of the surgeon (Figure 3). A linear regression with confidence bounds of 95% has been fitted to the data. It demonstrates the constant tremor increase based on the length of the operation and that it would be possible to predict the change in tremor during an operation given a baseline measurement. It also demonstrates that for every hour of operating, there is a 6.67% increase in tremor.

In the control arm of the study, the volunteers tremor increased throughout the day, although only fractionally (0.0133% per minute). A linear regression with confidence bounds of 95% has also been fitted to the data.

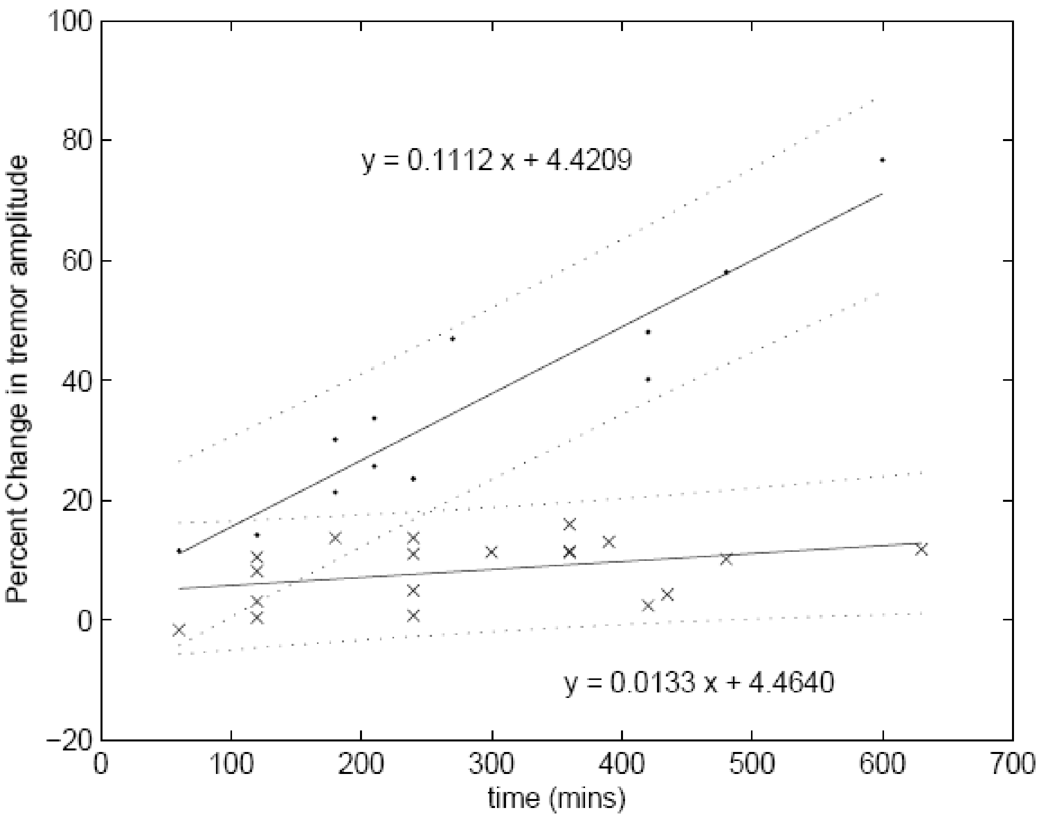

Figure 3: Percent tremor increase from baseline based on the length of operation and normal working day conditions. Points indicate the percent increase of the surgical tremor, the solid line is the fitted linear regression to the data, and the dashed lines indicate the 95% confidence interval for the fitted data. Crosses indicate the percent increase of the non-operating daily tremor, the solid line is the fitted linear regression to the data, and the dashed lines indicate the 95% confidence interval for the fitted data.

Discussion

The purpose of this investigation was to quantify surgeon's tremor amplitudes, their level of expertise, and to assess their tremor amplitude changes after performing an operation. This has been compared to the change in tremor throughout a day's desk work of healthy control subjects. Similar to related research, the collection of data was limited to a small number of participants[7].

Comparison with other studies

Past studies have examined tremor during goal directed pointing of a laser[8]. Others have assessed patients' clinical response to Amitriptyline[7], as well as physiologic tremor in adults[9], and age related tremors[10]. Numerous studies have also examined the effects of exercise related tasks on tremor. These included Viitasalo's[11] who compared forearm tremor amplitude and frequency characteristics during different types of loading scenarios, and Morrison[12] who studied the effects of fatiguing wrist extensor muscles on postural tremor. Both these studies demonstrated an increase in tremor after fatiguing by specific exercises. The effect of fatigue during an operative day has yet to be studied.

For the most part, measurement of these tremors has included the use of accelerometers[9-12]. Although opto-electronic motion capture systems have also been shown to be able to quantify accurate hand positioning[13], and could be used produce the same results, these systems are too difficult to integrate into surgery. The triaxial piezoelectric accelerometers are ideal for surgical implementation as they can be easily attached to the hand, and their signal can be integrated to provide a global positioning. They have not been used for the analysis of hand tremor developed throughout the day due to fatigue, and have been chosen as the method of tremor measurement for this study.

Clinical applicability

This study focused on the development of tremor as well as the level of expertise of the surgeon, over the length of various operations.

We demonstrated that there was no statistical difference between the pre operative hand tremor between the consultants and registrars. This suggests that hand tremor is not 'improved' with practice and it is likely that all people have an intrinsic level of tremor, over which they have little control. More interestingly, the percentage change in tremor caused by operating was not significantly different between the trainees and consultants. We would have assumed that as the operations reached a stage of complexity which the trainee had encountered infrequently, their tremor would have increased much more than a consultant who is likely to have performed the operation many times before. This unexpected result may be due to the fact that the consultant took over for the complex part of the operation for both trainees, leading to the trainee not experiencing any additional mental fatigue that could have increased their tremor.

Looking at the overall change in tremor over a day, and taking the controls initially, we demonstrated that there is a gradual, although very small, increase in hand tremor throughout the day, even when not performing physically or mentally demanding tasks. When this is compared to the change in hand tremor induced by operating, the difference is stark. Operating as opposed to performing routine desk work leads to an increase in tremor by a factor of 8.4. The increase in operative tremor is likely to be due to combination of the additional physical and mental fatigue induced by operating. However, it is very difficult to assess which of these two components is responsible for the increase in tremor.

The amplitude of hand tremor is only small even after many hours operating (1.305 ± 0.581 mm pre-operative, 1.818 ±1.078 mm post-operative). However, when a surgeon is holding an instrument, the tremor at the tip will be proportionally greater than the hand tremor, depending on the instrument's length. Therefore the effects of the hand tremor will have a more pronounced effect on accuracy.

These results confirm the hypotheses that there is an increase in tremor caused by operating. This is unlikely to affect the outcome of the majority of operations. However, if a particularly exacting step is needed towards the end of a long operation, the surgeon should be aware their tremor will be greater than their baseline tremor and may make this step more difficult.

Conclusions

There is no difference in the pre operative hand tremor of registrars compared to consultants. There is an increase in hand tremor, induced by operating of 0.111% per minute (6.67%per hour), Surgeons should be aware that their tremor will increase as an operation progresses. More complex parts of an operation should be performed as early as possible, or, in the case of very long operation, a change in surgeons may be necessary.

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The effect of operating time on surgeons' muscular fatigue

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Chapter 2.2

Abstract

Introduction:

A study was completed to determine if operating has an effect on a surgeon's muscular fatigue.

Materials and Methods:

6 Head and Neck surgery consultants, 2 ENT registrars, 20 normal controls from 2 tertiary referral centers in the West Midlands participated in the study. Electomyography (EMG) measurements were taken throughout a day of operating and fatigue indices were compared to controls performing desk work.

Results:

The percent change in mean frequency of muscular contractions were examined and found that there is no significant difference between fatigue level between consultants and registrars. Operating led to an increase in fatigue in all subjects, compared to no increase in controls performing desk work. It was also found that the brachioradialis muscle is used more than the mid deltoid muscle and hence fatigues at a faster rate.

Conclusions:

Surgeons should be aware that their muscular fatigue levels will increase as an operation progresses, therefore, if possible, more complex parts of the operation should be performed as early as possible, or, in the case of very long operation, a change in surgeons may be necessary.

Introduction

Surgical decision making is the most important factor determining operative success. However, once a decision has been made the performance of the surgeon comes into play. Similar to any job or task[1], it is believed that mental and muscular fatigue is developed during a day of operating. It is likely that an increase in arm fatigue causes an increase in hand tremor. This leads to a reduction in the surgeon's fine motor control, and hence a reduced precision of the surgeons hand movement. Muscular fatigue manifests itself during and after prolonged voluntary muscular contractions; the level of which can lead to higher or lower endurance times[2]. It has been described in some respects as the point by which a specific muscle can no longer sustain a contraction. This can be misleading in practice, as this defines fatigue as a specific point, where fatigue is in fact a development stage[1].

Fatigue is a very subjective term and therefore difficult to quantify. The preferred way to quantify a fatigue trend is to examine the shift in frequencies from captured Electromyographic (EMG) signals[3]. Numerous studies have demonstrated that as an individual fatigues, during a sustained isometric contraction, the Mean Frequency (MF) of these contractions decreases[4-6]. This is due the muscle being unable to sustain the high levels of contractions (high frequencies) as it fatigues. We can therefore relate an increase in fatigue with a decrease in the MF of the muscular contractions.

Our aim is to try to determine whether or not a surgeon's fatigue level does in fact increase, decrease, or remain the same throughout a day of surgery, compared to controls performing desk work. If the fatigue level increases during the day, then perhaps another surgeon should perform the more challenging parts of a single lengthy operation, or that the more difficult operations should be performed at the beginning of the day.

Methods

Subjects

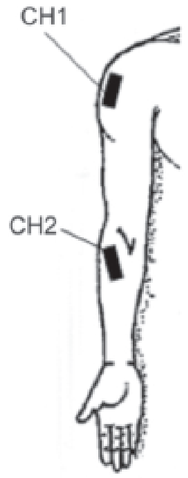
Eight healthy surgeons, six male consultants, one male registrar, and one female registrar volunteered to participate in the surgical arm of the study. Twenty non-surgical measurements were taken during the control arm. The surgeon's ages varied between 31 and 47, with a mean age of 40.63. The non-surgeon's ages varied between 25 and 35, with a mean age of 32.35. All the surgeons and all but one of the non-surgical controls were right handed. The surgical arm of the study consisted of acquiring fatigue measurements whilst performing an operation. The length of the operations varied from one hour to 10 hours as shown in Table 1. The control arm of the study consisted of acquiring 60 second fatigue measurements before and after several hours of routine desk work.

Table 1: surgery description, length of operation, and the time between sets.

Surgeon	Surgery description	Length (min)	Length between Readings (min)
#1	Panendoscopy excision biopsy (right brachial cyst)	120	8
#2	Tracheostomy Left selective neck dissection Mandibulotomy Resection of tumour left tonsil Left palate reconstruction with radial forearm flap Abdominal skin graft	600	8
#3	Left modified radical neck dissection	180	2.5
#4	Excision left submandibular gland	60	0.5
#5	Left mastoid obliteration Bone anchored hearing aid	240	8
#6	Right combined approach tympanoplasty (stage 2)	210	3
#7	Tracheostomy Left selective neck dissection Mandibulotomy Resection of tumour left tonsil Left palate reconstruction with radial forearm flap Abdominal skin graft	480	10.5
#8	Cochlear implantation	180	5.5

Measurement techniques

The electrodes were placed over the muscle belly of each subject's dominant arm. The deltoid lateral head (MD) and brachioradialis (BR) muscles (Figure 1) were chosen for analysis to attempt to compare their fatigue levels, and how they are used throughout a day of operating. These two were chosen as they are used primarily for stabilizing both the arm and forearm, and would be the most likely muscles to fatigue. The skin was cleaned with alcohol and all hair shaved, an interfacing film was attached to each of the electrodes, and these films were then attached to the skin. The EMG signals were collected using a Bagnioli-16 system (see Appendix).



Channel	Muscle	Abbreviation
1	Mid deltoid	MD
2	Brachioradialis	BR

Figure 1: Electrode placement on the Mid Deltoid (MD) and Brachioradialis (BR) muscles.

Procedures

The EMG measurements were taken from the beginning to the end of the operation. These consisted of 30 second sets, separated by 0.5 to 10.5 minutes between captures, depending on the operation length. Table 1 lists the time between sets based on the operation. The surgeons were asked to perform the operations as normal. The control's fatigue measurements were taken at a variety of times throughout the day.

Statistical comparisons were performed on the tremor data from all of the surgeons. All statistical and other analysis were performed using the Matlab R2006a (The Mathworks Inc, Natick, MA, USA) Statistical and Frequency Analysis Toolboxes. Any significant differences were defined at ($p < 0.05$).

Results

The results from all surgical EMG measurements indicate a decrease in the MF over the length of the operation for both the MD and the BR muscles. The analysis on operation #3's MD muscle has been used as an example. All calculated MFs are plotted in Figure 2a. A linear regression curve, with 95% confidence intervals, has been fitted to the data. Figure 2b demonstrates the mean %MVC (bar graph) for each repetition superimposed with the change in mean MF (line graph). This decrease in MF suggests an increase in muscular fatigue level.

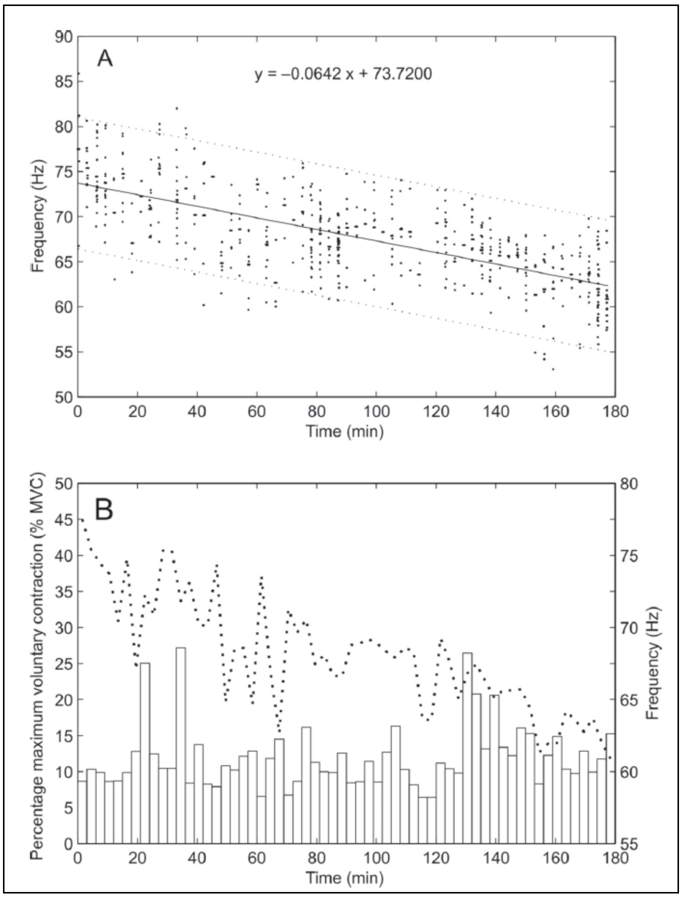


Figure 2a: The Mean Frequencies (MF) for the Mid Deltoid (MD) muscle calculated throughout operation #3. The data has been fitted with a linear regression curve with 95% confidence intervals.

Figure 2b: The mean Percent Maximum Voluntary Contraction (%MVC) for each repetition during operation #3 (bar graph). The superimposed dashed line represents the change in the mean of the Mean Frequencies (MF) during each repetition.

The MF readings taken at the beginning of the day did not show any significant difference between the consultants (#1, #2, #3, #4, #7, and #8) and registrars (#5 and #6), (ANOVA, p = 0.7193 (MD), p = 0.3458 (BR)).

By analyzing the percent change of the MF for each operation and correlating it with its length, we discover a linear relationship between the percent change in fatigue index and the length of the operation for both muscles. A linear regression with confidence bounds of 95% has been fitted to the data and is shown in Figure 3 and 4. These figures demonstrate the constant increase in fatigue based on the length of the operation. They also demonstrated that it would be possible to predict the change in a surgeon's muscular fatigue index during an operation given a baseline measurement. It is also apparent that the BR fatigues more than 1.5 times as fast as the MD muscle. The results demonstrate that for every hour after the first hour of operating, the MDs MF decreases by 0.84 %, and the BRs by 1.32 %, and which is associated with a fatigue rate.

There is also an offset of -10.781 % and -11.969% for the MD and BR respectively, which occurs after the first hour of operating.

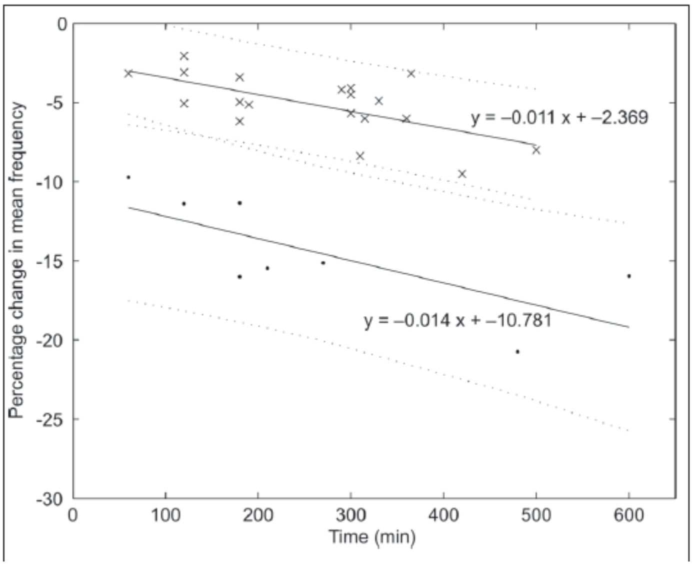


Figure 3: Percent decrease in Mean Frequency (MF) from baseline of the Mid Deltoid (MD) muscle. This is based on the length of operation and normal working day conditions. Points indicate the percent decrease of the surgical fatigue index (MF); the solid line is the fitted linear regression to the data, and the dashed lines indicate the 95% confidence interval for the fitted data. Crosses indicate the percent decrease of the non-operating fatigue index; the solid line is the fitted linear regression to the data, and the dashed lines indicate the 95% confidence interval for the fitted data.

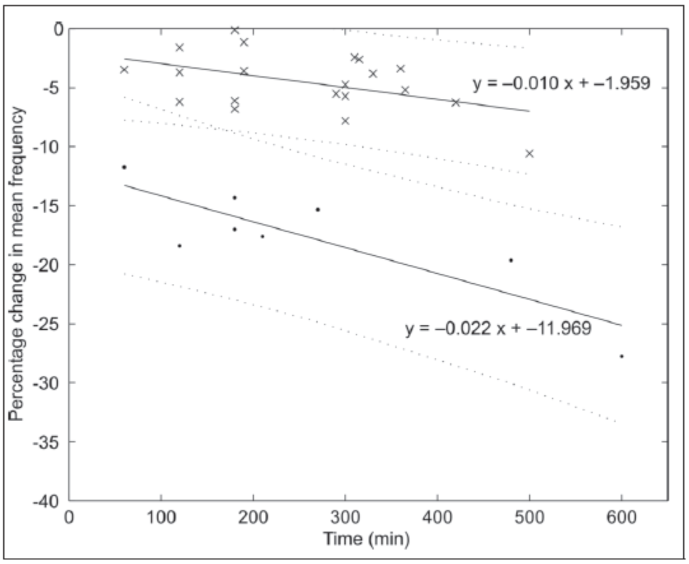


Figure 4: Percent decrease in Mean Frequency (MF) from baseline of the Brachioradialis (BR) muscle. This is based on the length of operation and normal working day conditions. Points indicate the percent decrease of the surgical fatigue index (MF); the solid line is the fitted linear regression to the data, and the dashed lines indicate the 95% confidence interval for the fitted data. Crosses indicate the percent decrease of the non-operating fatigue index; the solid line is the fitted linear regression to the data, and the dashed lines indicate the 95% confidence interval for the fitted data.

The mean %MVC for both muscles has been averaged over all operations. Figure 5 shows that the mean %MVC of the BR muscles is roughly higher than that of the MD muscles. This suggests that the muscular activity of the BR muscle is greater and indicates that the BR muscles are used more than the MD during the operations.

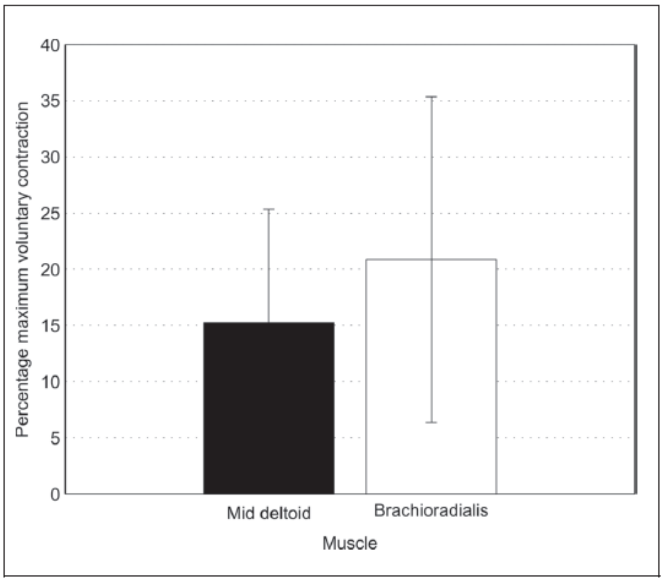


Figure 5: The Percent Maximum Voluntary Contraction (%MVC) contribution of the Mid Deltoid (MD) and Brachioradialis (BR) muscles throughout all surgical operations.

In the control arm of the study, the volunteers fatigue index increased throughout the day, although only fractionally (0.011%/minute (MD), 0.010%/per (BR)). A linear regression with confidence bounds of 95% has also been fitted to the data.

Discussion

Comparison with other studies

Fatigue analysis has been performed in many fields of study, such as postural control on voluntary movements[4] and during repetitive task dependent activities[5]. The EMG measurements are primarily captured using surface EMG, although they can be captured using needle electrode. These unfortunately cause some risks of infection, damage to muscle fibres, and are painful to the subjects[7]. These studies have determined that fatigue can be correlated with a shift in MF towards lower frequencies[4,5], and is increased by higher levels of muscular contractions. The surgical studies that have been performed have examined aspects of fatigue during simulated laparoscopic surgery. These were conducted over short periods of time, and during sustained isometric muscular contraction levels[8]. Others have examined the effects of laparoscopic training on muscular demand[9]. These studies have examined the muscular contribution during specific surgical tasks. They have concluded that certain muscles are used more often than others and are therefore at a greater risk of fatiguing. However, they have not shown that the studied muscles had fatigued.

EMG fatigue analysis has been primarily applied to shorter muscular bursts at the similar strength levels (constant %MVC)[10-12]. The problem arises, however, when dealing with daily routine movements and muscular contractions, as the strength level of these contractions varies. Little is known as to what happens to the frequency of the muscular motor units over the long periods. Long-term studies have been performed whereby EMG has been captured throughout a 24 hour period have examined parkinsonian and essential tremor[13], and wrist tremor[14]. Christensen[15] has examined the MF change throughout the day of the deltoid, trapezius, and infraspinatus muscles in subjects operating a pillar drill. However, to our knowledge this is the first study to have examined the change in the fatiguing muscles during a day of operating.

Clinical applicability

This study focused on the development of fatigue by analyzing the MF shifts over the length of various operations, and correlating trends with the level of expertise of the surgeon.

We have demonstrated that there was no statistical difference between the pre operative MF between the consultants and registrars. The decrease in MF throughout the day irrespective of the level of muscular contraction (%MVC), suggests that surgeons fatigue throughout an operation. It also suggests that baseline fatigue is not ‘improved’ with practice and it is likely that all people have different levels of muscular activation frequencies, over which they have little control.

We have shown that there is a very little decrease in fatigue index while performing desk work. This leads us to deduce that the decrease in fatigue index during an operation is solely due to the operating.

It should be noted that the MF shift can only be considered as a fatigue index, and not actual fatigue. Fatigue is a very subjective term, and can vary from individual to individual. The change in MF is therefore a representation of the muscle's shift towards a fatigued state.

As is shown from the %MVC, each of the surgeons used their BR muscles at a higher level than they used their MD muscles throughout the operations. Because of this, it stands to reason that both MD and BR muscles should fatigue at different rates. The rate at which the BR muscle fatigued was approximately 1.57 times more than the MD as shown in Figures 3 and 4. This suggests that this muscle is being used twice as much during the operations. This could be due to the fact that most of the actions performed during the operations use the forearms, and that they are continuously lifting the forearms and hands against gravity, and they are not being rested on supports for much of the operation. This correlates with all surgeons reporting that their forearms felt fatigued after a long operation. The linear relationship between percent in MF and time allows us to predict the fatigue index of both the MD and BR at the end of an operation based on an initial MF measurement.

The surgical day often falls into 2 different categories, either many short operations, up to 90 minutes in length, or one long operation, up to 10 hours in length. These can have differing levels of complexity requiring differing degrees of accuracy. It is likely that the decrease in fatigue index is associated with an increase in tremor. This will have an impact on long operations, as often the most technically difficult section, a vascularized free flap reconstruction, takes place at the end of the procedure. Surgeons should therefore be aware that their muscles will be fatigued by this stage and it may be worth a fresh surgeon performing this section of the operation. Short operations can also be very technically demanding, for example, a stapedectomy requires the creation of a 0.6mm stapedotomy through which is 0.4mm piston is inserted[16]. Excessive hand tremor caused by muscular fatigue would therefore decrease the surgeon's accuracy and subsequently the outcome of this operation. Operations requiring high degrees of accuracy should therefore be performed early on in the day.

Limitations

It is very difficult to apply this practically, as there is no specific point at which an individual is fatigued. All that we can determine is that a person does fatigue during an operation. And that the longer the operation, the more fatigued they will be.

Conclusions

Muscular fatigue increases throughout a day of operating directly proportional to time. There is no significant different in muscular fatigue between the consultants and registrars. The amount of muscular usage correlates with the level of muscular fatigue, with the brachioradialis muscle being used more than the mid deltoid and it fatigues more rapidly. Surgeons should be aware that their fatigue levels will increase as an operation progresses, therefore, if possible, more complex parts should be performed as early as possible, or, in the case of very long operation, a change in surgeons may be necessary.

Acknowledgements

The authors would like to acknowledge support from the EPSRC for the funding of the project. They would also like to acknowledge the surgeons and theatre staff at the Queen Elizabeth Hospital Birmingham, UK, and the University Hospital of North Staffordshire, UK that participated in the collection of the data.

Appendix

1. The EMG signals were collected using a Bagnioli-16 system, with a bandpass filter within the signal conditioning unit of 20-500 Hz, and preamplified with a system gain of 1000. The data was captured using the DE-2.1 electrodes, the Delsys EMGWorks Acquisition 3.1.0.5, and a National Instruments DAQ Card-6036E Data acquisition card sampled at a rate of 1000 Hz. The DE-2.1 electrodes are organized in a single differential configuration. It consists of two 10.0 x 1.0 mm Ag contacts separated by 10 mm. The contacts lie within a 41 x 20 x 5 mm casing. The data was acquired at a sampling rate of 1 kHz and 16-bit precision.

2. The raw EMG signals were analyzed off-line without any pre-processing other than the bandpass of the signal conditioning unit (20–500 Hz). Because of the non-stationarity nature and the length of the captured

signals[17], conventional Power Spectral Density (PSD) methods for determining fatigue were not used. The Mean Frequency (MF) or fatigue index was calculated within each acceptable contraction using a derivative of the Hilbert Huang Transform technique[18]. This method calculates the MF within a time window using the sum of the mean instantaneous frequencies from each empirical mode, and has demonstrated low MFs variances between different window sizes. A 500 ms window size was chosen so that small bursts of muscle activity during the operation could be captured. As it is impossible to keep each muscle contraction at a specific percent of their Maximum Voluntary Contraction (MVC), each surgeon's 100% MVC was chosen as 607 μV for the MD and 345 μV for the BR. These were chosen as MVC as it correlated to the average MVC voltage for the controls part of the study. All portions of the EMG signals were scaled as a percent of this maximum. This was performed by fitting a root mean squared (RMS) envelope to each recording's window, and the maximum RMS calculation was used as %MVC. During the day, the collected EMG data was then normalized as a percentage of the MVC, so that it would be represented as the total effort in a percent of the maximum required to complete the task. The choice of 100 %MVC seemed reasonable as most of the signal amplitudes analyzed fell within the 5-30 %MVC. Using the Borg scale to calculate MVC, this is described as extremely weak to moderate muscular activity. Only contractions above 5 %MVC were used to determine the MF.

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A comparative study of supported and unsupported wrists and their effects on hand tremor in simulated operating conditions

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Microsurgery in press February 2010

Chapter 2.3

Abstract

Background:
Operative tremor can greatly influence the outcome of certain, precise, microsurgical operations. Reducing a surgeons tremor may not only improve the operative results but decrease the operative time. Previous studies have only measured uni or bi directional tremor and therefore have been unable to calculate both the overall tremor amplitude and the tremor reduction by resting the wrists.

Materials and Methods:
We measured the tremor of 21 neurologically normal volunteers whilst performing a micromanipulation task, with and without wrist support. Measurements were acquired in 3 dimensions using 3 accelerometers attached to the hand, allowing an overall tremor amplitude to be calculated.

Results:
Resting the wrist on a gelled surface decreases an individuals tremor by a factor of 2.67(p=0).

Conclusions:
Supporting the wrists significantly decreases the amplitude of the tremor. Surgeons should consider using wrist supports when performing parts of operations which necessitate a high degree of accuracy.

Introduction

The majority of surgical operations do not necessitate operating at sub millimeter precision and therefore the surgeon's tremor does not play a significant role in the operative outcome. However, when operating requires a high degree of accuracy necessitating the use of an operating microscope, surgical tremor could adversely influence the result. For example, a stapedectomy involves removing the stapes suprastructure, creating a 0.6mm aperture in the stapes footplate, through which a 0.4mm prosthesis is inserted[1]. If the surgeon was able to decrease his/her tremor then they may spend less time performing the task. This has potentially a dual effect; it may lead to a more favorable result, and will limit the effect of the gradual increase in tremor that occurs as operative time progresses[2].

Tremor is a manifestation of the rhythmic involuntary movements resulting from regular oscillatory contractions of corresponding agonistic and antagonistic muscles[3]. Tremor experienced during a surgical procedure can be divided into postural, isometric, and physiologic components[4]. Postural tremor refers to the tremor exhibited by an individual attempting to maintain a body parts position against the effects of gravity. Isometric tremor refers to the tremor induced by muscle contractions against stationary objects. Physiologic tremor refers to a high frequency, low amplitude postural tremor that all normal persons exhibit.

All microsurgeons are aware of the impact of tremor on their operations and that supporting the operating hand will reduce its tremor. Previous studies have analyzed tremor in 1 or 2 dimensions[5,6], and therefore has not determined the overall tremor amplitude. In this study we will analyze tremor in 3 dimensions and calculate a mean overall tremor for both supported and unsupported wrists. We hope to demonstrate, for the first time, the full extent of tremor reduction by supporting the wrists. If tremor reduction afforded by supporting wrists is large then the invention of movable wrist resting devices would improve microsurgical accuracy.

Materials and Methods

Twenty one healthy volunteers, 17 males, and 4 females, participated in the trial. All subjects gave informed consent prior to their inclusion. The volunteers were asked to perform a micromanipulation task with no support for their arm, they then performed the same task with their wrist supported. The volunteer's ages varied between 24 and 40, with a mean age of 28.86. Only one of the volunteers was left handed. The readings were taken during a normal day of desk work.

The tremor measurements were acquired using three triaxial Delatron piezoelectric accelerometers (Bruel and Kjaer, Nærum, Denmark) as shown in (Figure 1). These were attached to a mounting mechanism, which was then attached to the back of the dominant hand with elastic bands. The mounting mechanism was manufactured from DSM 1770 plastic using a rapid prototype machine, and was positioned on the hand in such a way as to not impede the grip of the volunteers. This allowed for tremor measurements to be acquired directly above the hand. The first accelerometer had sensitivities of 95.72 mV/g in the X direction, 98.18 mV/g in the Y, and 95.26 mV/g in the Z (g – acceleration of gravity). The second accelerometer had sensitivities of 97.92 mV/g in the X direction, 100.7 mV/g in the Y, and 97.72 mV/g in the Z. The third accelerometer had sensitivities of 95.96 mV/g in the X direction, 95.07 mV/g in the Y, and 101.8 mV/g in the Z. The accelerometers were attached to an Endevco Isotron power supply (Model 2793) (Endevco, California, USA). The signals from the signal conditioning unit were in turn attached to a Delsys Inc. Universal Input Unit, and finally to National instruments Data Acquisition card (DAQCard 6036E) (Delsy Inc, Boston, USA). The acquisition software used was the Delsys EMGWorks Acquisition 3.1.0.5. The data was acquired at a sampling rate of 1 kHz and 16-bit precision.

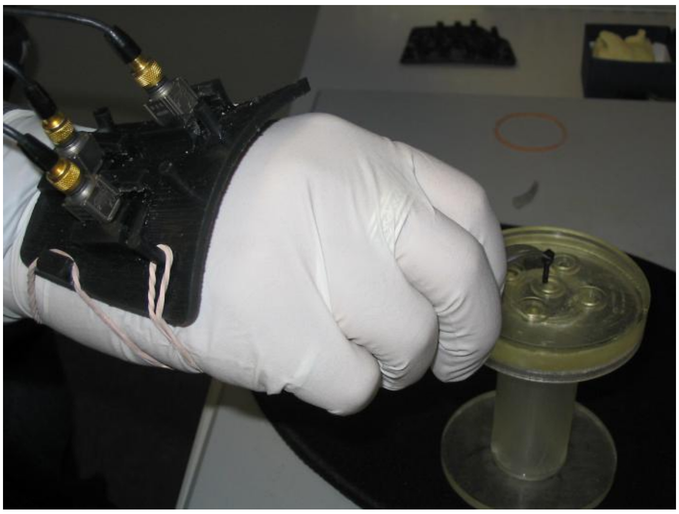

Figure 1: Placement of the 3 accelerometer's on the wrist.

Each of the tremor readings for the unsupported arm of the study consisted of ten, 10 second sets, which were conducted sequentially. The volunteers were asked to perform a seated dominant handed micromanipulation task by holding a 2 mm diameter pin between tweezers and attempt to hold it steady within a 4 mm diameter hole as shown in (Figure 2). The volunteers were also asked not to rest their arms at any time during this part of the study. They were then asked to support their wrists on a gelled surface and the measurements were repeated.

Figure 2: Demonstration of micro-manipulation task - holding a 2mm pin grasped between tweezers within a 4 mm hole, with both unsupported and supported wrists. The surgeons were asked to remain standing during this operation.

The raw piezoelectric accelerometer signals were first detrended by using an empirical mode decomposition method, which removed the lowest mode, or the trend from the signal. The new signal was then integrated to give the velocity, detrended again, and finally integrated one last time to provide the position. Once the positions were obtained for all three directions from each of the accelerometers, the relative position was obtained by calculating the Root Mean Square (RMS). The mean of the RMS tremor value was then calculated and provided us with the mean tremor amplitude over the full 140 second tremor readings. The average of the three accelerometer readings was used as the overall tremor amplitude.

Statistical comparisons were performed on the tremor data from all of the volunteers. All statistical and other analysis were performed using the Matlab R2006a Statistical and Frequency Analysis Toolboxes. Any significant differences were defined at ($p < 0.05$).

Results

There is a significant difference between the dominant hand tremor amplitudes for supported and unsupported wrists (ANOVA, $p = 0.00000062$). The boxplot in Figure 3 demonstrates differences between the unsupported and supported tremor amplitude readings. The mean unsupported amplitude of tremor was 1.930 ± 0.870 mm. Once the wrists were supported on a gel wrist pad, the amplitude of tremor decreased to a mean of 0.725 ± 0.333 mm.

The percent difference between the supported and unsupported amplitudes of -60.379% ± 15.494 as shown in Table 1. They indicate that by supporting the wrists while performing the micromanipulation task substantially decreases the tremor amplitude. There was no difference in baseline tremor and age.

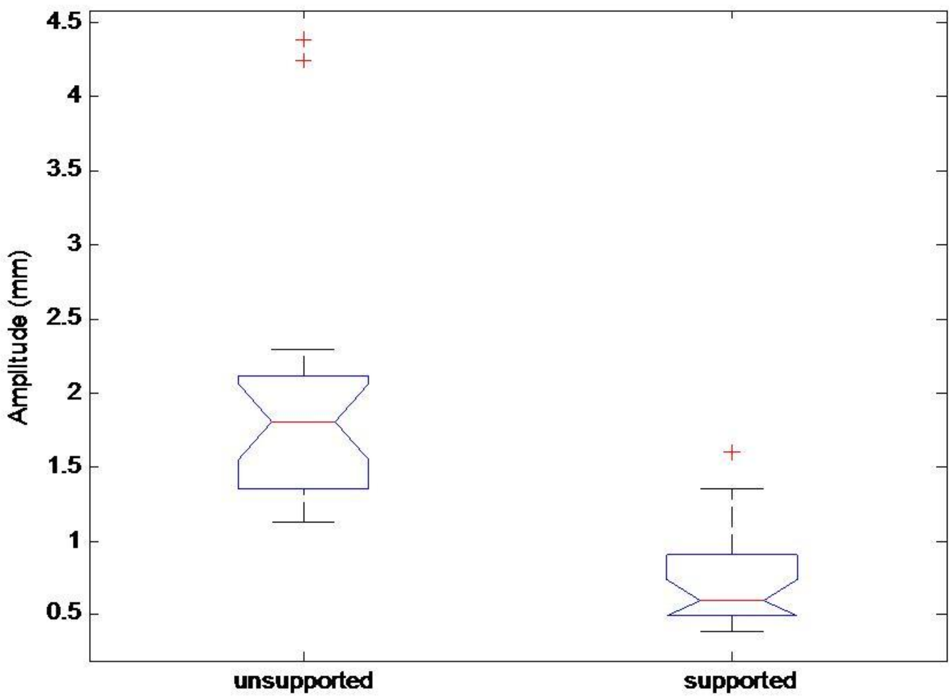

Figure 3: Boxplot of tremor amplitudes when wrists are supported and unsupported.

Table 1: Total amplitude of tremor for unsupported and supported wrists

		Mean (mm)	Standard Deviation (mm)	Mean % Change	Standard Deviation % Change
Amplitude	Unsupported	1.930	0.870	-60.379	15.494
	Supported	0.725	0.333		

Discussion

The purpose of this study was to determine whether supporting the wrists would decrease an individual's tremor, and to calculate the extent of the tremor reduction. The effect of supporting segments of the arm have been previously studied, however these studies have looked at tremor in 1 or 2 dimensions and haven't been able to assess the overall tremor amplitude by calculating the tremor from 3 dimensions[5,6]. The overall tremor amplitude needs to be measured before the effect of methods to reduce tremor be accurately assessed.

Murbe et al. examined hand tremor while performing a simulated microsurgical task using a force cell and a fine needle while supporting the wrist[7]. The subjects were asked to push and hold a modeled stapes head into a specific position and maintain it in place. The hand was stabilized using a counterweight, which lead to much smaller tremor amplitudes (in the range of 10 μm). Its displacement was measured using laser interferometry, and its frequency analyzed using Fourier analysis and amplitude analyzed using the alternating root mean square of the displacement. However, only one direction of tremor was analyzed, and as they examined the tremor at the tool point, they were not able to assess the hand tremor. They did however find that there was a significant decrease in the tremor amplitude in the one direction by using two hands to complete the task.

Hand steadiness has been previously investigated[8-10]. Hsu et al. used a video to analyze the effects of exercise on tremor amplitude, and found that tremor following exercise reduced to normal baseline levels after 2 hours[8]. The method of analysis proved to be is very time consuming, was limited by the frame rates of the video device, and was restricted to two dimensions. During the measurement, the subjects' dominant and non dominant extremities were fully supported to maximize torso stability. Arnold et al. studied hand tremor by pointing a laser at a target, again a two dimensional analysis, when subjected to a variety of stimuli[9].

They concluded that resting the wrist significantly steadied hand movements. Roels et al. examined the hand's frequency and tremor amplitudes during various wrist loading conditions and characterized their variability[10]. Unfortunately, during these studies they didn't compare the tremor differences between supported and unsupported upper arm segments during the tasks.

Davis et al. looked at the physiological tremor amplitudes contribution of the shoulder, elbow, wrists, and fingers while holding a laser pointer and found that the contributions of the wrist and fingers were much greater than the elbow and shoulder[11]. Growdon et al found the effect of using an armrest on resting tremor was 4-5 fold in 2 dimensions[5]. They examined the effect of mental stress on physiological tremor amplitude and mean frequency and found that mental stress increased tremor amplitude, and the mean frequency in all supported positions decreased.

Morrison et al. analyzed the tremor along the various segments of the upper limb while the level of support was increased[6]. It was found that as the support moved distally, the tremor amplitude decreased. The coherence between each of the adjacent limb segments readings was also assessed. The findings revealed a strong correlation between the distance of support from the hand, and the tremor. The readings, however, only looked at the uniaxial acceleration, and didn't take into account the movement or displacement of the limbs in a global space.

This study has analyzed tremor in x, y and z directions to determine a accurate overall amplitude of tremor and can therefore make an precise assessment of the change in tremor amplitude due to resting the wrist. Based on these results, there is a decrease in the overall tremor amplitude by a factor of 2.67 by resting the wrists.

The subjects in the trial were all non-microsurgeons and it is likely that their baseline tremor is greater than surgeons regularly operating under a microscope. However, we would anticipate that the proportion of tremor reduction would be the same. In a previous study on tremor and operating time[2] there was neither a difference in baseline tremor and surgical experience, from junior trainees to senior consultants, nor with age.

There is a possible damping effect on the tremor caused by attaching the mount and accelerometers to the hand. Whilst we anticipate that the effect would be minimal, any impact would reduce tremor amplitudes and therefore underestimate both the overall tremor and the influence of wrist resting.

The difference between the mean unsupported and supported tremor amplitudes indicate that if a surgeon was to support the wrists during an operation, the precision of their movements would be potentially improved during tasks that require the upmost accuracy. This increase in precision, may translate to a reduction in the number of attempts to perform the task, and as a result, the completion time. This in turn could lead to a reduction in fatigue of the surgeon throughout the operation.

Although supporting the wrists whilst performing a manipulation task significantly decreases the tremor amplitude, resting the wrists does have certain drawbacks. Doing so limits the range of motion of the hand and fingers. It is unlikely, however, that a surgeon would need a large range of motion of his hands and fingers when performing a task necessitating sub millimeter accuracy. The method of wrist resting will need to differ in the various surgical disciplines depending on the positions of patient and surgeon and the type of access to the operative area. This study was designed to analyze tremor for otological procedures where the most obvious place to rest your hands is on the patient. This support, however, is not movable if the surgeon needs to alter position. Arm rests that can be attached to an operative chair are excellent until the surgeon wants to change posture. Ideally a movable arm rest system would be depolyed to allow the surgeon to move his/her hands and arms freely and then be able to fix them when in the desired position.

Conclusion

Microsurgeons are all aware of the impact of tremor on their operations and that supporting their operating hand will reduce the tremor. This study has determined the extent to which the tremor is reduced by wrist support. Supporting the wrists significantly decreases the amplitude of the tremor by a factor of 2.67. Surgeons should consider using wrist supports when performing parts of operations which necessitate a high degree of accuracy.

Acknowledgements

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Assessment of disturbances within the cochlea during cochlear implantation

Chapter 3

Introduction to chapter 3

The reduction in residual hearing post cochlear implantation is caused by intraoperative trauma sustained by the cochlea. Utilizing 'soft surgical' techniques, it is possible to preserve hearing levels to within 10-40dB of pre operative thresholds. The precise cause of hearing loss, the effect of the different operative steps on hearing levels and the impact of different drill speeds and linear forces on intracochlea disturbances are all currently unknown. Once analysis of the factors causing disturbances within the cochlea are determined, then steps can be taken to reduce the trauma to a minimum.

The first paper in this chapter assesses the disturbances within the cochlea during cochleostomy drilling at different speeds and forces. The second paper compares robotic and human cochleostomy formation and the disturbances within the cochlea.

An assessment intracochlea disturbances caused by cochleostomy drilling at different speeds and forces

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Chapter 3.1

Abstract

Background:

For hearing preservation cochlear implantation to be successful, trauma sustained by the cochlea needs to be minimized at all stages of the operative procedure. The aim of this paper is to assess the disturbances sustained by the cochlea whilst a cochleostomy is created at different drill speeds and forces.

Materials and Methods:

Intracochlea disturbances were analysed in a porcine cochlea by creating a third window cochleostomy, preserving the underlying endosteal membrane, on the anterior aspect of the basal turn of the cochlea. A laser vibrometer was aimed at the third window whilst a cochleostomy was drilled at different drill speeds and linear forces.

Results:

The greater the drill force used, the greater the disturbance of the endosteal membrane. Drill speed was also important when drilling with moderate or high forces, interestingly our results reveal that drilling at lower speeds in these force categories led to a greater membrane disturbance than drilling at high speeds.

Conclusions:

Both drill speed and force of drilling independently effect the movement of the endosteal membrane during the cochleostomy procedure. Minimizing the force of drilling has the greatest impact on intracochlea membrane disturbances.

Introduction

Hearing preservation cochlear implantation (HPCI) is the focus of much interest in the cochlear implantation community. Standard cochlear implantation is an extremely successful intervention for patients with bilateral, severe to profound, sensorineural hearing loss. Whilst conventional hearing aids greatly benefit those with mild to moderate hearing losses. HPCI is intended to aid those patients who cross the borders between these 2 groups, i.e. patients with mild to moderate hearing losses in the low frequencies and severe to profound losses in the high frequencies. Gantz and Turner have demonstrated that combining electrical stimulation of hearing in the high frequencies and acoustic stimulation of hearing, via a hearing aid, in the low frequencies represents the ideal rehabilitation strategy, with the greatest monosyballic and words in sentence scores[1].

HPCI requires insertion of an implant electrode array whilst, ideally, maintaining the patients current hearing levels. This is technically difficult as hearing loss can be caused at many stages throughout the implantation process, and is most likely due to an additive effect of these insults. [2]

1. Drilling of a cortical mastoidectomy, implant well, posterior tympanotomy and bony cochleostomy will all subject the cochlea to noise induced trauma from drill noise[3] . Further, the cochlea will sustain a mechanical/ vibrational trauma during this process which may lead to further hair cell loss.[4]
2. Lenhardt recommends the ideal way to minimize trauma during cochleo-stomy formation is to perform a bony cochleostomy preserving the underlying endosteal membrane, which is subsequently opened with a pick. This method avoids introducing a running burr into the scala tympani. [5]
3. Suction of perilymph has been shown to be associated with further SNHL. [6]
4. Trauma to the spiral ligament or penetration of the basilar membrane can occur after the electrode has passed into the scala tympani, or the electrode may be directly passed into the scala vestibule.[7]
5. Insertional trauma can lead to subsequent new bone formation and fibrosis within scala tympani. [2]
6. Opening the cochlea is a portal of entry for infection and the development of infectious labyrinthitis.[8]

HPCI is achievable with many authors having published data with varying degrees of hearing preservation achieved during the implant procedure. The success rates vary between preservation in 100% with 6mm and 10mm electrodes in 6 patients[1], to preservation in 50% with 17mm insertion[9]. Even in the patients whose hearing is 'preserved', there is a wide range of hearing levels varying from 0.7dB[10] hearing loss to 40dB[11] hearing loss.

The ideal situation would be to preserve all the patients existing hearing, maximizing the combined electroacoustic simulation. To achieve this aim, trauma to the cochlea has to be controlled, and minimized, at all stages of the implantation process.

The aim of this research is to analyse the effect of different drill speeds and forces of drilling, during cochleostomy formation, on the disturbances of the endosteal membrane, independent of the noise levels. The velocity of movement of the endosteal membrane during the drilling process represents the underlying fluid pressure changes within the scala tympani and therefore reflects the degree of cochlea disturbance whilst drilling. This knowledge will allow implementation of strategies to minimize these disturbances, hopefully leading to greater preservation of residual hearing.

Methods

Measurement system

A laser vibrometer offers a non contact method of assessing the movement of a surface. It has the advantage over contact methods of avoiding adding a weight to the system and so doesn't alter the dynamics of the system. It uses the Doppler effect theory - when a laser beam is directed at a reflective moving surface, the frequency and phase of the backscattered light is altered compared to the original beam. Detection and analysis of the back scattered light can determine the movement of the test surface as the characteristics of the motion are completely contained within the backscattered light. Within a laser vibrometer a high precision interferometer detects the minute frequency shifts of the back scattered laser light by combining the back scattered light from the moving test surface with a reference beam of light to create a superposition of light. The superposition of light creates a modulator output detection signal revealing the Doppler shift in frequency. Signal processing and analysis provides the velocity and displacement of the test object.

See http://www.polytec.com/eur/_files/LM_VibVideo_P3_Principle_Mid_EN.wmv for further explanation.

Test specimens

The porcine cochlea were selected as the phantom test cochlea as they have a similar structure to a humans.[12] The cochleas' were harvested from a porcine temporal bone (Middle White breed) and fixed into a custom built test bed capable of fitting under a microscope used to focus the laser vibrometer. The test bed was designed to ensure that the cochlea remained stationary during the drilling process.

Experimental set up

Figure 1 demonstrates the experimental set up. A third window to the cochlea was performed on the far anterior aspect of the basal turn of the cochlea, approximately 9mm directly anterior from the anterior lip of the round window niche. The laser vibrometer was aimed at the endosteal membrane in this window to assess membrane displacement during cochleostomy drilling. To ensure accurate measurements of membrane deflection during the drilling process, the endosteal membrane in the third window must be intact after bone removal to maintain closed fluid chambers in the cochlea. This will allow the pressure changes to be manifest throughout the scala tympani. To preserve the integrity of the endosteal membrane our previously reported smart drilling robot was utilised,[13] this robot can ensure the preservation of an underlying membrane whilst performing a fenestration in a bone by analysing the force and torque changes during the drilling process. An algorithm is implemented to predict the point of medial breakthrough and ensure the drilling processes stops prior to this.

The laser vibrometer requires a reflective test surface to successfully analyze the back scattered light. To enable reflections from the endosteal membrane in the third window, 0.1ml of metallic paint was introduced onto the endosteal membrane (figure2). This provided the laser vibrometer sufficient backscattered light to successfully perform the analysis of movement.

Drilling speeds and forces

Drilling was performed anterior and inferior to the round window in the typical position for a cochleostomy during the cochlear implant procedure. The aim of this study was to assess the impact of drilling alone and therefore the breakthrough procedure was not performed during the study.

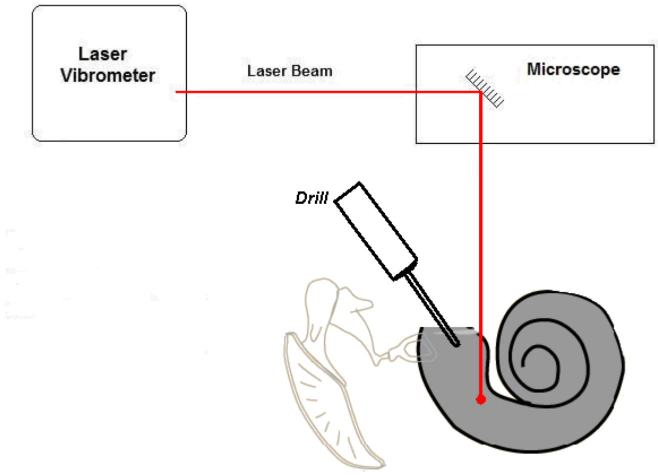

Figure 1: Experimental set up

Figure 2: Silver metallic paint on endosteal membrane in 3rd window

To assess the impact of drilling force and drill speed whilst creating a cochleostomy, drilling was performed at 4 different speeds 20,000, 10,000, 5,000 and 1,000 revs per minute each at 3 different force categories. The lightest force approximately 0.5N was when the burr was only just in contact with the bone. The greatest force, approximately 5N was when the surgeon was pressing hard on the bone with the drill. The middle force was approximately 2N.

Interpretation of results

During each of the drilling trials the displacement of the membrane was analysed against time. The average velocity of movement of the membrane throughout the drilling process, and the peak movement of the membrane will be calculated for the different drill speeds and forces used.

Results

Figures 3-5 demonstrate the membrane displacement in 4 cochlea's associated with the range of test drill speeds, at different forces of drilling.

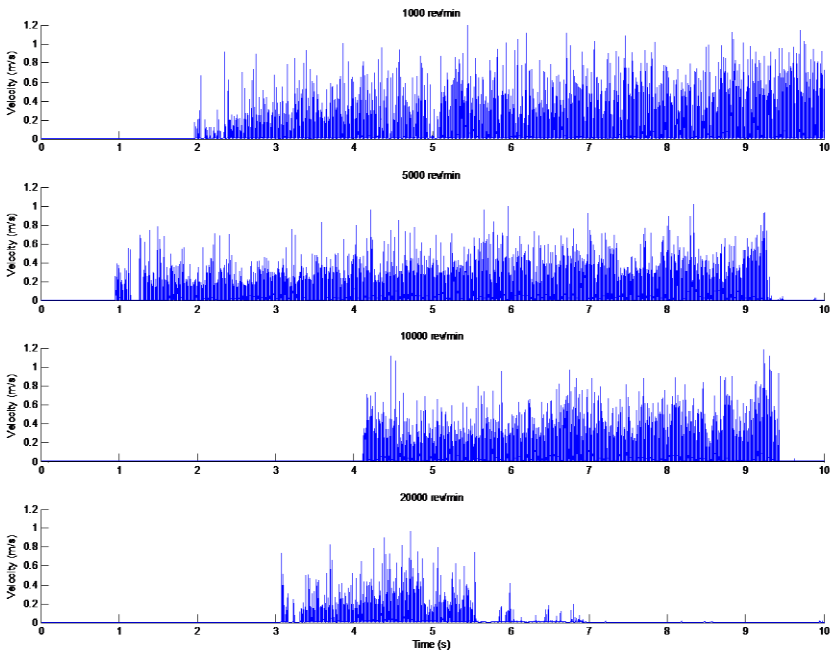

Figure 3: 5N drilling

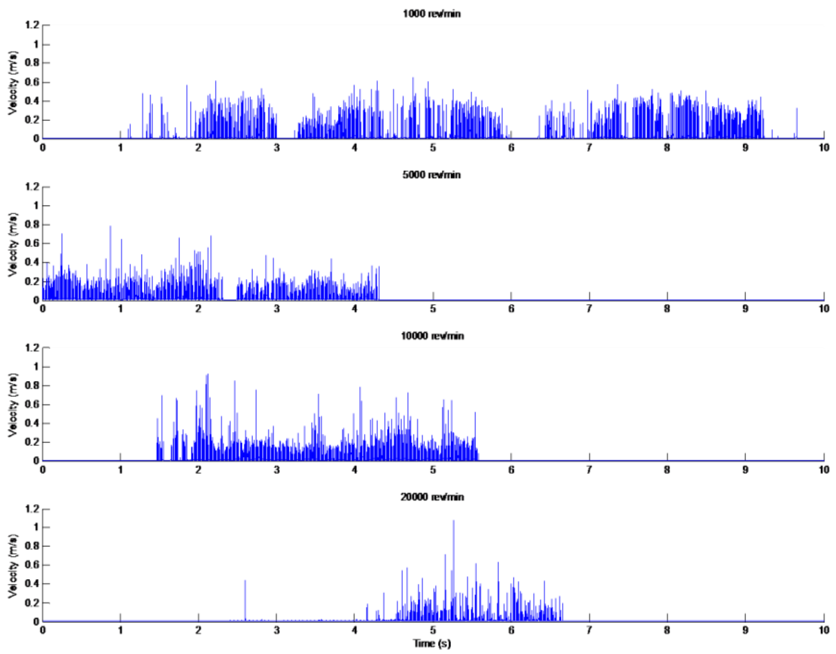

Figure 4: 2N drilling

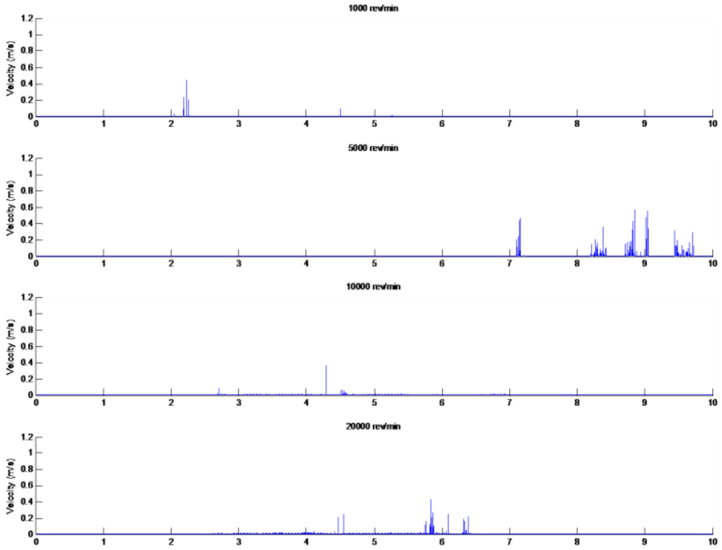

Figure 5: 0.5N drilling

Table 1: A table demonstrating the average and peak velocities of the endosteal membrane during drilling at different speeds and forces.

	Force ≈ 5N		**Force ≈ 2N**		**Force ≈ 0.5N**	
	Mean (mm/s)	Peak (mm/s)	Mean (mm/s)	Peak (mm/s)	Mean (mm/s)	Peak (mm/s)
20000	40.1	970	22.2	1017	5.1	432
10000	50.6	1179	29.9	921	4.3	362
5000	53.8	1017	32.9	786	9.6	536
1000	64.2	1241	46.3	643	5.9	446

The results demonstrate that force of drilling has the greatest impact on endosteal membrane disturbance, both in terms of average disturbance of the membrane and the peak disturbance of the membrane. The greater the drill force used, the greater the disturbance of the endosteal membrane. Drill speed was also important when drilling with moderate or high forces, interestingly our results reveal that drilling at lower speeds in these force categories led to a greater membrane disturbance than drilling at high speeds.

Discussion

The results from our study have demonstrated that both drill speed and force of drilling independently effect the movement of the endosteal membrane during the cochleostomy procedure, and are likely to be independent variables causing trauma to the cochlea. Force of drilling appears to be the main factor that affects the average and the peak membrane displacement, this is due to the increase in energy transferred from the drill to the cochlea when higher forces of drilling are used. The unexpected finding was that lower drill speeds within the same force range appeared to cause greater endosteal membrane disturbance than high speed drilling. Our hypothesis to explain this surprising finding is that at lower speeds the burr is likely to exhibit more bounce after removing a section of bone than at high speeds when it is likely to be smoother. This affect disappears at low drilling force. The use of high speed drilling, to minimize the cochlea disturbance will need to be weighed against the noise trauma of drilling at greater speeds.

Our study reinforces the concepts presented by Zou[4] that vibrational trauma is likely to be a factor in the trauma sustained by the cochlea independent of noise induced trauma.

HPCI offers its recipients improved monosyballic and words in sentence scores, compared to cochlear implantation or hearing aids alone, representing the ideal hearing rehabilitation strategy for patients with serviceable hearing in the low frequencies[1]. The technical challenges of implanting patients and preserving hearing is demonstrated in the wide variability in clinical outcomes. Gantz preserved hearing in 6 patients within 10-15dB of pre-operative thresholds with short electrodes of 6 and 10mm. Gstoettner[14], in a multi centre trial, achieved hearing preservation in 66.6% of 18 patients. Preservation was defined as ability to amplify hearing with an acoustic aid, the actual thresholds were not reported. James et al[9], preserved hearing in 50% of their patients in a multicentre trial using a 17mm insertion. Again, successful hearing preservation was defined as the ability to aid with a conventional hearing aid. Keifer has performed 2 studies of HPCI, in his first study[10] hearing was preserved within 0-10 dB in 9/14 subjects and within 11-20 dB in 3/14; in 2/14 subjects hearing was completely lost in the implanted ear. His second study[11] using an atraumatic electrode insertion procedure with an insertion depth of 360° (18-24 mm), hearing preservation could be achieved in 18/21 patients (85.7%). Three patients (14.3%) lost their residual low-frequency hearing after the implantation. Residual hearing was preserved completely in 13 patients (61.9%) (<10dB, range 0.7dB to 8.6dB) and partial hearing preservation (up to 40dB loss) was possible in 5 (23.8%). From these studies it becomes clear that not only is hearing preservation possible, but there is a wide range of hearing loss that can take place even in the hearing preserved group.

Analysis of the factors assumed to cause hearing loss during implantation reveals a lack of quantification of the effect of the different traumatic steps.

Drilling of a cortical mastoidectomy, implant well, posterior tympanotomy and bony cochleostomy will all subject the cochlea to noise induced trauma from drill noise. Holmquist[15] determined that the average noise levels were 116dB for an 8mm diamond burr and 109dB for a 4mm diamond burr. Zou's[4] elegant study on guinea pigs measured hearing losses, using ECoG to determine whether vibrational forces had a further additive effect to the noise induced trauma from drilling. They demonstrated a threshold shift in hearing level secondary to vibration induced damage, independent of noise level.

The formation of the cochleostomy is thought to be a key component in preserving hearing.[5] It is recommended that a bony cochleostomy is created with preservation of the underlying endosteal membrane, which is subsequently opened with a knife / pick. This is assumed to minimize the trauma to the cochlea compared to introducing a running burr into the scala tympani. The presence of a running burr in the scala tympani is hypothesized to cause hearing loss through 3 mechanisms. Pressure disturbances within the scala tympani due to the movement of the perilymph cause by the burr, introduction of bone dust into the scala tympani and inadvertent protrusion of the burr into the basilar membrane. Whilst none of these theories are yet to be proven or quantified, analysis of James's[9] results indicates that opening the membrane with the burr lead to the poorer hearing outcomes.

Suction of perilymph has been shown to be associated with further SNHL.[6]

Electrode arrays have been inadvertently inserted into the scala vestibule, scala media, traumatized the spiral ligament and penetrated the basilar membrane[7,16]. These situations all represent non ideal insertions and are likely to be associated with poorer hearing outcomes. The reason for these insertional mistakes is thought to occur from a combination of factors. Briggs believes this is an issue primarily of cochleostomy location and insertion angle, and recommends a cochleostomy formation directly inferior to the round window, rather than the classically advised anteroinferior or the round window approach[7]. Penetration of the basilar membrane can occur even if the electrode is initially in the scala tympani and it is believed[10] that this could be one of the causes of hearing loss if a full insertion is undertaken whilst attempting to preserve the endosteal membrane.

This research poses questions which will require further investigation. Does drilling in and around the temporal bone have a similar effect on endosteal membrane disturbances to that of cochleostomy drilling? If so, then maybe all drilling should be performed at controlled low forces, and the quantity of drilling minimized wherever possible. Should we look further into image guided approaches to the cochlea which will minimize drilling and hence cochlea trauma? What is the impact on reducing the overall cochlea trauma on hearing levels post operatively? Is this an important factor when attempting to preserve hearing levels?

It would appear a sensible approach to control and minimize the trauma to the cochlea at all stages. We envisage this would entail using a suite of smart sensing robots to achieve this

Conclusions

Both drill speed and force of drilling independently effect the movement of the endosteal membrane during the cochleostomy procedure. The increase in energy transferred from the drill to the cochlea associated with higher force of drilling causes greater endosteal membrane displacement and hence greater trauma sustained by the cochlea. Lower drill speeds within the same force range appeared to cause greater endosteal membrane disturbance than high speed drilling, it is likely that at lower speeds the burr exhibits more bounce after removing a section of bone than at high speeds when it is likely to be smoother. This affect disappears at low drilling force. The use of high speed drilling, to minimize the cochlea disturbance will need to be weighed against the noise trauma of drilling at greater speeds.

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Robotic vs Manual cochleostomy formation – an assessment of comparative cochlear trauma

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Chapter 3.2

Abstract

Background:

Cochleostomy formation is a key stage of the cochlea implantation procedure. Minimizing the trauma sustained by the cochlea during this step is thought to be a critical feature in hearing preservation cochlear implantation. The aim of this paper was to assess the intracochlea disturbances during human and robotic cochleostomy formation.

Materials and Methods:

Intracochlea disturbances were analysed in a porcine cochlea by creating a third window cochleostomy, preserving the underlying endosteal membrane, on the anterior aspect of the basal turn of the cochlea. A laser vibrometer was aimed at the third window whilst a cochleostomy was drilled. Human cochleostomy formation was compared to robotic cochleostomy formation.

Results:

The robotic drilling process preserved the endosteal membrane in all 3 cases. The velocity of movement of the endosteal membrane during manual cochleostomy is approximately 20 times higher on average ($p=0.00647$) and 100 times different in peak velocity ($p=0.00478$), than for robotic cochleostomy.

Conclusions:

Our experiment has revealed that controlling the force of drilling during cochleostomy formation and opening the endosteal membrane with a pick will minimize the trauma sustained by the cochlea by a factor of 20.

Introduction

High frequency sensorineural hearing loss is the commonest pattern of adult hearing impairment. In mild to moderate losses patients can be adequately rehabilitated with conventional hearing aids. Standard cochlear implantation is used once bilateral, severe to profound, sensorineural hearing loss has developed. Hearing preservation cochlear implantation (HPCI) is intended to aid those patients who cross the borders between these 2 groups, i.e. patients with mild to moderate hearing losses in the low frequencies and severe to profound losses in the high frequencies. Gantz and Turner[1] have demonstrated that combining electrical stimulation of hearing in the high frequencies and acoustic stimulation of hearing, via a hearing aid, in the low frequencies represents the ideal rehabilitation strategy, with the greatest monosyballic and words in sentence scores.

The success of hearing preservation in HPCI varies widely from preservation in 100% (within 10-15dB)[1] using 6mm and 10mm electrodes, to preservation in 50%[2] inserting the electrode to 17mm (preservation was defined as hearing in the threshold range for an ipsilateral HA). There is no formal definition for what constitutes successful 'preservation of residual hearing‘ and currently this term encompasses a wide array of entities ranging from preservation within 0.7dB of preoperative level[3] through hearing losses up to 40dB[4], to hearing that is serviceable by an acoustic aid (regardless of hearing level)[2].The factors determining the disparity in outcomes are currently unknown, but are presumed to be related to trauma during the implantation procedure.

The cochlea sustains trauma during all the steps of the implantation procedure. Accessing the middle ear and preparing the implant bed will subject the cochlea to a combination of noise induced trauma from drill noise and the cochlea will further sustain a mechanical/ vibrational trauma during this process which may lead to further hair cell loss[5]. The formation of the cochleostomy is thought to be a key component in preserving hearing[6]. Lenhardt recommends a bony cochleostomy is created preserving the underlying endosteal membrane, this is opened with a knife / pick rather than a running burr in an attempt to reduce the trauma to the cochlea. Performing a bony cochleostomy will again subject the cochlea to noise and vibrational trauma. Suction of perilymph has been shown to be associated with further SNHL[7]. Insertion of the electrode may cause trauma to the spiral ligament or penetrate the basilar membrane even if the electrode originally passed into the scala tympani, or the electrode may be directly passed into the scala vestibuli[8]. Insertional trauma can lead to new bone formation and fibrosis within scala tympani[9].

The ideal situation would be to preserve all the patients existing hearing, enabling maximization of electroacoustic stimulation. To achieve this aim, trauma to the cochlea has to be controlled, and minimized, at all stages of the implantation process.

The aim of this research is to compare the effect on the cochlea of human and robotic cochleostomy formation. An ideal cochleostomy would minimize the 3 areas of trauma associated with this step.

- Vibrational trauma through the drilling process appears to be related to the force of drilling, controlling this force will minimize the vibrational trauma sustained by the cochlea.
- The noise trauma can be minimized by drilling at lower speeds[10]
- The envisaged trauma caused by breaking through the endosteal membrane with a running burr[6].

The force controlled smart drill produced by the authors[11], controls force during the drilling process by manipulating the linear movement (out to in) of the drill, this dictates the force of the burr on the bone and therefore the force can be kept constant, within strict limits. By sensing the changes in force and torque transients during the drilling process, the smart drill can reliably stop on the interface of bone and soft tissue, preserving the endosteal membrane. This process also minimizes any jolting of the burr caused by the initial impact of a running burr against the bone. Our aim is to analyze whether the use of this drill will minimize the disturbances within the cochlea.

Methods

Autonomous drilling robot

The autonomous drilling unit consists of 3 parts (Figure 1).

1. The drilling unit and linear actuator
2. The arm and theatre mount
3. Computer

Figure 1: Autonomous drilling robot

The drilling unit consists of 2 specially commissioned electrical motors, one for the drill and one for the linear actuator (power to the forward motion of the drill). A 1.0mm diamond paste burr was used. The drill speed was 700revs/min, the linear actuator advanced the drill forward at 0.1mm/s. The drilling unit is attached to a snake arm which is locked once the drill is in position. The drill bit is advanced onto the promontory, once the surgeon confirms the trajectory of drilling, the autonomous process is begun. The drilling unit is entirely controlled by the computer, with the surgeon retaining executive control. The computer analyses the force and torque imparted onto the drill bit in real time (Figure 2) to discriminate the state of the tissue-toolpoint interaction from which actuation strategies are selected.

Torque is proportional to the surface area of burr in contact with the bone and therefore rises steadily as the drill advances forward. Once the burr is 1 radius into the bone the maximum cutting surface area is in contact with the bone and hence an equilibrium point is reached (point A on Figure 2 and Figure 3). After this point the torque is constant. Initially the force rises steadily as it penetrates the bone because the linear movement of the drill is slightly faster than the cutting speed. The axial drill force is limited to 2N. By maintaining this maximum safe working can be assured as unacceptably high force levels leading to premature penetration through failure of the tissue can be avoided.

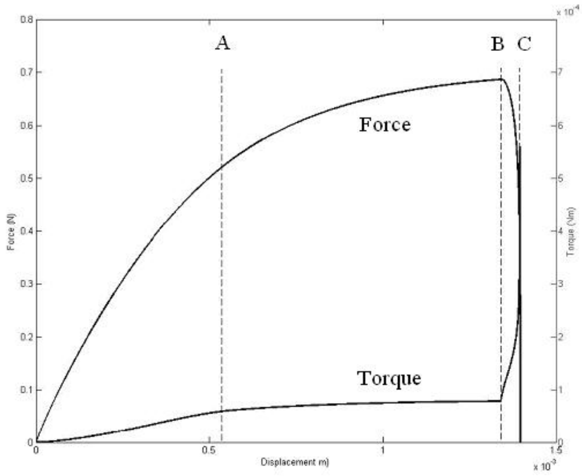

Figure 2: Graphical representation of the force and torque during the drilling process. Point a – the point at which the burr is 1 radius into the bone. Point b – the start of breakthrough. Point c – complete hole formed

At the beginning of breakthrough, point B (figure 2 and figure 3), the central tip of the drilled hole becomes sufficiently thin that it is deflected medially. This leads to a sudden drop in the reactive force at the drill bit. This enables the burr to cut bone with its side rather than the tip and hence increases the cutting rate, generating a sharp increase in torque. The combination of a drop in force and a rise in torque is indicative that the process leading to breakthrough has begun. We used a control strategy to stop the burr when a force drop of 10 units was coupled with a torque rise of 10 units.

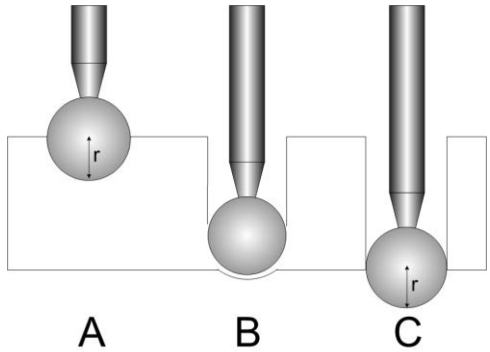

Figure 3: Diagrammatic representation of the stages of the drilling process. Point a – the point at which the burr is 1 radius into the bone. Point b – the start of breakthrough. Point c – complete hole formed.

Measurement of disturbances within the cochlea

To determine the effect of performing a cochleostomy on the cochlea, an analysis of the endosteal membrane movement at a site distant from the cochleostomy formation was performed. Perilymph movement and pressures changes, within the scala tympani, as a result of drilling will be detectable by measuring the scala tympani endosteal membrane movement at a distant site as the effects will occur throughout the scala tympani. The movement of the endosteal membrane is a direct representation of the underlying pressure changes within the scala tympani. High velocity of membrane displacement reflects greater pressure changes within the scala tympani and hence greater potential trauma.

Laser Vibrometery

A laser vibrometer offers a non contact method of assessing the movement of a surface, this has the advantage over contact systems in that it avoids altering the dynamics of a system. It uses the Doppler effect theory, when light is shone at a reflective moving surface, the frequency and phase of the backscattered light is altered compared to the original beam. Detection and analysis of the back scattered light can determine the movement of the test object as the characteristics of the motion are completely contained within the backscattered light. Within a laser vibrometer a high precision interferometer detects the minute frequency shifts of the back scattered laser light. The Interferometer combines the back scattered light from the moving test object with a reference beam of light to create a superposition of light revealing the Doppler shift in frequency. Signal processing and analysis provides the velocity and displacement of the test object.

Test specimens

Porcine cochlea's were chosen as the phantom test cochlea as they have a similar structure to a humans[12]. The cochlea's were harvested from a porcine temporal bone (Middle White breed). and fixed into a custom built test bed capable of fitting in the microscope used to focus the laser vibrometer. The test bed was designed to ensure the cochlea remained stationary during the drilling process.

Experiment set up

Figure 4 demonstrates the experimental set up. A third window to the cochlea was performed on the far anterior aspect of the basal turn of the cochlea, 9mm anterior to the anterior lip of the round window Figure 5. The laser vibrometer will be aimed at the endosteal membrane in this window to assess membrane displacement during cochleostomy formation. To ensure accurate measurements of membrane deflection during the drilling process, the endosteal membrane in the third window must be intact after bone removal to maintain closed fluid chambers in the cochlea. To ensure this the window was created with the autonomous smart drilling robot[11] discussed drilling section.

For the laser vibrometer to successfully analyse the back scattered light, the test surface must be reflective. To enable reflections from the endosteal membrane in the third window, 0.1ml of metallic paint was introduced onto the endosteal membrane. This provided the laser vibrometer sufficient backscattered light to successfully perform the analysis of movement.

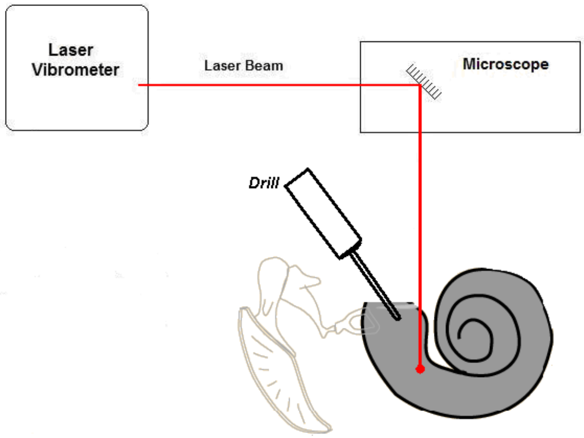

Figure 4: Experimental set up

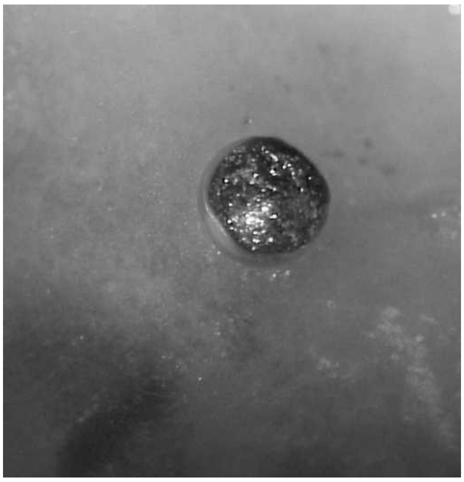

Figure 5: Third window with reflective particles

Drilling strategies

6 cochleostomies were performed, 3 in the handheld group and 3 in the robotic group.

The handheld cochleostomies were performed by a 1mm diamond paste burr turning at 10,000 rev/min. No attempt was made to preserve the underlying endosteal membrane. The robotic drill was performed with the robot attached to a snake arm, a bony cochleostomy was created at the drilling speed of 700 rev/min, the endosteal membrane was subsequently opened with a needle.

Data Analysis

A Students t-test was performed to analyse whether the was a significant difference between the 2 groups.

Results

The robotic drilling process preserved the endosteal membrane in all 3 cases, tested with visual inspection of the membrane. The membrane was subsequently opened with a pick. Figures 6,7 and 8 demonstrate the velocity of membrane displacement against time during the handheld and robotic cochleostomy formation and the membrane displacement associated with opening the endosteal membrane with a pick. Drilling transients during the robotic cochleostomy process are displayed in figure 9. Table 10 presents the mean and peak membrane displacements during both robotic and human cochleostomy formation.

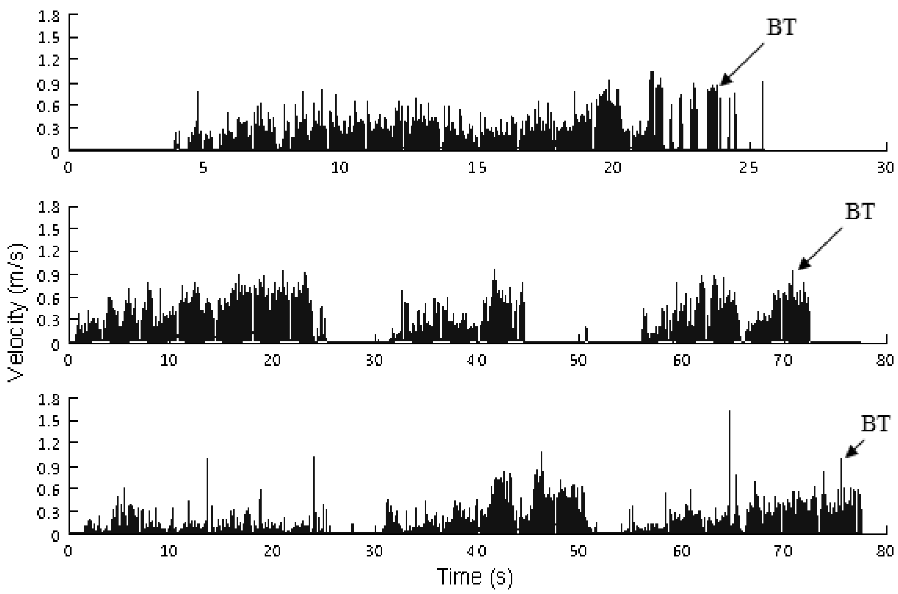

Figure 6: Velocity of endosteal membrane movement during human cochleostomy formation. BT - breakthough

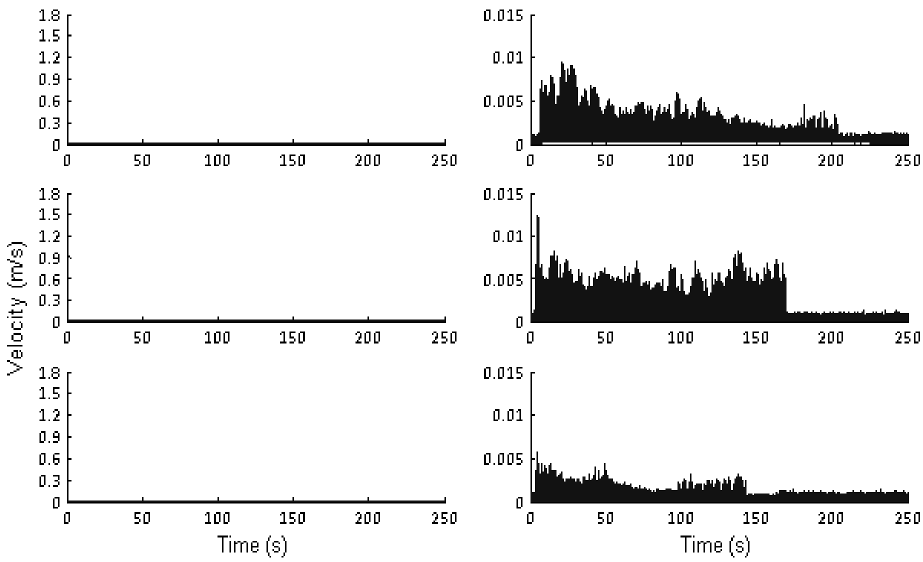

Figure 7: Velocity of endosteal membrane movement during robotic cochleostomy formation. (graph on right with adjusted velocity scale)

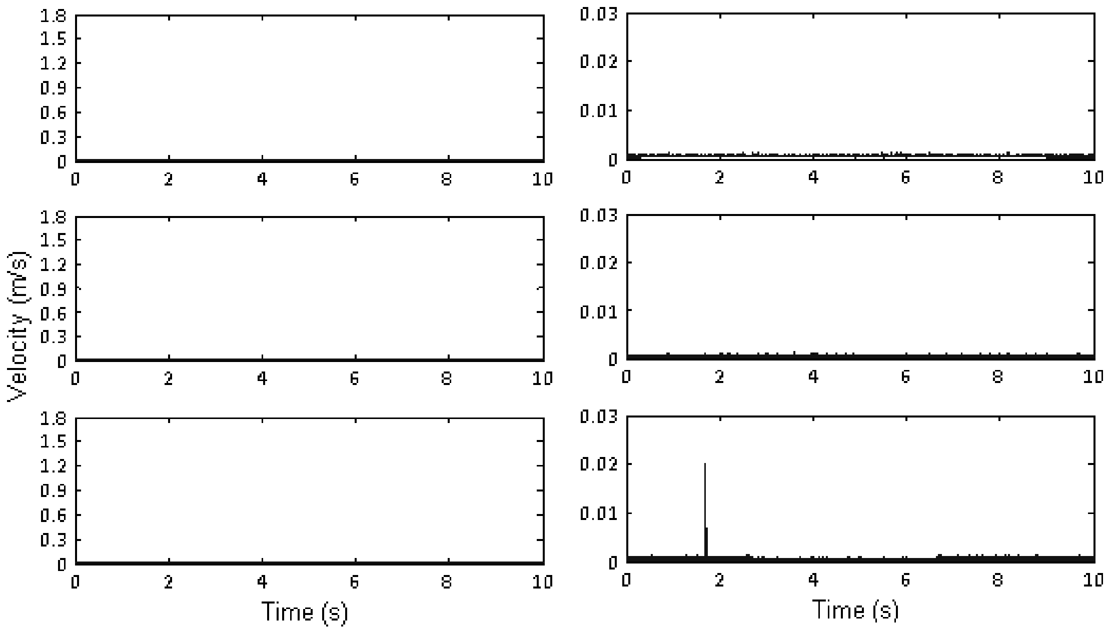

Figure 8: Velocity of endosteal membrane movement during needle opening of endosteal membrane. (graph on right with adjusted velocity scale)

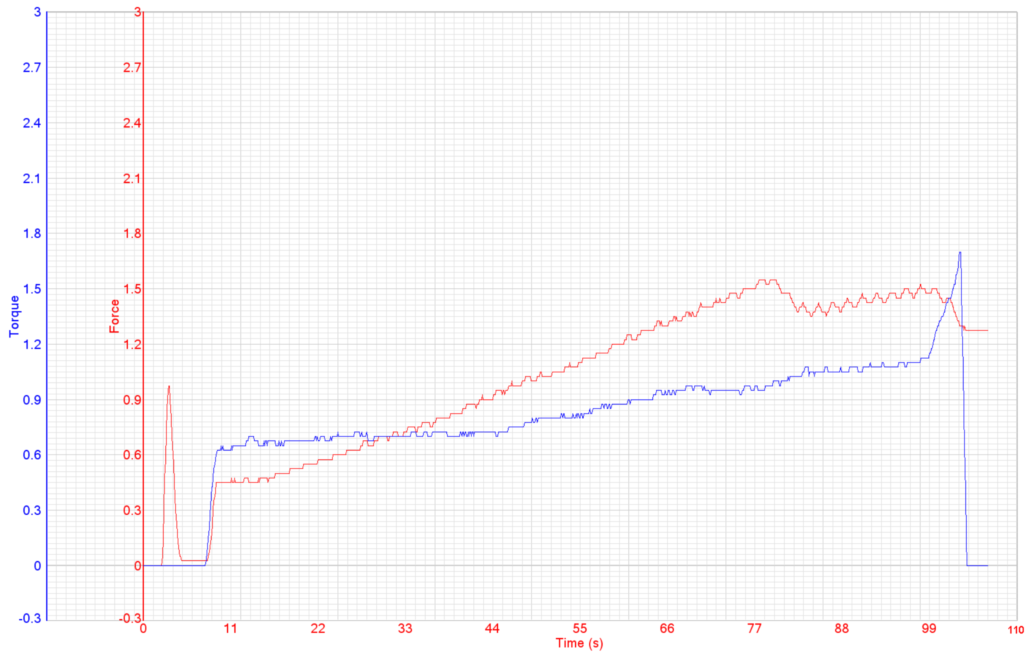

Figure 9: Force (red) and torque (blue) transients during the robotic drilling process

Table 1: Table of average and peak endosteal membrane velocity during robotic and human cochleatomy formation

Robotic Drilling		Manual Drilling	
Mean (m/s)	Peak (m/s)	Mean (m/s)	Peak (m/s)
0.0024	0.0094	0.049	1.0523
0.0026	0.0123	0.0555	0.9575
0.002	0.0057	0.0287	1.6383

The velocity of movement of the endosteal membrane during manual cochleostomy is approximately 20 times higher on average and 100 times different in peak velocity, than for robotic cochleostomy. The process of breakthrough with a running burr into the scala tympani did not appear to be any more traumatic than the human drilling process itself. Once the robotic drilling process was complete, opening the membrane with a pick resulted in no discernable membrane movement on 2 occasions and a 0.02m/s disturbance on one occasion.

A students t-test demonstrates a significant difference between the groups both in terms of the peak disturbance ($p = 0.00478$) and the mean disturbance ($p = 0.00647$).

Discussion

This experiment has revealed some unexpected results. Whilst we expected the force controlled drilling robot to cause less disturbance to the cochlea, we did not expect the difference to be quite as stark. When we analyse the factors that make this possible we discover that these findings may have implications for drilling technique. The robotic device is able to ensure that a constant force is applied from the burr to the bone at all times, it achieves this by controlling the linear displacement of the robot to ensure that drill advances or retracts in response to the bone depending on drilling characteristics. Human drilling usually involves many impacts onto the bone, one with each sweep. On application of pressure the bone will move away from the burr, but will also bounce back, leading to an increase again in the force applied into the bone. As bone is removed the forces will continually alter, these forces are below the range controllable by humans.

A further factor that is thought to be important is the approach to drilling. The robotic drill, works perpendicular to the bone with the force being transmitted directly down the shaft of the drill to the force sensor, this subsequently manipulates the linear movement of the drill to ensure that a constant, predefined, force is delivered at the drill tip (Fig 9). In human drilling, the point of contact of the burr and bone is at right angles to the drill shaft. This method is used to avoid inadvertent penetration of the underlying membrane. Drilling in this manner will have 2 main effects:

1. Force is predominantly perpendicular to the drill shaft, leading to flexing of the shaft during the drilling process, resulting in recoil of the shaft as bone is removed, causing spikes in the force delivered to the bone.
2. With robotic drilling the tip of the burr is used which not only stabilises the bone, but will avoid differing shapes and sizes of diamond paste to come across the bone. With human drilling there will be a continual, asymmetric removal of bone which will add to the force variability.

Analysis of the breakthrough results reveals if the endosteal membrane is preserved and the scala tympani is opened with a knife, there is minimal or even absent membrane displacement during this process (figure 8). Human drilling revealed that the disturbances created during breakthrough were similar to that during the drilling process (figure 6). Opening the cochlea with a running burr continues the current level of trauma to the cochlea as the drilling process. Whilst surgeons performing hearing preservation cochlear implantation regularly attempt to preserve the endosteal membrane and in doing so may reduce accidental damage to the basilar membrane and the osseus spiral ligament. We have demonstrated that the vibrational forces involved in breakthrough are similar to that of the drilling process at 10,000 revs/min, and so attention needs to be directed at controlling disturbances during the drilling process in addition to breakthrough.

For HPCI to become a routine addition in the armoury of an implantation otologist, the results of surgery need to be repeatable and successful, i.e. preserving an accepted amount of hearing in a high proportion of cases. Whilst this is the case in some series[11], these results are far from universal[2]. Implantation appears to be possible with only very mild loss of hearing, 0.7 dB[4]. Currently the methods used to reduce hearing appear to be a combination of soft surgery[6], round window insertion which regularly requires some bone work and may lead to misplaced electrode[8] and the use of a short electrode[1]. Whilst these methods may in individual cases improve the outcome, we believe that all steps of the implantation procedure need to be analyzed and steps taken to minimize trauma

Conclusion

Our experiment has revealed that controlling the force of drilling during cochleostomy formation and opening the endosteal membrane with a pick will minimize the mean trauma sustained by the cochlea by a factor of 20 ($p = 0.00647$). The impact of controlling these events on residual hearing levels is unknown but it is likely that minimizing trauma at all stages of the procedure will lead to better post operative hearing level.

Mechanisation of key steps in a procedure represents an ideal method of making the results of the operation more reproducible across different health care systems.

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Potential Solutions

Chapter 4

Introduction to Chapter 4

Chapters 2 and 3 have demonstrated the need for robotic solutions in hearing preservation cochlear implantation. The first paper in chapter 4 assesses otolaryngology in general and identifies potential procedures that may benefit from the use of smart tools and suggests potential robotic solutions.

Papers 2, 3 and 4 describe the development of an autonomous surgical drilling robot capable of performing a bony cochleostomy whilst preserving the underlying endosteal membrane. The engineering concepts underlying the project are discussed and porcine and human trials are described.

ENT challenges at the small scale

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Int J Med Robot.2007; 3(2): 91-96

Chapter 4.1

Abstract

Background:

In this paper we will consider 2 relatively frequently performed operations in the field of Ear, Nose and Throat and consider how they could be improved by using robotic applications. We will consider both currently available robots and propose theoretical robotic solutions.

Methods:

We considered the application of robotic systems for both cochlear implantation and endoscopic sinus surgery. We reviewed currently available robotic systems and identified the ones with potential use in ENT surgery. For aspects of the operation where there is no available technology we have hypothesized how robots could help.

Results:

Three robotic systems were identified with potential usage in ENT, the pathfinder neurosurgical robot, the ACROBOT knee replacement system and the autonomous smart drill for drilling a cochleostomy.

Conclusions:

The challenge for the future of ENT is being able to perform tasks beyond the level of human perception, and abilities. The examples presented here demonstrate that microtechnologies could be used to reduce complications, decrease operating time and improve clinical results.

Introduction

Successfully operating in the field of Ear, Nose and Throat surgery involves working at the very limit of human perception and dexterity. Surgeons are continually striving to identify methods of improving their operative capabilities. The past 30 years has been great improvements in surgical instruments. Some example are the deployment of endoscopy and image guided operating. We are in an era of minimal access surgery where most of the advances have been in improving surgical visualisation and miniaturising surgical tools points. Whilst these improvements have allowed surgeons to perform operations whilst reducing surgical trauma, they haven't necessarily made the surgeon more accurate. There is a limit to human perception and dexterity, beyond this point the surgeon will be unable to improve his/her operating without employing instruments that have a higher degree of accuracy than the surgeon. To make a leap forward in operative success we need to operate beyond the limits of human perception and dexterity.

In this paper we will consider 2 relatively frequently performed operations in the field of Ear, Nose and Throat and consider how they could be improved by using robotic applications. We will consider both currently available robots and propose theoretical robotic solutions.

Materials and methods

We considered the application of robotic systems for both cochlear implantation and endoscopic sinus surgery. We reviewed currently available robotic systems and identified the ones with potential use in ENT surgery.

Results

Two robotic systems were identified from different surgical disciplines with potential usage in ENT. The pathfinder neurosurgical robot and the ACROBOT knee replacement system.

Discussion

Cochlear implantation

Over the past 20 years cochlear implantation has become the standard treatment for the severe to profoundly deaf patient[1]. The operation involves inserting an array of reducing lengths of electrodes into the spiral shaped cochlea (Latin: snail shell). The cochlea is tonotopically organised, sensing high frequency noises at the base of the spiral and low frequency noises at the apex. When the speech processor and receiver are attached to the electrode array, sound received in the speech processor is broken down into its constituent frequencies and presented to the cochlea down the appropriate length of electrode (figure 1). The different length electrodes excite the neurons responsible for different frequencies of sound in the cochlea. This information is transferred to the auditory cortex by the cochlea nerve. The auditory cortex amalgamates this information and enables the patient to hear.

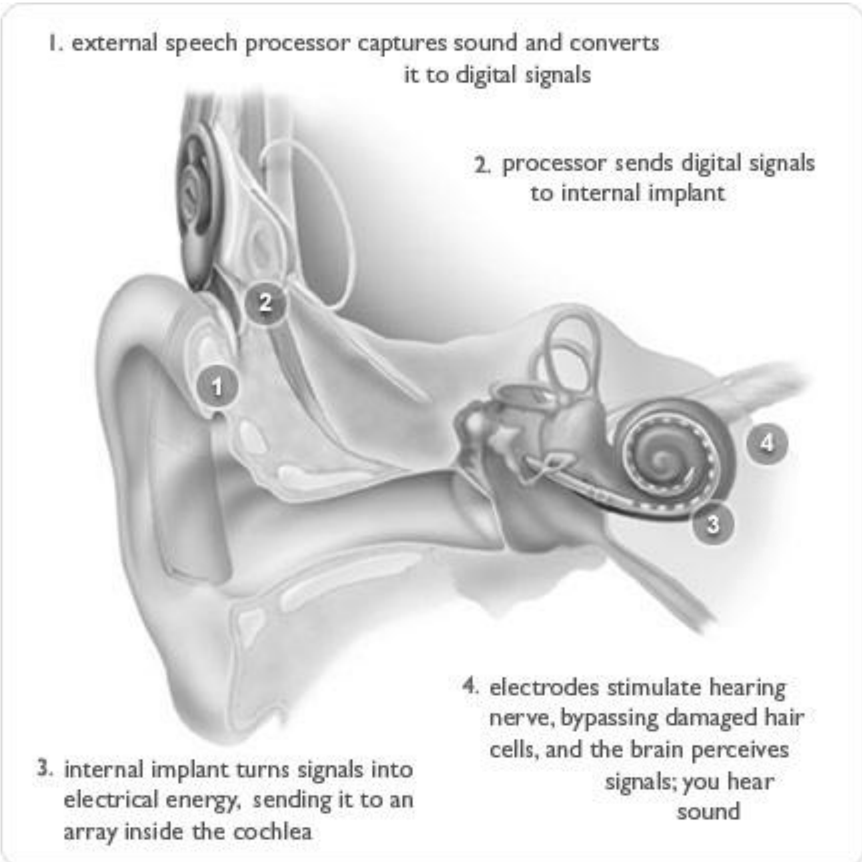

Figure 1: How a cochlear implant works (reproduced with kind permission from Cochlear Europe Ltd)

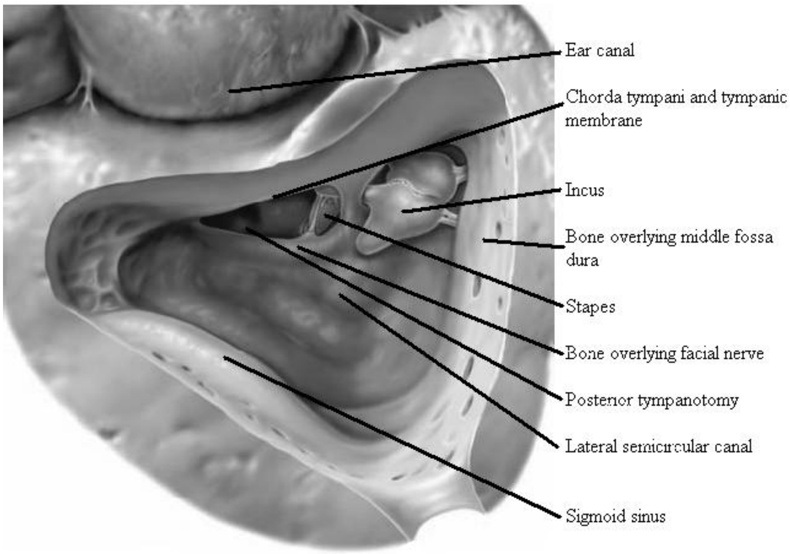

Figure 2: Cortical mastoidectomy and posterior tympanotomy (reproduced with kind permission from H. Hildmann, H. Sudhoff. Middle Ear Surgery, Springer-Verlag Berlin, Heidelberg, New York)

The operation can be broadly separated into 3 sections:

The approach
The cochleostomy
The insertion of the electrode array

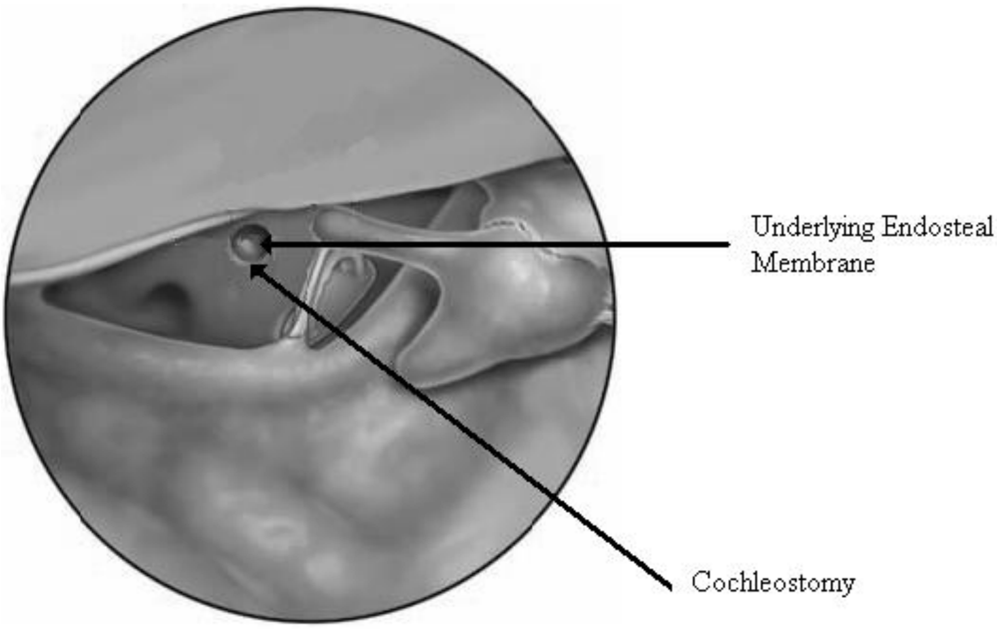

Figure 3: Cochleostomy with underlying endosteal membrane (reproduced with kind permission from H. Hildmann, H. Sudhoff. Middle Ear Surgery, Springer-Verlag Berlin, Heidelberg, New York)

The approach is performed by drilling a cortical mastoidectomy followed by a posterior tympanotomy. A cortical mastoidectomy is an inverted truncated cone drilled into the mastoid bone. The mastoid is the bone located immediately behind the ear and comprises numerous air cells which are in continuity with the middle ear. The mastoid is bounded superiorly by the dura of the middle cranial fossa, inferiorly by the sigmoid sinus, anteriorly by the external auditory canal wall, and the apex by the lateral semicircular canal (Figure 2). The posterior tympanotomy is a hole drilled from the mastoidectomy into the middle ear, it is approximately 4mm in the anterior posterior direction and 2mm medial to lateral. Medially sits the facial nerve, which supplies all the muscles of the facial expression, laterally sits the chorda tympani (responsible for taste in the anterior 2/3 of the tongue) and tympanic membrane (figure 2). The objective of the cortical mastoid and posterior tympanotomy is to provide the surgeon with access to the middle ear to make the cochleostomy (hole through the outer bony wall of the cochlea) and insert the electrode array into the cochlea. The electrode array can then be routed through the mastoid to the receiver which is sat above and behind the ear.

Drilling the cochleostomy appears to be one of the critical steps of the cochlear implantation procedure. On the medial (inner) surface of the bony cochlea wall is a thin membrane (endosteal membrane) (figure 3) under which are the fluids which move in the presence of sound and allow a person to hear. This membrane has to be opened to insert the electrode array. It has been shown that if the underlying membrane (0.1mm-0.2mm thick[2]) is perforated by the drill whilst performing the cochleostomy, rather than opened with a knife, the patient is more likely to experience a decrease in any residual hearing[3]. This is due to the excessive trauma caused by the drill rotating at 12,000 revs/minute in the inner ear. This further damages the hair cells and neurons. If this membrane can be preserved during the drilling process and then opened with a knife, it enables an implant to be inserted as atraumatically as possible and can preserve the patients residual hearing[4,5]. Currently this step of the operation is performed by hand, with the membrane being perforated by the drill in over 60% of cases.

Insertion of the electrode through the cochleostomy and winding the two and a half turns around the cochlea is essentially a blind procedure. The electrode is pre-curved into 2.5 turns, but is initially held straight by an introducer wire. As the implant is inserted the wire is gradually withdrawn allowing the electrode to curve around the cochlea. This rather crude method of insertion is generally successful, we cannot, however, be sure of any further damage being caused by the electrode inside the cochlea.

Potential robotic solutions

Surgical navigation improving the approach to cochleostomy

The purpose of the cortical mastoidectomy and posterior tympanotomy is to form a route from behind the ear into the middle ear for the electrode array to pass, ensuring that none of the previously detailed essential structures are damaged. Use of surgical navigation would enable the surgeon to identify a route from the lateral surface of the mastoid terminating after creating the posterior tympanotomy avoiding all the important structures. A three dimensional reconstructed CT scan could be used by the surgeon to decide on a straight path though which the electrode could be inserted from the lateral mastoid into the middle ear (figure 4). An automated drill that could register itself to the patient's key anatomical features and precisely drill down a predetermined path would reduce both the operating time and the extent of surgery. Similar systems have already been implemented in neurosurgery[6]. The pathfinder robot allows precise targeting of intracranial lesions from reconstructed CT scans. This system offers sub-millimetre accuracy whilst using fiducial implanted markers[7], and the accuracy of the skin markers is continually improving. The robot registers itself with the skin markers on the patient in theatre and then drills down a predefined path into the tumour, this allows biopsies to be taken, minimizing the impact on the patient. This has allowed neurosurgical biopsies to be performed without needing to fit a stereotactic surgical frame to the patients head.

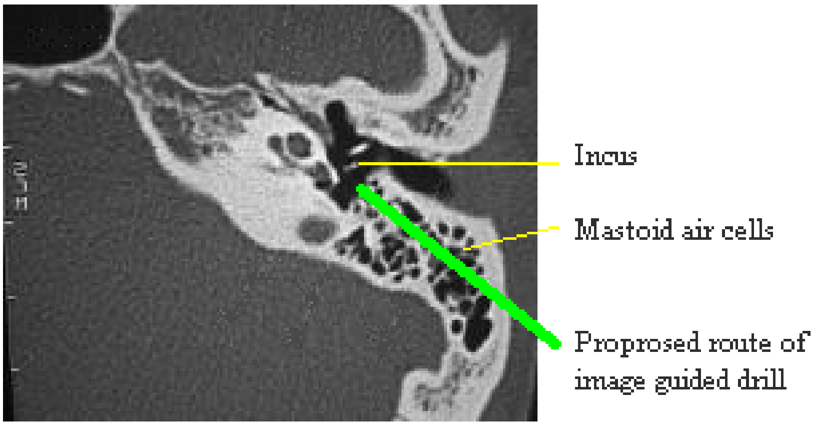

Figure 4: CT planned path for access to the middle ear for inserting a cochlear implant

A surgical navigation system has been trialled on a cadaveric cochlear implantation[8]. This system used both anatomical landmarks and bone implanted fiducials, after pre operative scanning the surgeon identified the important structures he/she wanted to avoid during the operation and the optimal place of insertion of the implant. A microscope with a heads-up display was used to allow the surgeon to see a superimposed view of the critical structures and pre planned implant path, whilst the cortical mastoidectomy and posterior tympanotomy were drilled.

An ideal system would allow the path to be identified pre operatively and a single drill pass could then be used to avoid performing a cortical mastoidectomy and posterior tympanotomy. The accuracy offered by these robots is probably sufficient to perform the access to the middle ear in cochlear implantation, whilst avoiding the surrounding important structures. Ideally skin markers would be used, but the accuracy of this would need to be as good as the implanted fiducials before this could be contemplated. Use of such a system would greatly reduce the time of the operation, thus making the procedure inherently safer.

Autonomous drilling robot with breakthrough detection for performing the cochleostomy

Drilling the cochleostomy appears to be the critical part of the procedure as far as hearing outcome is concerned. The ability to drill a cochleostomy without penetrating the underlying endosteal membrane would minimise alteration to the patients existing hearing. This would allow surgeons to implant patients with poor hearing in high frequencies only (the classic picture with age related hearing loss). The patient would then have their normal hearing mechanism for low frequency sounds and the implant for high frequency sounds. This indication is currently controversial as there is no guarantee that the patients hearing will not be completely lost in that ear, leaving the patient relying solely on the cochlear implant for hearing which has inferior sound quality compared to ‘normal’ hearing.

Our research group has developed an autonomous surgical drilling arm to enable the surgeon to accurately and reproducibly drill a cochleostomy and stop on the membrane without it being damaged[9,10]. The drill works by sensing the force and torque transients imparted on the drill bit throughout the drilling process.

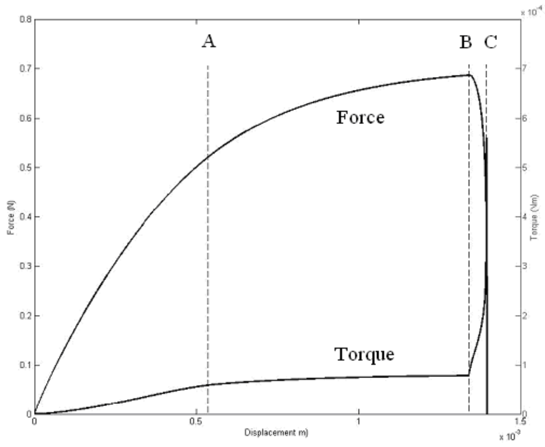

Figure 5: Graph of force and torque during autonomous drilling process

Torque is proportional to the surface area of the burr in contact with the bone and therefore rises steadily as the drill advances forward. Once the burr is 1 radius into the bone the maximum cutting surface area is in contact with the bone and hence an equilibrium point is reached, point A on figure 5 and figure 6. After this point the torque is constant. Initially the force rises steadily as it penetrates the bone because the linear movement of the drill is slightly faster than the cutting speed. The axial drill force is limited to 1.5N.

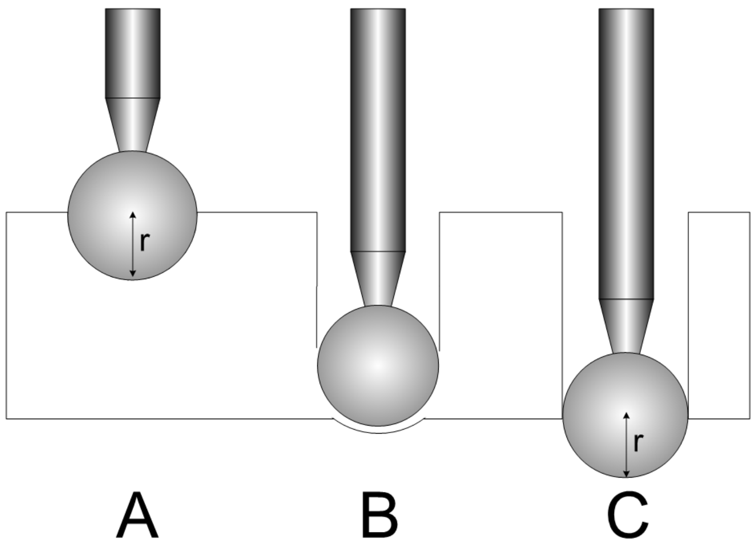

Fig 6: Position of drill at the different stages of cochleostomy drilling

At the beginning of breakthrough, point B (fig 5 and fig 6), the central tip of the drilled hole becomes sufficiently thin that it is deflected medially. This leads to a sudden drop in the reactive force at the drill bit. This enables the burr to cut bone with its side rather than the tip and hence increases the cutting rate, generating a sharp increase in torque. The combination of a drop in force and a rise in torque is indicative that the process leading to breakthrough has begun. A control strategy is then implemented to stop the drilling process at this point and the drill is backed off until it imparts no force on the bone.

Figure 7 demonstrates the completed cochleostomy with an intact endosteal membrane. The surgeon is now able to open the membrane with a knife to insert the electrode array. Using this autonomous drill, the surgeon can ensure that the membrane is not opened with the burr and therefore residual hearing is preserved in patients.

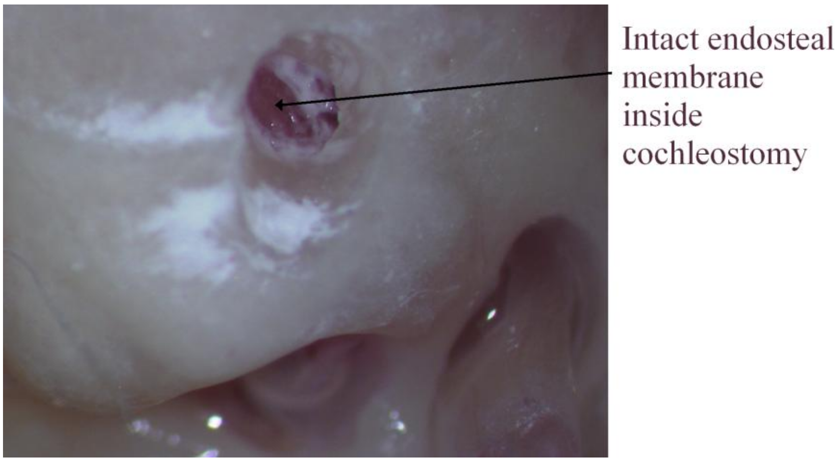

Figure 7: Completed autonomous cochleostomy with intact membrane

Electrode array insertion

Insertion of the electrode array is a freehand procedure reliant on the pre-curved array following its way around the cochlea. The impact of this insertion on residual hearing is unknown. There are currently no other described methods of inserting the electrode. Trauma could be sustained by the cochlea due to the direct force of the electrode array, or by the pressure changes imparted in the cochlear by introducing an array into a closed system. We believe there are potential methods to decrease the trauma sustained by the cochlea.

If the surgeon was able to visualise or ‘feel’ forces imparted on the electrode array and then guide the array around the path of least resistance, he/she would have been able to place the electrode whilst minimizing the trauma to the cochlea. This may improve the hearing results of the cochleostomy as it would minimise the trauma to the cochlea.

Flexible digits have been designed and applied both in engineering and medically. The original fully flexible endoscope was inverted by Hirschowitz in 1956[11]. This allowed movement of the tip of the endoscope and hence visualisation of the whole of the internal aspect of a hollow organ was possible. A miniturized flexible digit with visualisation (the scala tympani being about 1mm^2 in cross section) would allow the tip to be manoeuvred through the hollow portion of the scala tympani. This may be technically very difficult as some source of illumination would also be needed to get an adequate view. The degree of control needed is probably very small, if the tip could be manoeuvred up to 30º then the surgeon could probably insert the array without directly abutting the outer or inner bony walls.

Another potential solution would be to fit the electrode array with sensing elements at the tip which could feed back onto a monitor informing the surgeon whether the tip was against the solid outer cochlea wall or in the middle of the hollow scala tympani. This would mean that a light source and fibre optics are not needed. Again control of the digit of up to 30º would be needed.

Either of these methods would decrease the direct force trauma caused by the electrode array on the cochlea.

Limiting the effect of pressure changes in the cochlea could be performed by having an outlet channel in the electrode array, with a pressure gate on it which would automatically open when the pressure rises above a pre determined level.

The result of using robotic applications in the cochlea implant procedure, we believe, would make it a quicker, safer, less traumatic operation with greater clinical results

Endoscopic sinus surgery

Operations on the nasal sinuses are usually performed to help the management of chronic rhinosinusitis (CRS). The nasal sinuses drain, by small ostia (approximately 1-2mm^2), into the nasal cavity. Inflammation of the lining of the sinuses, due to allergy or infection, may lead to blockage of the sinus ostia with resulting retention of infected products. This leads to decreased ventilation of the sinuses and results in the patient experiencing nasal blockage, facial pains, decreased smell and nasal discharge. The aim of operating on the nasal sinuses in CRS is to open up the ostia of the sinuses to ensure aeration of the sinuses, this has a dual effect. It allows adequate drainage of the sinuses, which may alone be sufficient to settle the inflammation of the sinus lining down and it allows entry of topical steroid sprays or drops into the sinuses to treat the diseased mucosa. It is therefore important to be able to open up all the diseased sinuses.

The complications of endoscopic sinus surgery are rare but very serious. The ethmoid sinuses are bounded laterally by the orbit and superiorly by the anterior cranial fossa, traversing their upper border are the anterior and posterior ethmoidal arteries (figure 8). The sphenoid sinus has the optic nerve and carotid arteries going through it and is also bounded superiorly by the anterior cranial fossa. Surgical navigation is already possible in sinus disease[12]. These systems allow the surgeon to locate their position within the sinuses and nasal cavity to within 1.5mm[13]. After registration of the patient with the computer in theatre, the surgeon has, in addition to the endoscopic view, a view of the CT scan. This allows a view of the instrument tip on the scans in the coronal, sagittal and axial planes whilst operating. This gives the surgeon, the knowledge of exactly where he is in relation to the boundaries of the sinuses. The surgeon is still performing the operation freehand, and could still transgress these outer limits of the sinuses.

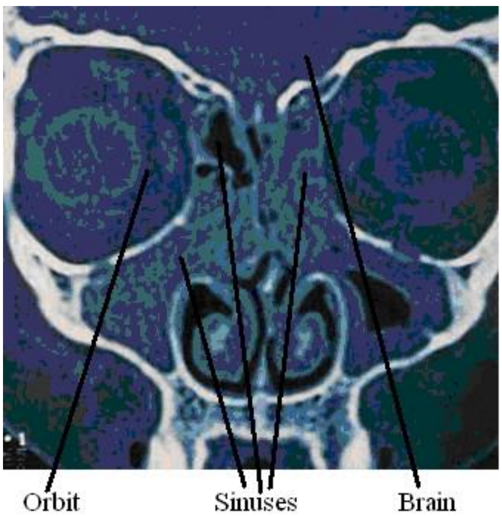

Figure 8: CT scan demonstrating the boundaries of the sinuses

Potential robotic solutions

Any new method of operating on the sinuses need to be aimed at decreasing the rate of complications whilst allowing sufficient disease clearance to improve symptoms.

Surgical robotics could help a surgeon in 2 respects. If a specific sinus is to be targeted for localised disease, this could be identified by a preoperative CT scan. A safe path from the nasal vestibule into the disease sinus could be identified. The information would then be downloaded to a robot which would register itself to the patient's anatomical features. After registration the robot would drill down a pre-defined path into the diseased sinus without damaging any of the delicate surrounding structures.

More often a more generalised approach is necessary, this involves opening up the majority of the sinuses but not transgressing, the outer, bony limits of the sinuses and therefore not damaging the eye or brain. Ideally the surgeon needs a system which permits free movement of operating instruments within the nose, allowing the operation to progress at the surgeon's discretion, but, would stop the surgeon introducing the instrument past any predefined borders. This would offer a distinct advantage over the existing surgical navigation.

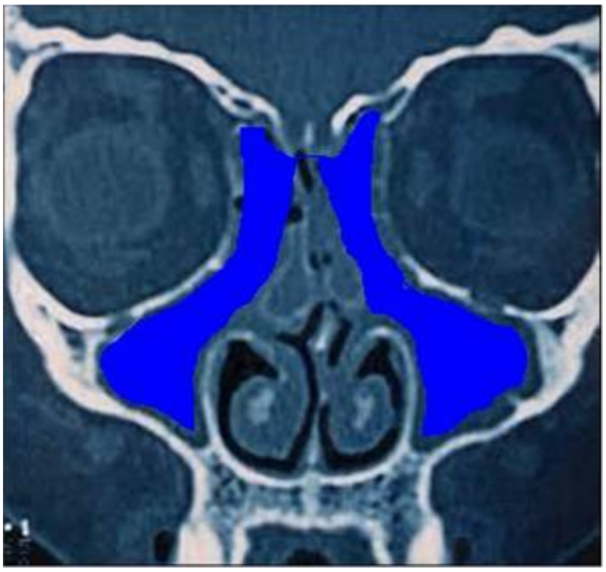

Figure 9: CT scan showing pre-operative highlighted area in which surgeon is free to move instruments

The structures the surgeon wishes not to breach can be identified on pre operative CT scanning (figure 9). This information could be down loaded to a robot that attaches to the surgeons operative instrument. After robot registration with the patients key anatomical features, the surgeon would have free movement of the instrument in the safe areas of the nasal cavity. As the surgeon approaches the predefined limits to his resection a constraint system would be activated ensuring the surgeon cannot introduce the instrument through these boundaries. This system would enable the surgeon the confidence to fully eradicate disease without the concern of causing more damage. A similar system is already in use for unicondylar knee replacements[14], the 'Acrobot' is an active constraint robot which allows a surgeon to delineate, pre-operatively, the volume of bone he wishes to drill during the operation. This allows the surgeon to ensure that the exact amount of bone is removed to accurately fit the required prosthesis. Intra-operative, after registration of the acrobot to the patient, the acrobot is attached to the drill. The drilling is then performed by the surgeon, up to, but not beyond the pre defined boundaries. This has led to greater accuracy of placement of unicondylar knee replacements.

Both of these robotic applications for sinus surgery would allow the surgeon to eradicate the necessary disease whilst ensuring the boundaries of the sinuses are maintained.

Conclusion

The challenge for the future of ENT is being able to perform tasks beyond the level of human perception, and abilities. The examples presented here demonstrate that microtechnologies could be used to reduce complications, decrease operating time and improve clinical results.

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A surgical robot for cochleostomy

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Chapter 4.2

Abstract

In this paper a robotic micro-drilling technique for surgery is described. The device has been deployed in cochleostomy, a precise micro-surgical procedure where the critical stage of controlling penetration of the outer bone tissue of the cochlea is achieved without penetration of the endosteal membrane at the medial surface. The significance of the work is that the device navigates by using transients of the reactive drilling forces to discriminate cutting conditions, state of tissue and the detection of the medial surface before drill break-out occurs. This is the first autonomous surgical robot to use this technique in real-time as a navigation function in the operating room and unlike other fully autonomous surgical robotic processes it is carried out without the use pre-operative data to control the motion of the tool. To control tool points in flexible tissues requires self-referencing to the tissue position in real time. There is also the need to discriminate deflections of the tissue, tissue interface, involuntary patients/ tissue movement and indeed movement induced by the drill itself, which require different strategies to be selected for control. As a result of the design of the final system, the break-out process of the drill can either controlled to the required level of protrusion through the flexible interface or can be avoided altogether, with the drill bit at the medial surface. This enables, for the first time, the control of fine penetration with such great precision.

Introduction

Over the last 20 years, robotic surgery has made its mark as a precise means of tool deployment in surgical procedures. The majority of applications have focused on the control of tools on trajectories defined using preoperative scan data. These pre-determined trajectories are appropriate where tissue movement between scanning and surgical therapy processes can be considered insignificant, or within acceptable limits. This level of assistance has its value in many procedures, however more complex tool paths and variations in strategy are required in many other procedures that will benefit from the precise nature of robotic manipulation technology[1,2] are different example systems. To an extent this has been achieved by introducing the surgeon operator into the control loop, where master-slave systems have attempted to harness the decisions on interpretation of the state of tissue tool interaction, the formulation of strategy by the surgeon and the response and accuracy of the robotic device. 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.

In addition to automatic and master-slave robotic systems in surgery there is a need for sensor-guided robotic devices that interpret or react to tissues in order to control the state of interaction relative to the target tissue. These can 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. Sensory guided robots can be used to control penetration through flexible tissues and to control relative motion to moving or deforming tissue targets and interfaces as in micro-surgery. In such applications, precision would otherwise be compromised by deflection induced by the action of tool forces. The micro-drilling robotic system is the first example of this new class of autonomous surgical tool applied in practice. 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 used to demonstrate the technique, the design of elements of the micro-drilling system, the sensing technique and a description of clinical trials.

Preparing a cochleostomy

Cochlear implantation has become the standard treatment for severe to profoundly deaf patients over the last 20 years[3]. This implant is within the inner ear hearing organ. 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 Figure1. 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 flu-ids with bone dust, will lead to a reduction in residual hearing and will increase 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 complete the hole without penetrating the endosteal 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 into the fluid space of the cochlea during the drilling process.

Access to the cochlear surface is prepared by the surgeon. Normally this is behind the ear and typically results in a hole 10mm in diameter and 15mm deep, narrowing towards the drilling site. Of importance is the need to maintain visual focus at the working site of the binocular surgical microscope and of the 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.

The implant is finally inserted through a pool of antiseptic gel at the cochleostomy to maintain sterile conditions. By using the micro-drill, it is possible to avoid the ingression of drilling debris and to avoid penetration into the cochlear before the antiseptic gel is applied.

In the operating theatre, the drilling system has been constructed to observe high integrity on sterility to be expected of invasive surgical instruments. Other practical measures include earth linking, minimising the number of cables to one USB connection and the minimum set-up time in the operating theatre.

The autonomous system

The system function diagram of figure 2 shows the principal functions of the drilling system. The drill point is interacting with flexible bone tissue. Sensory force and torque transients are interpreted to infer the movement of tissue and patient, and the state of cutting conditions, drill bit and tis-sues. Using these states as information, the system is able to discriminate different tissue behaviour and, most important, to identify the tissue break-through process immediately before it occurs. To achieve precise results, the system automatically selects and implements control strategies based on this information. The drill unit comprises precision linear feed actuator, drill drive sys-tem and sensing elements; The flex and lock arm, incorporating fine and coarse adjustment; The hard-wired unit integrating sensing and control functions; The user interface is via the hand-held remote unit and the computer display screen.

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. The drilling process is controlled through the hard-wired unit either by using the computer or by using the hand held remote unit.

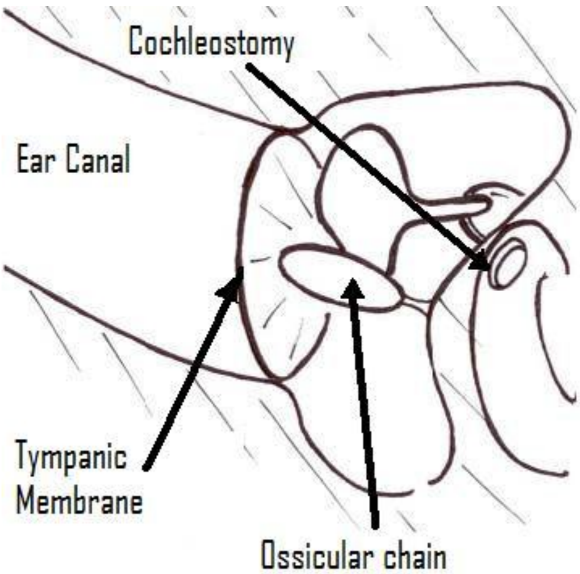

Figure 1: Diagram illustrating the anatomy of the ear and location of a cochleostomy

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. It is then locked in position. Automatic operation of the system is then triggered by using the hand-held remote unit.

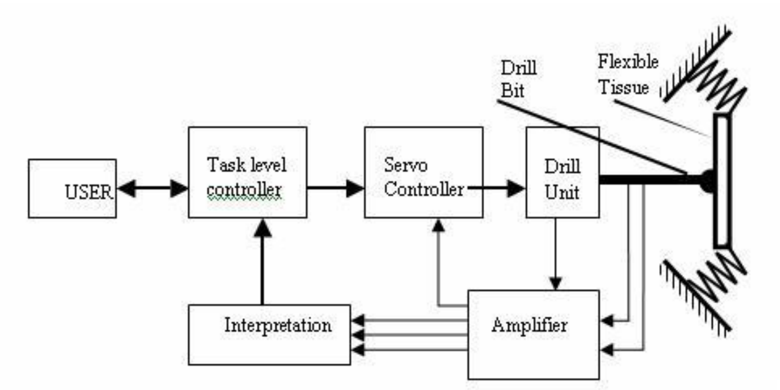

Figure 2: System function diagram

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. The drilling then stops with the drill bit retracted until the feed force reduces to zero, such that the drill tip rests on the base of the drilled aperture. The choice is then made by the surgeon to penetrate by the minimum displacement to achieve a fully formed hole or to re-tract leaving a minimum thickness of bone tissue. At any point the drill bit can be retracted for visual inspection and drilling can then recommence at the same point.

Drilling force characteristics and sensing the medial surface

The process of drilling through the bone tissue wall of the cochlea can be divided into stages based on the geometrical description of the drilling process. The dividing lines between these are:

a) the start of drilling;
b) the start of drill bit cutting across the full diameter of the drill bit;

c) the start of equilibrium drilling with the drill tip fully in the tissue;
d) the start of breakthrough;
e) the completion of breakthrough.

Depending on the compliance, the drilled material thickness and the cut-ting conditions, b) and d) may occur together and c) may not occur at all.

The start of breakthrough and its identification are key to controlling 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. Compliance results in the deflected drilled material returning to its natural position, potentially leaving the drill bit protruding significantly beyond the far surface.

The rate at which a burr drill bit progresses in the bone tissue is dependent upon factors such as the drill rotational velocity, cutting efficiency, friction coefficient and feed force. A model combining these factors was shown by[4] to provide a close representation of the drilling characteristics in bone tissue, constant feed velocity, and for low shaft speeds in the order of 2Hz. Figure 3 shows drill bit feed force and torque plotted as a function of displacement when drilling with constant feed velocity.

These force characteristics are typical of drilling in practice. When drilling, the system monitors the force and torque transients at the tool point and interprets these in real-time. The relationship between the transients are used to distinguish between different states and phenomena, such as patient or tool movement, the approach to tissue boundaries, tissue hardness and stiffness, and drill break-through. Using part of this information it is possible to interpret the critical break-through event before it occurs and to automatically control drill tip penetration to the desired level through the flexible tissue interface, or to avoid protrusion completely. The method is reliable, is independent of force level and is able to compensate for axial deflection of the tissue, patient or drilling unit.

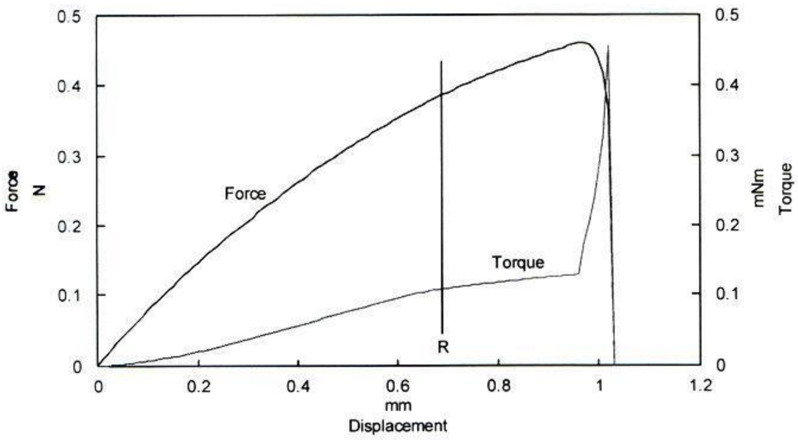

Figure 3: Typical drilling force and torque transients

Micro-drilling in practice

Leading up to clinical trials, other tests were carried out on porcine and cadaver specimen. This tested the system in tissues of similar properties to those in live patients and tested the suitability of the configuration of the flex arm and micro-drill unit in a set-up similar to that of the operating room. Trials under microscope are shown in Figure 4. Figure 4a shows the drill bit entering the cochlear and Figure 4b shows the resulting cochleostomy where the tissue has been fully perforated, leaving the inner membrane intact.

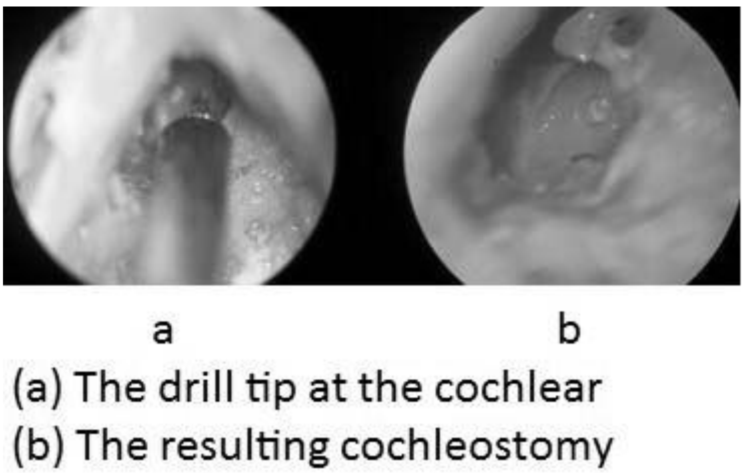

Figure 4: The preparation of a cochleostomy in pre-theatre trials

Following the proving trials, the robotic micro-drill was used autonomously in theatre guided by sensory information on tissue state in order to discriminate the approach towards the flexible tissue interface, figure 5. It is the first example of a robotic surgical tool being used in a totally autonomous mode of operation in this way, and achieved excellent results.

Figure 5: The micro-drilling unit in the operating theatre

Conclusion

The configuration and method of the first fully autonomous surgical robot applied in clinical practice, discriminating the working conditions at the tool-point in order to control tool point-tissue interaction precisely through automatically selecting the appropriate control strategy has been described in this paper. The sensing and controlling functions of the micro-drilling device are implemented in hardware. The method for sensing the critical state of breakthrough of flexible tissue interfaces operates by the detection of reliable and simultaneous features in the feed force and torque transients. This level of automated perception enables the system to automatically control the breakthrough process in flexible tissues such that drill tip protrusion can either be avoided or controlled to the desired value.

In cochleostomy, this paper has shown a resulting cochleostomy produced by the drill that is able to penetrate the bone tissue of the cochlear leaving the endosteal membrane intact. This maintains sterility and avoids ingression of drilling debris. Fewer complications and higher performance in patient residual hearing are expected as a result of this approach compared with conventional methods.

Acknowledgements

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An Autonomous Surgical Robot for Drilling a Cochleostomy – Preliminary Porcine Trial

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Preliminary Porcine Trial. Clin Otol. 2008; 33(4): 343-347

Chapter 4.3

Abstract

Objective:
To produce an autonomous drilling robot capable of performing a bony cochleostomy whilst minimizing the damage to the underlying cochlear endosteum.

Design:
In this laboratory based study, a robotic drill was designed to measure the changes in force and torque experienced by the tool point during the drilling process. This information is used to predict the point of breakthrough and stop the drill prior to damaging the underlying endosteal membrane.

Setting:
Aston University.

Participants:
5 porcine cochleas.

Main outcomes measures:
An assessment was made of whether a successful bony cochleostomy was performed, the integrity of endosteal membrane was then assessed.

Results:
The autonomous surgical robotic drill successfully performed a bony cochleostomy and stopped without damaging the endosteal membrane in all 5 cases.

Conclusions:
The autonomous surgical robotic drill can perform a cochleostomy whilst minimizing the trauma to the endosteal membrane. The system allows information about the state of the drilling process to be derived using force and torque data from the tool point. This information can be used to effectively predict drill breakthrough and implement a control strategy to minimize drill penetration beyond the far surface.

Introduction

Cochlear implantation has become the standard treatment for severe to profoundly deaf patients over the last 20 years[1]. The creation of a cochleostomy is one of the key steps in the procedure.

Our aim was to produce an autonomous drilling robot capable of performing a cochleostomy whilst minimizing the damage to the underlying endosteum. This could offer many potential advantages over human drilling:

1. Protrusion of the drill tip through the endosteal membrane will damage the osseous spiral lamina and basilar membrane and is likely to lead to a reduction of residual hearing[1]. The ability to guarantee that the endosteal membrane is not perforated during the drilling process, and is opened by a needle, will minimize damage to the membranous cochlea, preserving residual hearing. This becomes especially important if hearing preservation implantation (so called "soft surgery") is being attempted[2]. Currently this involves "blue-lining" the endosteal membrane and then opening the membrane with a knife or needle. James et al[2] demonstrates the difficulty in this process in his paper on preserving residual hearing. The surgeons involved inadvertently opened the endosteal membrane with the drill in 2 of 8 cases reported. One of these cases led to a destruction of residual hearing. Despite soft surgery techniques, there is still a 10%-20% chance of complete loss of hearing[3]. Balkany et al[3] managed to completely preserve hearing in 32% (<10dB loss) and partially in 57% (>11dB loss but some hearing still present) of patients. Whether the cause of hearing loss is due to inadvertent cochlea damage by the drill was not indicated by the authors.
2. An autonomous drill would allow a single narrow hole of exact size to be drilled. This is likely to reduce drilling time, decreases the trauma sustained by the cochlea and leads to a smaller hole to seal after the implant has been inserted.
3. Nadol et al[4] suggests that early post-operative meningitis is due to contamination of the inner ear at time of surgery. This is most likely to occur when bone dust is forced into the scala tympani when the drill breaches the endosteal membrane. A controlled opening of the endosteal membrane with a knife or needle, once the bone dust has been removed, is likely to minimize inner ear contamination.

Methods

The autonomous drilling unit consists of 3 parts (Figure 1).

4. The drilling unit and linear actuator
5. The arm and theatre mount
6. Computer

The robotic drill was produced by Aston University, Birmingham. All parts were custom made. The drilling unit consists of 2 specially commissioned electric motors, one for turning the drill and one for the linear actuator (propels the drill forward). A 1.2mm diamond paste burr was used. The drill speed was 25revs/s; the linear actuator advanced the drill forward at 0.1mm/s. The drilling unit is attached to an arm which is freely movable in 3 dimensions. The surgeon manoeuvres the drill to aim at the point he/she wants the cochleostomy to be formed, and with the required trajectory. Compressed air is used to lock the arm once the drill is in position. The drill bit is advanced onto the promontory, once the surgeon confirms the trajectory of drilling, the autonomous process is begun (Figure 2). The drilling unit is entirely controlled by the computer, with the surgeon retaining executive control. The computer analyses the force (linear) and torque (rotational force) imparted onto the drill bit in real time. Analysis of the force is by a cantilever sensor on the drill bit. The torque is determined by the electrical power needed to turn the drill at a specified speed.

Figure 1: The drill, arm and theatre mount

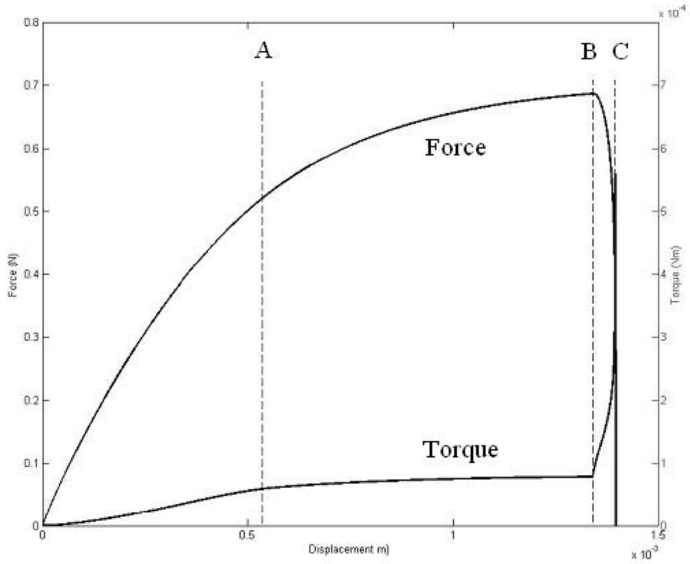

Figure 2: Graphical representation of the force and torque during the drilling process. Point A - the point at which the burr is 1 radius into the bone. Point B - the start of breakthrough. Point C – complete hole formed.

The surgeon is in complete control of aiming the drill, and therefore decides on the cochleostomy position and the trajectory of drilling. The robot's function is to drill the bony cochlea wall until its reaches medial surface, and to stop prior to disrupting the underlying endosteal membrane.

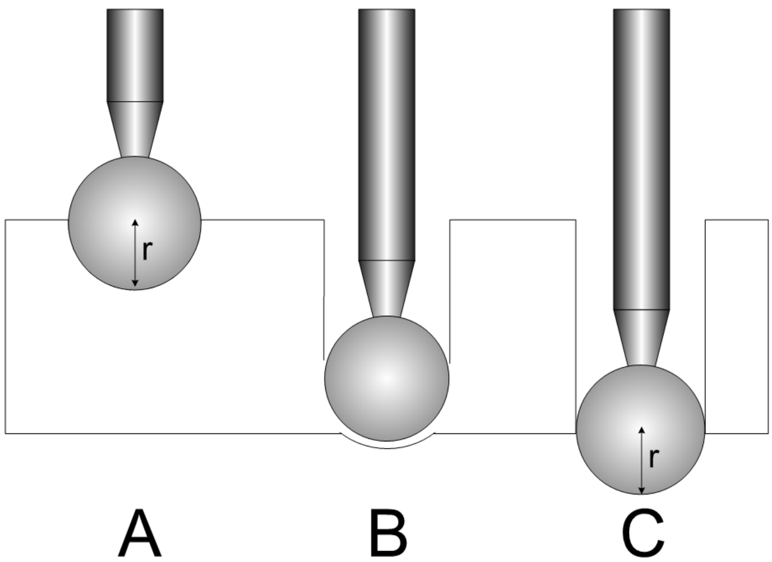

Figure 3: Diagrammatic representation of the stages of the drilling process. Point A - the point at which the burr is 1 radius into the bone. Point B - the start of breakthrough. Point C – complete hole formed.

Torque is proportional to the surface area of burr in contact with the bone and therefore rises steadily as the drill advances forward. Once the burr is 1 radius into the bone the maximum cutting surface area is in contact with the bone and hence an equilibrium point is reached, point A on figure 2 and figure 3. After this point the torque is roughly constant. Initially the force rises steadily as it penetrates the bone because the linear movement of the drill is slightly faster than the cutting speed. The axial drill force is limited to 1.5N. A 1.5N maximum force and 25revs/s drill speed were chosen as repeated empirical testing found that this force and drill speed would cut through the cochlea bony wall with an acceptable speed (about 30 seconds). These parameters also ensured that on medial breakthrough, i.e. the tip of the burr exposing the underlying endosteal membrane, the drill bit would not over penetrate and rupture the endosteal membrane.

At the beginning of breakthrough, point B (figure 2 and figure 3), the central tip of the drilled hole becomes sufficiently thin that it is deflected medially. This leads to a sudden drop in the force at the drill bit. This enables the burr to cut bone with its side rather than the tip and hence increases the cutting rate, generating a sharp increase in torque. The combination of a drop in force and a rise in torque is indicative that the process leading to breakthrough has begun. We used a control strategy to stop the burr when a force drop of 10 units was coupled with a torque rise of 10 units. Drilling can be stopped at this point or continued until a completed hole is formed, (C, figure 3).

To test our automated drilling robot we harvested 5 porcine (Middle White breed) cochleas, the cochleas were then held in position using “helping hands” (Maplin Electronics), the drilling arm was manoeuvred into position and locked, drilling was commenced under control of the computer. Once the automatic detection stopped the burr, we retracted the drill and assessed the accuracy of the breakthrough detection strategy.

Two criteria were used to assess the integrity of the membrane, visual inspection of the membrane and the presence of endolymph leaking from the inner ear.

Results

The drilling process took 30-40 seconds on all samples. During the drilling process, the hole was created at exactly the position determined by the surgeon.

All 5 membranes were visually intact and there was no leak of endolymph from the cochleostomy. The drill detected breakthrough when both the tip of the drill bit and the side were the first to break through. The cochleostomies were all of slightly differing sizes depending on the area of the medial aspect of the cochleostomy that fractured at the point of breakthrough. The remaining pieces of bone could be removed from the membrane creating a 1mm cochleostomy.

Figures 4 show the 5 drilled porcine cochleas with the endosteal membrane intact.

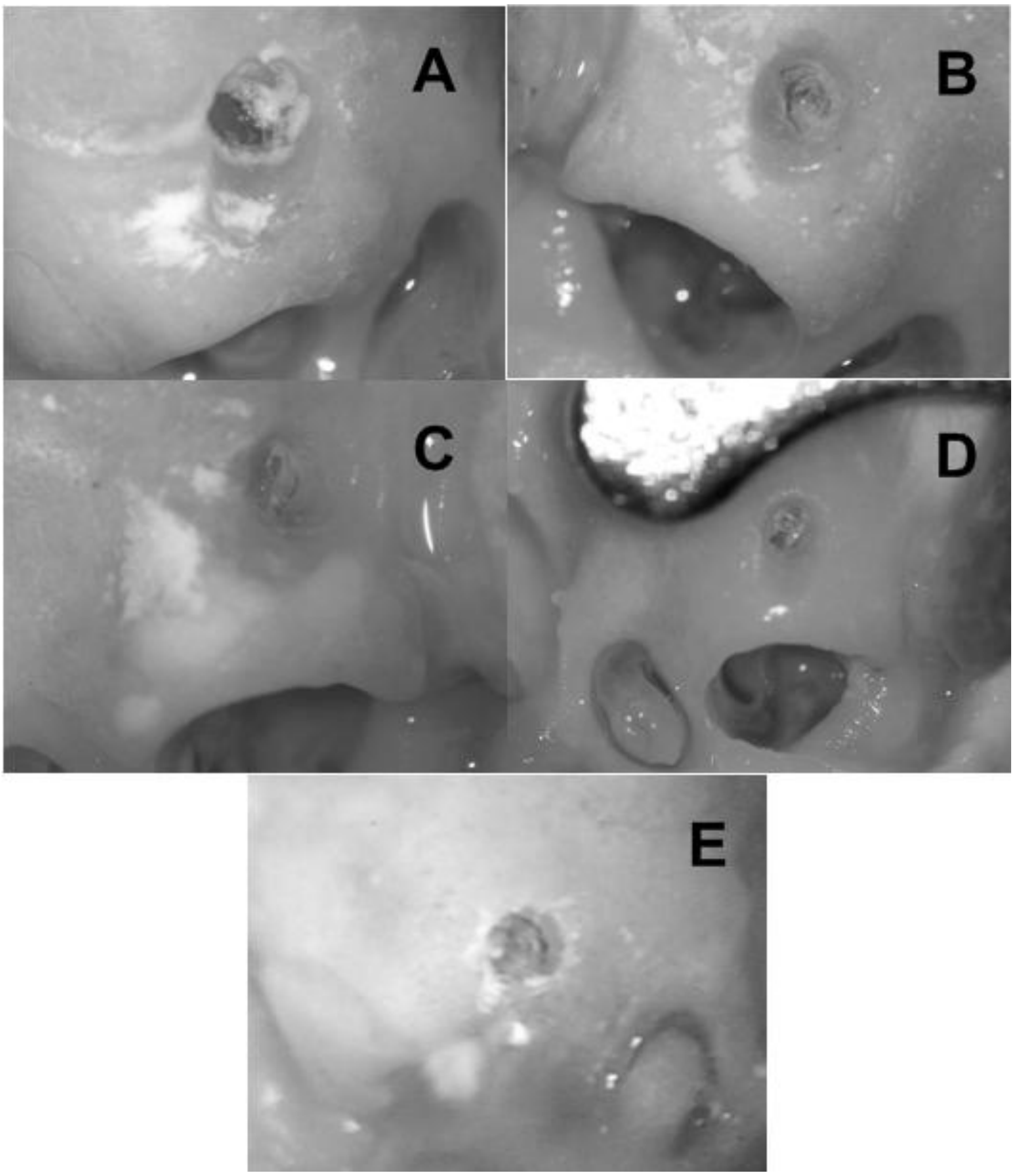

Figure 4: Cochleostomies created by autonomous robotic drilling arm.

Discussion

Synopsis of key/new findings

The autonomous surgical drill can successfully predict breakthrough and can stop at the point of breakthrough, thus preserving the integrity of the underlying cochlear endosteal membrane. This is the first autonomous surgical robotic device that has been designed.

Comparisons with other studies

An automatic drilling system with breakthrough detection has been previously described by Ong[5] who designed a process for drilling through long bones with 2 cortices. The drill measured the force whilst penetrating the first cortex, and assumed that drilling the second cortex would have a similar force parameter. The computer then could predict the breakthrough point assuming the second cortex was identical to the first. When drilling a cochleostomy we need to predict the breakthrough point without any previous reference points, and to deal with the flexible nature of the medial surface as it is approached and penetrated by the drill tip. An autonomous system that senses its way through a tissue regardless of thickness allows for this.

Clinical applicability of the study

The robot offers a distinct step forward over the currently available breakthrough detection systems which cannot sense their way through the tissue, predicting breakthrough regardless of depth.

Using this system in human cochlear implantation would minimize the trauma sustained by the cochlea. The effect of the autonomous robotic drill on complications and residual hearing is subject to ongoing investigations.

Conclusions

We present the world's first autonomous surgical drilling arm. It is capable of drilling a cochleostomy whilst minimizing the damage to the membranous cochlea. The system allows information about the state of the drilling process to be derived using force and torque data from the tool point. This information can be used to effectively predict drill breakthrough and implement a control strategy to minimize drill penetration beyond the far surface. This prevents protrusion through the endosteal membrane, minimizing trauma to the inner ear.

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An Autonomous Surgical Robot for Drilling a Cochleostomy – Human Trial

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Human Trial. Submitted to Otology & Neurotology December 2009

Chapter 4.4

Abstract

Objective:
To design and perform a human trial of a robot capable of performing a bony cochleostomy whilst preserving the underlying endosteal membrane.

Study Design:
Preliminary human trial of 3 subjects.

Setting:
University Hospital Birmingham, cochlear implantation tertiary referral centre.

Patients:
3 adult patients who meet the National Institute of Health and Clinical Excellence criteria for undergoing cochlear implantation.
Intervention(s):
A robotic cochleostomy was attempted in all 3 subjects as part of the cochlear implantation procedure.

Main Outcome Measure(s):
Completion of a bony cochleostomy with preservation of underlying endosteal membrane.

Results:
The robot was safely utilised in theatre in all 3 cases and successfully created a bony cochleostomy whilst preserving the underlying endosteal membrane.

Conclusions:
The robot can safely perform a bony cochleostomy in humans and preserve the integrity of the underlying endosteal membrane. The use of the robot in the cochlear implant procedure will minimize the damage sustained by the cochlea and may help preserve residual hearing levels.

Introduction

Cochlear implantation has become the standard method of hearing rehabilitation for severe to profoundly deafened patients over the last 25 years. The success of the implantation procedure has led to changes in the audiological criteria, which can now include patients with preservation of low frequency hearing and severe to profound hearing losses in the high frequencies[1]. The ideal rehabilitative strategy for these patients is to preserve their low frequency hearing during implantation and use a combination of electrical stimulation (via the cochlea implant) in the high frequencies and acoustic stimulation (by a conventional hearing aid) in the low frequencies. Utilising a combined electo-acoustic stimulation of hearing has the potential to improve speech recognition in both quiet and noise above the use of cochlear implant alone[2]. This has presented otologists with the challenge of inserting a cochlear implant whilst preserving the residual hearing.

Lenhardt first proposed the concept of soft surgery to minimize the trauma sustained to the cochlea during implantation[3]. This entails performing a cochleostomy with a slow turning burr (<10,000 revs/min), to reduce the acoustic trauma, and preserving the endosteal membrane of the scala tympani. Preservation of the endosteal membrane stops the scala tympani from sustaining pressure surges caused by a rotating drill within it, secondarily; it prevents contamination of the perilymph with bone dust, and finally stops inadvertent damage of the basilar membrane by the drill. The endosteal membrane would then be opened with a knife prior to electrode insertion. Despite there being no accepted drill speed for performing a cochleostomy it is assumed that the acoustic trauma decreases as the burr speed decreases

The other hypothesized causes of loss of residual hearing are related to suction of perilymph after opening the endosteal membrane, trauma during insertion of the electrode array and the presence of a foreign body within the cochlea. Trauma during insertion is likely to alter residual hearing levels through both direct trauma to the basilar membrane and via pressure fluctuations in the scala tympani during introduction of the electrode array into a closed system.

There is no current evidence to suggest which of these factors predominates as the cause of loss of residual hearing, although it is likely that they all are involved to varying degrees. A combination of soft surgery and inserting a short electrode has been utilised with some success in preserving residual hearing, however currently hearing preservation is achieved in only 80%-90%[1,4] of patients. The term 'perservation of residual hearing' appears to encompass a wide array of entities ranging from preservation within 15dB of preoperative level[5] to hearing that is serviceable by an acoustic aid (regardless of hearing level)[1]. In all studies on combined electroacoustic stimulation of hearing, in the group of the patients who have successful preservation of hearing, some undergo a 0-5dB change in thresholds, whilst others sustain a 20dB drop. The cause of loss of residual hearing, and maybe the discrepancies between 'successful preservation' results, is thought to be due to an inability to perform the soft surgery technique correctly – i.e. accidental protrusion of the drill through the endosteal membrane into the scala tympani[6].

The focus of this research is to determine if a custom made robotic microdrill designed by our research department could create a bony cochleostomy and preserve the underlying endosteal membrane during the human cochlea implantation process. If the membrane can be reliably and reproducibly preserved we can subsequently assess whether utilizing this technology enables otologists to reliably preserve residual hearing.

Automatic drilling systems with breakthrough detection have been previously described by Allotta[7] and Ong[8]. Both described a process for drilling through long bones with 2 cortices. The drill measured the force whilst penetrating the first cortex, and assumes that drilling the second cortex would have a similar force parameter. A computer algorhithm then could predict the breakthrough point assuming the second cortex was identical to the first. Cochleostomy drilling requires prediction of the breakthrough point without any previous reference points, and also has to cope with the flexible nature of the medial surface as it is approached and penetrated by the drill tip.

The 'smart' microdrill has been shown to be successful in performing a cochleo-stomy on a porcine demonstrator[9]. We now present the implementation of this technology to humans.

Materials and Methods

Ethical approval was obtained to perform a robot assisted cochleostomy in three patients. All three patients met the criteria set down by the National Institute for Health and Clinical Excellence for cochlear implantation[10].

In all three patients a standard cortical mastoidectomy and posterior tympanotomy was performed. The robotic drill was used to create a bony cochleostomy, the integrity of the membrane was assessed prior to implant insertion.

The autonomous drilling unit consists of 3 parts (Figure 1).

1. The drilling unit and linear actuator
2. The arm and theatre mount
3. Computer

Figure 1: The drill, arm and theatre mount

The drilling unit consists of 2 specially commissioned electrical motors, one for the drill and one for the linear actuator (power to the forward motion of the drill). A 1.2mm diamond paste burr was used. The drill speed was 25revs/s (1500revs/min), the linear actuator advanced the drill forward at 0.1mm/s. The drilling unit is attached to an arm which is freely movable in 3 dimensions. Compressed air is used to lock the arm once the drill is in position. The drill bit is advanced onto the promontory, once the surgeon confirms the trajectory of drilling, the autonomous process is begun. The drilling unit is entirely controlled by the computer, with the surgeon retaining executive control. The computer analyses the force and torque imparted onto the drill bit in real time (Fig 2) to discriminate the state of the tissue-toolpoint interaction from which actuation strategies are selected.

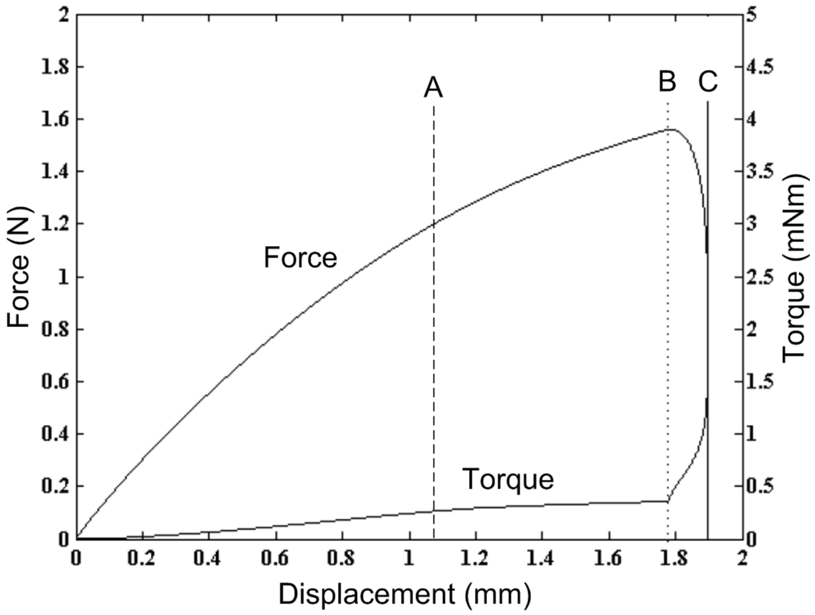

Figure 2: Graphical representation of the force and torque during the drilling process

Torque is a function of the radial distribution of the reaction force on the drill tip by the bone tissue. Consequently as the feed force rises so does the torque. Once the burr is 1 radius into the bone the maximum cutting surface area is in contact with the bone and hence an equilibrium point is reached (point A on Figure 2 and Figure 3). After this point the torque is constant. Initially the force rises steadily as it penetrates the bone because the linear movement of the drill is slightly faster than the cutting speed and the consequent rate of removal of tissue. The axial drill force is limited to 1.5N. By maintaining this maximum safe working can be assured as unacceptably high force levels leading to premature penetration through failure of the tissue can be avoided.

At the beginning of breakthrough, point B (figure 2 and figure 3), the central tip of the drilled hole becomes sufficiently thin that it is deflected medially. This leads to a sudden drop in the reactive force at the drill bit. The reaction force distribution changes in response to changes in the structure of the bone tissue ahead of the tool point.This enables the burr to cut bone with its side rather than the tip and hence increases the cutting rate, generating a sharp increase in torque. The combination of a drop in force and a rise in torque is indicative that the process leading to breakthrough has begun. We used a control strategy to stop the burr when a force drop of 10 units was coupled with a torque rise of 10 units.

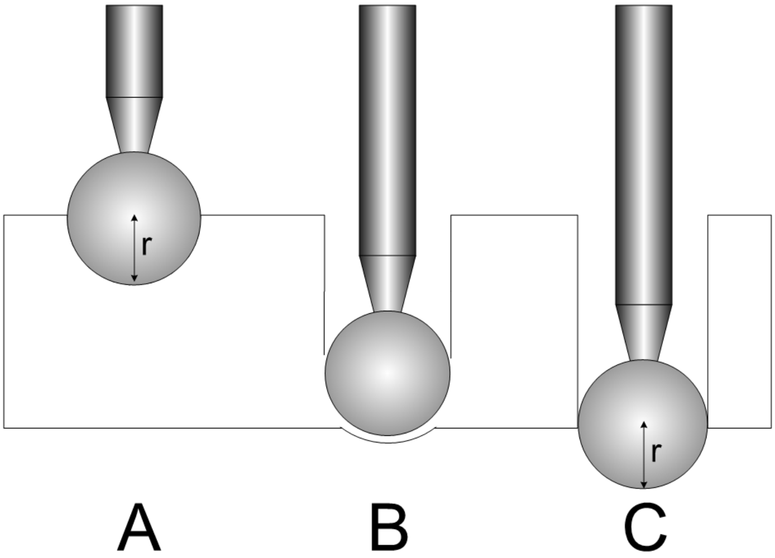

Figure 3: Diagrammatic representation of the stages of the drilling process

Results

The robotic drilling arm was manoeuvred into the precise location for cochleostomy drilling by the surgeon. The set up time for the robotic drill was approximately 2 minutes. The direction and angle of drilling achieved through the posterior tympanotomy was similar to that of conventional handheld cochleostomy formation, with an adequate view of the drilling site. An indentation, produced with a 0.6mm diamond burr, was required on the promontory at the intended site of the cochleostomy to aid the robotic drill to ‘key in’ to the bone and prevent the drill slipping anteriorly. The autonomous drilling process was commenced and the drill successfully located the drilling surface. The drilling process took 69 seconds and a successful cochleostomy with an intact endosteal membrane was created (figure 4).

Figure 4: Bony cochleostomy with preservation of endosteal membrane

Drill breakthrough was detected and controlled within 15 μm of the distal surface. Figure 5 is the graphical representation of the force and torque experienced by the drill. Both respiration and the heart rate can be determined from the traces, demonstrating the sensitivity of the drill.

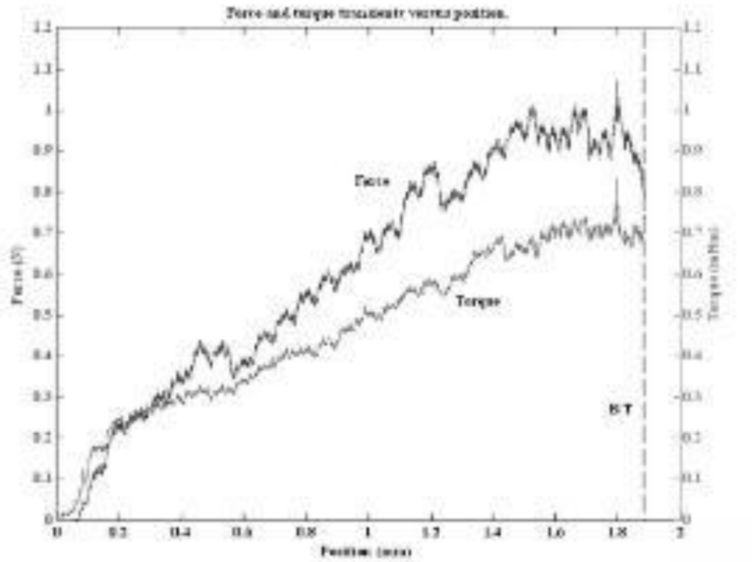

Figure 5: Force (green line) and Torque (blue line) characteristics during successful drill trial demonstrating fluctuations caused by respiration and heart rate.

Discussion

The smart drill was introduced to the clinical environment and successfully created a cochleostomy with preservation of the underlying endosteal membrane. The drill was brought into the clinical setting and, with a set up time of 3 minutes didn't unduly halt the operation, the successful drilling time of 69 seconds was faster than the average human made cochleostomy. This is the first demonstrated autonomous surgical robot guided by the discrimination of state, in terms of tissue response to interaction with the tool-point, used in theatre on patients. In this respect the machine automatically registered itself to the flexible tissue structure to detect the interface before penetration and hence was able to control the breakthrough process with precision and with respect to the tissue interface. All of the patients in the trial had profound hearing losses across the frequencies preoperatively and so no assessment can be made on the impact of a robotic cochleostomy on hearing levels. Moreover, with only 3 subjects in the trial, the hearing results wouldn't be conclusive.

By guaranteeing the preservation of the endosteal membrane and drilling at a much slower speed than the currently used skeeter drill (1500 revs/min compared to 10,000revs/min), the robot will certainly minimize the acoustic, direct and pressure trauma sustained by the cochlea during cochleostomy formation. Further research is ongoing to determine its effect on post operative hearing levels.

Whilst the primary aim of the autonomous drilling robot is to preserve residual hearing, there are also other potential advantages. Reefhius et al [11] hypothesized that possible mechanisms of post cochlear implantation meningitis include preparing a larger cochleostomy than is necessary and Nadol et al[12] suggests that early post operative meningitis is due to contamination of the inner ear at time of surgery. The autonomous drill allows a single narrow hole of exact size to be drilled rather than gradually thinning the bony cochlea anterior and inferior to the round window, until the membrane is reached. This leads to a smaller hole to seal after the implant has been inserted. Late, and clean opening of the endosteal membrane may reduce the small, but inherent, risk of meningitis.

The cochleostomy is usually performed towards the end of the operation after drilling a cortical mastoidectomy, posterior tympanotomy and implant well. Surgical tremor and fatigue increase with operative time[13,14] and performing the most important step of the procedure at the end will lead to greater potential for error. Hence, many surgeons perform the cochleostomy before the implant bed is created. Even though the cochleostomy is covered whilst the implant well is created, the inner ear is open for longer than is necessary, increasing both the risk of contamination with bone dust and bacteria, and the leak of perilymph out of the scala tympani. With an autonomous drilling system the cochleostomy can be performed at the end of the operation without compromising accuracy.

Cochlear implantation with preservation of the best hearing thresholds possible will only be achievable if trauma is minimized at all stages of the operative procedure. The robotic drill can minimize the trauma during cochleostomy formation. Preservation of the endosteal membrane will reduce the direct trauma to the basilar membrane and pressure related trauma as a result of a running burr in the scala tympani. The acoustic trauma will also be diminished by using a drill turning at much slower speeds than conventionally used. We envisage the robotic drill being used along with a suite of advanced intelligent tools designed to minimize trauma during the approach to the middle ear and implant electrode insertion.

Conclusions

We present the first successful use of an autonomous surgical drilling arm in a human operation able to control precisely penetration through specified tissue layers guided by the discrimination of states in the process. It is capable of drilling a cochleostomy whilst minimizing the damage to the cochlea. The system allows information about the state of the drilling process to be derived using force and torque data from the tool point. This information can be used to effectively predict drill breakthrough and implement a control strategy to minimize drill penetration beyond the far surface. This prevents protrusion through the endosteal cochlea membrane, minimizing trauma to the cochlea. The effect of using the robot in preserving residual hearing during implantation is under further study.

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Conclusions

Chapter 5

Conclusions

This thesis has demonstrated that a novel robotic solution can minimize the disturbances sustained by the cochlea in the cochlear implantation procedure and this robot can successfully be used in human cochlear implantation.

Chapter 2 analysed intraoperative surgical performance. All surgeons are acutely aware of their operative performance and take steps to maximize this wherever possible. Many surgeons will not drink coffee on a theatre day or exercise prior to operating – both factors known to increase tremor. Procedures requiring a high degree of accuracy are usually performed early in the day, although this is not possible with longer procedures and when more than 1 surgical team may be used. These measures are usually borne out of trial and error and the aim of this chapter was to quantify the components affecting surgical performance, allowing surgeons a greater understanding of the factors that may influence patient outcomes.

Hand tremor in all people gradually increases through the day at a rate of 0.013% per minute; this will lead to a hand tremor being 9.4% greater after 12 waking hours, than at the beginning of the day. Performing operations causes an additional increase in hand tremor by a factor of 8.4 times over and above this baseline, leading to a rate of hand tremor increase of 0.1% per minute. This increase in operative tremor is likely to be due to combination of the additional physical and mental fatigue induced by operating. Rate of increase and baseline operative hand tremor was unaffected by surgical experience.

Fatigue is also adversely affected by operating. A control group of subjects performing desk work fatigued their brachioradialis and mid deltoid muscles, gradually throughout the day. In the surgical arm of the study these muscles fatigued at an accelerated rate. This affect was more marked in the brachioradialis muscle, which fatigued at twice the rate of the mid deltoid. This muscle is used to counter the affects of gravity and hold the forearm out straight and in the operative position and is therefore in use throughout all operations. The mid deltoid muscle abducts the arm and so its use is less marked during operations leading to its slower rate of fatigue. Again there was no difference in pre, intra or post operative fatigued states related to experience of the surgeon.

These 2 papers confirm and quantify features that surgeons already anecdotally are aware of – their operative performance decreases slowly with time. This has key importance in the context of hearing preservation cochlear implantation. Minimizing the trauma sustained by the cochlea requires maximizing surgical performance. It is crucial that the cochleostomy formation step of the implant procedure is performed with the upmost accuracy and utilising methods to reduce tremor and fatigue are likely to produce an improved operative result. The operation should be the first to be performed in the morning, and methods of decreasing operative tremor, i.e. resting a surgeon's hand, or using mechanisation should be considered.

Our final paper in the surgical performance section assessed the use of a wrist rest on surgical tremor. Surgeons are all aware that resting their wrists will decrease their tremor and our aim was to quantify the extent of this. We demonstrated there is a decrease in the overall tremor amplitude by a factor of 2.67 by resting the wrists. Wrist rests are therefore likely to improve surgical accuracy, although this often comes at a cost of decreasing the range of movement of the surgeon.

The aim of chapter 3 was to quantify the effect of cochleostomy formation on disturbances within the cochlea. Minimizing the trauma sustained during this step of the procedure is the key of Lehnhardt's soft surgery. We demonstrated that both drill speed and force of drilling independently effect the movement of the endosteal membrane, and hence cochlea trauma during cochleostomy formation. Force of drilling was the main factor affecting cochlea disturbances. Interestingly, speed of drilling was found to have the opposite affect to that anticipated – higher speed drilling was associated with lower membrane displacement than low speed drilling; this is likely to be due to an increase bounce of burr at lower speeds. This paper demonstrates that if the force of drilling can be controlled, and minimized, then the cochlea will sustain decreased disturbances during the cochleostomy process.

The second paper in chapter 3 directly compared the disturbances within cochlea by human and force controlled robotic cochleostomies. The velocity of movement of the endosteal membrane during manual cochleostomy is approximately 20 times higher on average ($p = 0.00478$) and 100 times different in peak velocity ($p = 0.00647$), than for robotic cochleostomy. Rupturing the endosteal membrane with a running burr did not cause any additional membrane disturbance compared to the drilling process itself. However, opening the endosteal membrane with a pick, lead to no discernable membrane movement.

These studies suggest that control is the key to minimizing trauma. The ability to control the force of drilling and preserve the underlying endosteal membrane will ensure that the traumatic effect of performing a cochleostomy is reduced to a minimum. The robotic drill is capable of performance at levels not achievable by humans and indicates that the use of robotics will be necessary to minimize the trauma during the implantation procedure.

The assessment of the use of a robotic drill during the implantation procedure requires initially animal testing and then subsequent translation into successful use in human implantation, prior to use within a clinical trial to assess the effect on hearing levels. This process was investigated in chapter 4.

The use of a robotic drill capable of analysing changes in force and torque at the drill bit, in real time, during the drilling process is able to perform a bony cochleostomy and preserve the underlying endosteal membrane in both porcine and human trials. This is a major breakthrough in not only surgical tools, but also the cochlear implantation procedure.

Surgical tools have seen little advancement in the last 100 years; resection tools of knife, scissors and drill are still used. The main improvements in the last century have been in vision, with endoscopes and microscopes allowing surgeons a greater visualisation of the operative field. This has been augmented by the use of telemanipulators, which are able to improve some of the inherent problems with human performance. Tremor reduction, motion scaling and the use of endoscopic tools with higher degrees of freedom compared to regular operative tools have gone some way to improving surgical accuracy. Unfortunately they continue to rely on vision to assess interfaces and have no haptic feedback. Operating beyond the boundaries of human visual and tactile perceptions, necessitates the design of smart tools capable of ‘feeling’ their way through tissue, using parameters that offer greater accuracy than vision.

The robotic microdrill represents the first occasion an autonomous robot has been used in a human operation to fully complete an independent step of a procedure without human input. It marks the start of a new era of operative tools that are custom made for particular steps in operations that are accuracy and performance critical.

We have demonstrated that the use of such a robot is capable of making a large improvement on human performance and a novel robot can be successfully transferred from laboratory to operating theatre. Currently, its effect on hearing preservation during the cochlear implant procedure is unknown and will undergo further investigation. In the future, we envisage HPCI to utilise a suite of smart tools to ensure disturbances within the cochlea are minimized and residual hearing is preserved.

Summary / samenvatting

Chapter 6

Summary

Hearing preservation cochlear implantation represents the ideal audiological strategy for rehabilitating patients with severe to profound hearing losses in the high frequencies, but residual hearing in the low frequencies. Acoustic stimulation of the residual low frequency hearing, and electric stimulation of the high frequencies leads to improved speech perception in noise when compared to typical cochlear implantation users. This poses a surgical challenge, how to insert a cochlear implant whilst preserving the patients' residual hearing? 'Soft surgery' techniques have been proposed to minimize the trauma sustained by the cochlea, and thereby preserving residual hearing. These have been used with a variety of success in a number of centres. In this thesis we have investigated the causes of disturbances sustained by the cochlea and have proposed a robotic solution to minimize the trauma.

Cochleostomy formation and electrode insertion are commonly hypothesized to be the operative steps responsible for hearing loss during implantation. However, it is likely that all facets of the operation contribute varying amounts towards the final hearing result. The disturbances sustained by the cochlea during cochleostomy formation are directly related to the force of drilling and inversely related to the speed of drilling. Controlling the force imparted by the burr on the bone minimizes the disturbances sustained by the cochlea during the process of cochleostomy formation.

Performing a complete bony cochleostomy with preservation of the underlying endosteal membrane is possible for a human, although success is not guaranteed. Humans are susceptible to an increase in tremor and fatigue during operating. The effect of tremor can be minimized by resting a surgeons wrist, however a tremor will always be present. The presence of tremor and fatigue during the cochleostomy formation will lead to 2 main effects; firstly the underlying endosteal membrane may be penetrated, this will lead to contamination of the scala tympani with bone dust, the drill may damage the basilar membrane or stria vascularis and disturbances within the cochlea due to the drilling process are prolonged. All these processes are assumed to increase the risk of hearing loss during the procedure. Secondly, the effect of human tremor during the drilling process leads to fluctuations in the force exerted by the drill on the bone. This causes a marked variation in the disturbances experienced within the cochlea.

The ability to drill at constant force leads to a drop in the disturbance within the cochlea of a factor of 20.

Controlling the force of drilling and ensuring the preservation of the endosteal membrane minimizes the traumatic effect of the cochleostomy step of the implant procedure. It is likely that this will aid in preserving hearing during implantation. An autonomous cochleostomy drilling robot was designed to allow mechanisation of this step during human cochlear implantation. The robot senses the changes in force and torque throughout the drilling process and uses these transients to both ensure the drilling force is constant and to determine the start of the breakthrough process. An animal trial confirmed the robot was able to perform a bony cochleostomy whilst guaranteeing preservation of the underlying endosteal membrane. Transfer of the hardware to the theatre environment led to a successful human trial with endosteal membrane preservation. This was the first time an autonomous robot has been used in human operations.

This thesis has demonstrated that mechanisation of one of the key steps of the cochlear implantation procedure can significantly reduce the trauma sustained by the cochlea, and that the robot can be successfully used during human cochlear implantation. We envisage that the autonomous cochleostomy drilling robot will become a key tool during hearing preservation cochlear implantation.

Samenvatting

Een in opzet gehoorsparende chirurgie bij cochleaire implantaten is een methode om bij personen met een zeer ernstig gehoorverlies in de hogere frequenties en een nog betekenisvolle gehoorfunctie in de lagere frequenties een bimodale gehoorrevalidatie te kunnen realiseren, namelijk revalidatie van het gehoor met een cochleair implantaat vanwege de doofheid in de hogere frequenties en met een conventioneel luchtgeleidingshoortoestel vanwege de in de lagere tonen behouden gehoorrest.
Een akoestische stimulatie in het gebied van het restgehoor in de lagere frequenties en een elektrische stimulatie in het gebied van de hogere frequenties leidt aldus tot een beter spraakverstaan in een gestandaardiseerde rumoerige omgeving, wanneer die resultaten vergeleken worden met de resultaten die in die situatie verkregen worden met alleen toepassing van een cochleair implantaat. Dit betekent voor de chirurg een uitdaging om een cochleair implantaat zo te plaatsen dat het nog bestaande restgehoor behouden blijft. “Soft surgery” technieken zijn daartoe voorgesteld om de kans op een trauma van het binnenoor bij deze cochleaire implantatie te helpen verminderen en om aldus de preoperatief nog aanwezige gehoorrest te behouden. In verschillende cochleaire implantcentra is deze “soft surgery” al met een wisselende mate van succes toegepast.
In dit proefschrift zijn oorzaken van schade aan het binnenoor bij dergelijke chirurgie onderzocht en wordt robot chirurgie als een mogelijke oplossing voorgesteld om het trauma aan het binnenoor te helpen beperken.

Het aanleggen van de cochleostomie, dus het aanleggen van een benige en vliezige opening naar het binnenoor om de electrode vanuit het middenoor in het binnenoor toe te laten en het inbrengen van de electrode in het binnenoor worden beschouwd als de chirurgische momenten tijdens een cochleaire implantatie waarbij gehoorschade aan het nog bestaande restgehoor kan worden toegebracht. Het is echter aannemelijk dat alle andere stappen tijdens de chirurgische behandeling, weliswaar in verschillende mate, de grootte van het uiteindelijke restgehoor kunnen beïnvloeden. De verstoringen die aan het binnenoor worden toegebracht tijdens het aanleggen van de cochleostomie zijn direct gerelateerd aan de kracht waarmee geboord wordt en zijn evenredig gerelateerd aan de snelheid (de kracht en het aantal omwentelingen per tijdseenheid) waarmee geboord wordt. Het controleren van de kracht die door de boor op het botoppervlak wordt aangebracht, vermindert de verstoringen die aan het binnenoor (cochlea) worden toegebracht tijdens het aanleggen van de cochleostomie.

Het is voor een chirurg mogelijk om op de conventionele microchirurgische wijze een benige cochleostomie aan te leggen en tevens de onderliggende endosteale membraan intact te houden, maar dat lukt niet steeds.
Mensen zijn vatbaar voor een toename van hun handtremor tijdens het verloop van een operatie en evenzo met een toename van hun vermoeidheid in de loop van een operatie. De mate van een handtremor kan beperkt worden door de pols van de hand af te steunen, maar desondanks zal er ook dan toch iets van een handtremor overblijven. De aanwezige handtremor en de toenemende vermoeidheid zullen tijdens het aanleggen van een cochleostomie tot 2 effecten leiden:

1. De onderliggende endosteale membraan kan geopend raken, waardoor beenstof terecht komt in de scala tympani. Verder kan de boor de basilaire membraan en de stria vasculairs beschadigen. Veranderingen in de cochlea als gevolg van het boren kunnen aanhouden.
   Al deze genoemde factoren worden verondersteld het risico op extra gehoorschade tijdens de operatie te kunnen vergroten.
2. De tremor van de eigen hand van de chirurg leidt tijdens het boren tot fluctuaties in de kracht die door de boor op het bot wordt uitgeoefend. Dit leidt weer tot een opmerkelijke variatie in de mate waarin het binnenoor verstoord wordt. De mogelijkheid om met een constante kracht te kunnen boren zorgt ervoor dat de mate van verstoringen binnen de cochlea met een factor 20 afneemt.

Het controleren van de kracht waarmee geboord wordt en het er voor zorgen dat de endosteale membraan tijdens het aanleggen van de benige cochleostomie intact blijft vermindert het traumatisch effect van het aanleggen van de cochleostomie zeer.
Het is zeer aannemelijk dat dit zal bijdragen aan het behoud van de gehoorresten tijdens een cochleaire implantatie. Een robot werd ontworpen om zelfstandig een cochleostomie te kunnen aanleggen en om zo deze stap van de operatie mechanisch te kunnen verrichten.
De robot kan de veranderingen in kracht en torsie tijdens het boren waarnemen en de robot gebruikt deze informatie om enerzijds er voor te zorgen dat er met een gelijkmatige kracht geboord wordt en anderzijds om het moment te bepalen waarop het laatste laagje bot van de cochleostomie weggeboord gaat worden.

Een dierproefexperiment bevestigde, dat de robot in staat is om een benige cochleostomie uit te voeren terwijl de endosteale membraan met zekerheid intact blijft. Het aanpassen van de robot aan de omstandigheden zoals die in een

operatiekamer van een ziekenhuis gelden leidde tot een eerste succesvolle toepassing van een mechanische cochleostomie met behulp van een robot met tevens het intact houden van de endosteale membraan.
Wereldwijd gezien was dit de eerste keer dat met een robot een cochleostomie bij een mens werd uitgevoerd.

Deze proefschriftstudie toont aan dat het mechanisch uitvoeren van een van de belangrijkste chirurgische momenten van een cochleaire implantatie mogelijk is en dat daarmee het trauma dat hiermee voor het binnenoor gepaard gaat aldus enorm kan worden beperkt.
Een robot kan dus succesvol worden ingezet bij het aanleggen van een cochleostomie bij een mens. Wij voorzien daarom, dat de autonoom werkende cochleostomie robotboor een onmisbaar chirurgisch instrument gaat worden om gehoorsparende cochleaire implantaties te verrichten.

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Curriculum Vitae

Chris Coulson was born on the 26th September 1975 in Lancaster, England. His pre-university educated was at Broughton High School (1987-1992) and Preston College (1992-1994). He studied medicine at the University of Nottingham Medical School, graduating in 1999. Basic surgical training was undertaken at Birmingham City Hospital 2000 – 2004, during which he spent 6 months in Perth, Australia in 2001. He was appointed onto the West Midlands Otolaryngology Specialist Registrar training program in 2004. Upon completion of specialist registrar training in 2010 he will commence an otology and neurotology fellowship in Toronto (Prof J Rutka). In 2011 he will begin as a consultant otologist at The Queen Elizabeth Hospital, Birmingham.

His investigations into Microtechnologies in Cochlear Implantation began in 2004 under the supervision of Professor Peter Brett and Professor David Proops in the school of engineering and applied sciences at Aston University, Birmingham and The Queen Elizabeth Hospital, Birmingham.

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