

Assessment

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A first exploration of the economic consequences of an autonomous surgical robot for lateral skull base surgery: an early health technology assessment

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Abstract

Objectives: Lateral skull base procedures, such as translabyrinthine approach (TLA), are challenging. An autonomous surgical robot might be a solution to these challenges. Our aim is to explore in an early phase the economic consequences of an autonomous surgical robot compared with conventional TLA.

Methods: An early decision analytic model was constructed in order to perform a step-wise threshold analyses and a sensitivity analysis to analyze the impact of the several factors on the incremental costs.

Results: Using surgical robot results in incremental costs – EUR 5,562 per procedure – compared to conventional TLA. These costs are most reduced by higher number of procedures, followed by lower price of the robot, saved operation time, and reduced risk of complication, respectively.

Conclusions: The incremental costs of using an autonomous surgical robot can be decreased by choosing applications with a high turnover rate, a long operation time, and a high complication rate.

Introduction

The lateral skull base – or the temporal bone – is a complex anatomical region of the skull located behind the ear. The lateral skull base comprises multiple structures playing a critical role such as the cochlea, vestibular system, facial nerve, and tegmen. Surgical procedures in this region are challenging. However, these procedures are sometimes required to remove a benign or malignant tumor or to place a cochlear implant. At least 1,200 procedures per annum are already performed in the Netherlands to remove cholesteatoma, a benign tumor, and to place a cochlear implant (1;2). These procedures require drilling in the temporal bone to create a pathway to the target, the tumor for removal, or the cochlea for implantation of electrodes, without damaging critical structures. During these procedures, the surgeon uses these critical structures as landmarks and drills extremely close to them. Therefore, these procedures are correlated with complications, such as hearing loss, (partial) facial palsy, balance disorders, or cerebrospinal fluid leak (CSF leak). Because of the complexity of the lateral skull base, surgical procedures within this region can require long and exhaustive bone removal, taking up to 5 hr. Exhaustion of the surgeon may also contribute to a higher complication rate. Each of these complications has a significant impact on the patient's quality of life and needs to be avoided (3–5).

Furthermore, lateral skull base surgeries involve excessive healthy bone removal to reach the target. Some surgeons suggest that minimally invasive bone removal results in shorter recovery time, better esthetic outcomes, reduced risk of infection, and preservation of the function of the mastoid. However, in order to reduce the risk of complications, minimally invasive bone removal requires knowledge of the exact location of structures without exposing them during surgery, which is currently not achievable. Therefore, minimally invasive bone removal is not yet attractive.

In order to deal with these challenges of lateral skull base procedures, an autonomous image-guided surgical robot might be a solution. Currently, several autonomous surgical robots are being developed to perform bone drilling in the lateral skull base (6–9). These robots can drill autonomously based on a pre-operatively defined surgical path using computed tomography

scan (CT scan). By unburdening the surgeon during the drilling part of temporal bone procedures and by using CT scan for path planning, autonomous surgical robots are believed to add value to the conventional surgery in terms of reduced procedure time, increased procedure precision, reduced complication rates, the possibility to drill minimally invasively, and eventually improved cost-effectiveness (6–9).

During this development phase, it is not only essential to analyze the clinical performances of such a robot, but also the potential economic consequences compared to current care (10). The aim of this study is to explore the impact of various factors, among others, the advantages of an autonomous surgical robot (reduced operation time and complications) on the incremental costs of it compared with conventional surgery, using a decision analytic model. This information could be used by the developers to steer the further development of autonomous surgical robots toward areas where the most room of improvement can be detected. Additionally, this information is also of interest for hospital healthcare policy makers and health authorities to consider when making decisions about this kind of robotic surgery (e.g., considering to purchase such an autonomous surgical robotics). In this study, we focused on translabyrinthine approach (TLA) for vestibular schwannomas (VS), because these robots are designed especially for lateral skull base procedures. Of the lateral skull base procedures, TLA is one of the most complicated procedures and therefore we expect that such a robot will have the most added value for this type of skull base procedures. A vestibular schwannoma is a benign and slow-growing tumor that grows on the vestibulocochlear nerve, the nerve for hearing and balance that passes from the inner ear to the brain.

Methods

Model Structure

A decision analytical model was constructed to compare a care pathway of conventional surgery with a potential pathway using an autonomous surgical robot. RoboSculpt Gen1 (6) was used as an example of an autonomous surgical robot for TLA (Figure 1). The pathway of the conventional surgery has been constructed based on expert opinion. It starts with “preparation”; the surgeon prepares the surgery by evaluating the location of the critical structures on a preoperative CT scan. Thereafter, the care pathway takes place in the operating room (OR). We assumed that one surgeon, three OR assistants, and an anaesthesiologist are necessary. The patient will be prepared for surgery by delivering

anesthesia and fixating the head using a Mayfield clamp (Figure 1 – “fixation”). When the head is fixated in the right position, the procedure starts with removal of the skin, followed by the drilling of the bone to get access to the inner ear canal by drilling bone away (Figure 1 – “bone removal”). After the inner ear has been reached, the VS can be (partially) removed.

The decision model branch of surgery using RoboSculpt Gen1 includes the same four outcomes, but the care pathway differs. As can be seen in Figure 1, several additional steps are necessary when using RoboSculpt Gen1: placement of marker screws in the skull, making an additional CT scan with markers in place, and segmentation to define the drilling path for RoboSculpt Gen1 in the CT images. Furthermore, a longer fixation time was assumed when using RoboSculpt Gen1, as not only the patient but also the device needs to be fixated.

For the pathway using RoboSculpt Gen1, we assumed that the complications are mainly caused during tumor removal and not during bone drilling. Facial palsy is the only complication of the three previously described complications that can be caused by heating or mechanic damage during drilling, and can thus in theory be reduced by using RoboSculpt Gen1. Other types of complications associated with TLA, such as CSF-leak and meningitis are caused by damages and exposure of the dura mainly, which are not due to the drilling, and will probably not be impacted by using RoboSculpt Gen1. Therefore, both the conventional pathway and the RoboSculpt Gen1 pathway are associated with two different outcomes which are used as the end stages of the model: no complications or complications consisting of facial palsy. In this study, we defined facial palsy as a House–Brackmann grade (11) for facial function of three or higher.

Model Input

Model input was mainly based on literature. However, not all required information was described in the literature or has (not yet) been studied. Therefore, the missing information was obtained from experts. Our clinical expert is one of the few Dutch lateral skull base surgeons with more than 15 years of experience internationally in lateral skull base surgery. Our experts about autonomous robot surgery are two of the designers of RoboSculpt Gen1.

Probabilities

The probabilities for one of the different outcomes (either “no complications” or one of the three defined complications) for the conventional surgery were derived from the literature. A literature search was undertaken in January 2019 using PubMed and

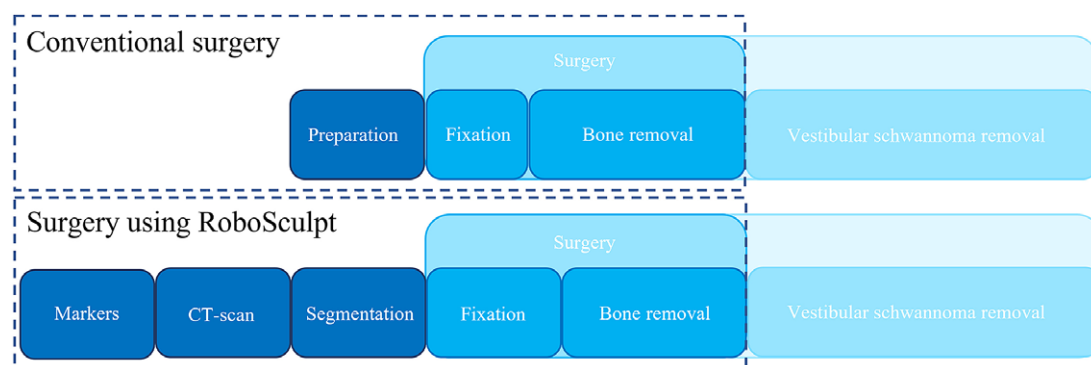


Figure 1. Simplified representation of care pathways for conventional surgery and surgery using RoboSculpt Gen1. CT, computed tomography; VS, vestibular schwannoma.

EMBASE to identify the probabilities of no complications and facial palsy correlated with TLA. Two studies were selected based on their quality and relevance to our model. Brackmann et al. studied the facial nerve function after TLA. This study showed that 149 patients of 392 TLAs had a facial palsy with a House–Brackmann score of three or higher (38.0 percent) (12).

Literature showed a strong correlation between the size of the VS and risk of complications (13–15), indicating that facial palsy might not always be caused during drilling bone away. Therefore, we assumed that RoboSculpt Gen1 could not reduce the risk of facial palsy to 0 percent in the ideal situation. Based on expert consultation, the maximum reduction of facial palsy by using this robot has been assumed to be 10 percent. Facial palsy caused by heating or mechanic damage during drilling is almost always temporary and will mostly recover within 1 year. Sporadic facial palsy persisting beyond 1 year usually lasts a lifetime. This is extremely rare and likely to have little influence on our results. Therefore, we decided to not include this scenario in our analyses.

Cost Information

Table 1 shows the costs used for our analysis. The cost analyses were performed from a hospital perspective and comprise the costs that can be influenced by the intervention. Costs were based on standard cost prices presented in the Dutch guideline for economic evaluation (16;17), internal hospital prices, and input by the manufacturer of RoboSculpt Gen1.

The costs per complication were estimated by first making a selection of the Diagnosis–Treatment Combinations (DBC in Dutch) of relevant diagnoses comparable to the possible complications of TLA; facial paresis or palsy, CSF leak, and meningitis. Multiple DBCs were applicable. Therefore, the costs and volumes of these DBCs were retrieved and the mean costs per unique patient per complication outcome were calculated.

The additional costs per procedure for RoboSculpt Gen1 consisted of the price for and placement of the marker screws, additional CT scan, segmentation of CT images, additional fixation time prior to surgery, a derivative of the purchase price, the yearly maintenance costs depending on the purchase price, useful life, and interest-rate of the robot. The costs of education of the staff are included in the purchase price. The maintenance costs are an average of costs for maintaining the device including exceptional higher maintenance costs when the robot is used more frequently or when there are unexpected defects of the device.

All costs were assessed in 2021 Euros (EUR) and converted to 2021 Euros using Dutch Consumer Prices indices (18) if necessary. Various costs, such as personnel costs were based on ZIN 2018 and converted to 2021 Euros using Dutch Consumer Prices indices (18).

Analysis

Using the constructed model a step-wise threshold analysis has been performed. The time horizon for calculating total costs and effects was set at 1 year, as we assumed that all relevant effects on costs and complications can be expected within 1 year after surgery, and will not last longer than a year. Although a 10 percent reduction in facial paralysis risk can be regarded as substantial, this reduction will result in minimal absolute improvement in terms of QALYs as the incidence of facial paralysis is already very low. Therefore, we decided to calculate the incremental costs as primary outcome.

The base-case scenario consisted of the following parameters: fifty procedures per year, a purchase price of EUR1,000,000, 0 percent facial palsy reduction, and no OR time saved compared to conventional surgery. We assumed fifty procedures per year were performed in the Netherlands based on the number of TLA performed in Maastricht University Medical Center (MUMC+) multiplied by the number of skull base centers in the Netherlands and rounded in consultation with an expert. We assumed based on expert's opinion and procedure times of MUMC+ that the drilling time of TLA is about 120 min.

First, the effect of variation in number of procedures per year on incremental costs was analyzed, ranging from 10 to 350 procedures per year. The main components in the additional cost of using RoboSculpt Gen1 are the purchase price and the yearly maintenance costs. Since these costs are spread over the number of procedures performed, the additional cost is dependent on the number of procedures per year.

Second, the incremental costs for fifty procedures per year were calculated for a range of reduced OR time (0–120 min) in combination with a range of reduced risk of facial palsy (0, 5, and 10 percent reduction). We chose a wide range of OR time reduction in order to explore the threshold for cost-saving.

Third, the incremental costs for no reduction of facial palsy followed by the maximum reduction of facial palsy were calculated for a range of procedures per year combined with the range of OR time reduction (0–120 min).

Thereafter, a sensitivity analysis was performed using a tornado diagram to assess the influence on the incremental costs of various parameters: procedure per year, purchase price, saved OR time, and the reduction of facial palsy as complication.

The pivot point for decision making is when the incremental costs are negative, meaning that the robot will save costs compared to conventional care. All analyses were conducted using Microsoft Excel (365 Pro Plus).

Secondary Outcome and Analysis

In order to explore the influence of our assumption that the potential cost-effectiveness of RoboSculpt Gen1 would not be influenced by an effect on QALY, we performed a secondary analysis including an effect on QALYs with the incremental net monetary benefit (INMB) as an outcome. The INMB was analyzed for various numbers of procedures per year in combination with saved OR time and 10 percent risk reduction of facial palsy.

The Quality Adjusted Life Year (QALY) was used to measure the effect. This is a combination of quality of life (in terms of utility) and the duration of this quality of life, with a utility value of 1 representing 1 year in full health, and a utility of zero representing death. Having a complication will result in a decrease in utility, a so-called *dis-utility*. These disutility values were derived from literature. Literature search was performed using PubMed and using references of studies to identify the utility of no complications and facial palsy correlated with TLA. Gait et al. studied the cost-effectiveness of various treatment strategies for vestibular schwannomas (19). Their utilities were based on a detailed literature search and expert opinion. One of these studies included was Godefroy et al. (20). This study analyzed the QALY after TLAs using the Short Form-36 questionnaire. Based on these studies and a verification by expert opinion, the disutilities of the outcomes of our model were estimated (Table 1).

Table 1. Detailed overview of all model parameters

Input parameter	Value	Source
Base-case scenario		
Procedures per year	50	
OR time for drilling bone (minutes)	120	Expert opinion; MUMC+
Purchase price RoboSculpt Gen1, including education of staff (EUR)	1,000,000	
Useful life-time RoboSculpt Gen1 (years)	5	Guideline for performing economic evaluations in healthcare (16)
Interest rate RoboSculpt Gen1 (%)	4,2	Guideline for performing economic evaluations in healthcare (16)
Resale value RoboSculpt Gen1 (EUR)	0	
Yearly maintenance costs (EUR)	10,000	
Probabilities of outcome		
Facial palsy	0.380	Brackmann <i>et al.</i> (12)
CSF-leak – maximum reduction by RoboSculpt Gen1 (%)	0	Expert opinion
Meningitis – maximum reduction by RoboSculpt Gen1 (%)	0	Expert opinion
Facial palsy – maximum reduction by RoboSculpt Gen1 (%)	10	Expert opinion
Costs (EUR)		
Facial palsy	4,504.68	Radboud University Medical Center
Operating room – rent per minute	13.63	Radboud University Medical Center
Personnel costs (EUR/ minute)		
Surgeon	1.88	ZIN (16–18)
3 OR assistants	9.82	ZIN (16–18)
Anesthesiologist split over 2 OR room ^a	2.81	ZIN (16–18)
Additional costs per use (50 procedures per year) for RoboSculpt Gen1 – depending on number of procedures per year	5,037.03	
<i>Purchase price per patient</i>	4,821.36	Eindhoven Medical Robotics; ZIN
<i>Maintenance per patient</i>	213.44	Eindhoven Medical Robotics
<i>Screwdriver</i>	2.23	KLS Martin
Additional costs per use (50 procedures per year) for RoboSculpt Gen1 – per procedure	680.00	
<i>Marker screws – material</i>	132.54	KLS Martin
<i>Marker screws – placement</i>	362.04	ZIN (16–18)
<i>CT scan</i>	143.26	ZIN (16–18)
<i>Segmentation by surgeon</i> (Assuming 30 min of nonpatient bound time of specialist)	42.15	ZIN (16–18)
Additional fixation time of patient and robot on OR table (Assuming 15 min of additional fixation time)	217.70	Radboud university medical center
Disutilities of 1 year		
Facial palsy	0.292	Gait <i>et al.</i> (19)
No complication	0.266	Goderoy <i>et al.</i> (20)

^aIn the Netherlands, the anesthesiologist works in two OR rooms at the same time in collaboration with one anesthesiology assistant per OR room who works in one OR room at the same time. The anesthesiology assistant is included as OR assistant.
ZIN, Zorginstituut Nederland.

The INMB is calculated as followed: $INMB = (\Delta QALY \times \lambda) - \Delta \text{costs}$.

$\Delta QALY$ or incremental QALYs = QALY RoboSculpt Gen1 – QALY conventional surgery
 Δcosts or incremental costs = costs RoboSculpt Gen1 – costs conventional surgery
 λ = Cost-effectiveness threshold (EUR 20,000 per QALY) (17;21).

The decision-making threshold of EUR20.000 per QALY is based on the disutility of 0.266–0.292 for surgically removed vestibular schwannomas (19–23). This threshold is based on a research report conducted by the Council for Public Health and Care to the Minister of Health, Welfare and Sport (22) and research reports of National Health Care Institute of the Netherlands (21;23). They

suggest a model consisting of three levels of disutility correlated with three levels of willingness-to-pay based on a model assuming that the willingness-to-pay has a linear correlation with the disutility with a maximum willingness-to-pay of EUR 80,000 per QALY. A positive INMB means that using RoboSculpt Gen1 is cost-effective compared to conventional TLA. A positive INMB is therefore the pivot point of the threshold analysis for decision making.

Results

Incremental Costs for Various Numbers of Procedures Per Year

The incremental costs for using RoboSculpt Gen1 compared to conventional surgery, assuming using RoboSculpt Gen1 is as effective as conventional surgery by using the base-case scenario, were EUR5,934 per procedure. Figure 2A shows the incremental costs per procedure using RoboSculpt Gen1 compared to conventional surgery for various numbers of procedures per

year, ranging from 10 to 350. The graph shows that the incremental costs decrease exponentially from EUR26,082 to EUR1,905 per procedure for ten to 350 procedures per year, respectively. It seems it will not cross the pivot point, resulting in saving costs.

Incremental Costs for Variations of Operation Time, Facial Palsy, and Procedures Per Year

Figure 2B shows the incremental costs for various degrees of reduced OR time (0–120 min) in combination with various degrees of reduced risk of facial palsy (0, 5, and 10 percent reduction). When we assumed 0 min OR time saved combined with 0 percent reduced risk of facial palsy, the incremental costs were EUR 5,934 per procedure. Zero minutes OR time saved combined with 10 percent reduced risk of facial palsy resulted in incremental costs of EUR 5,763. When we assumed 120 min OR time saved in combination with 0 percent reduced risk of facial palsy, the incremental costs were EUR 4,193 per procedure. OR time saved of 120 min in

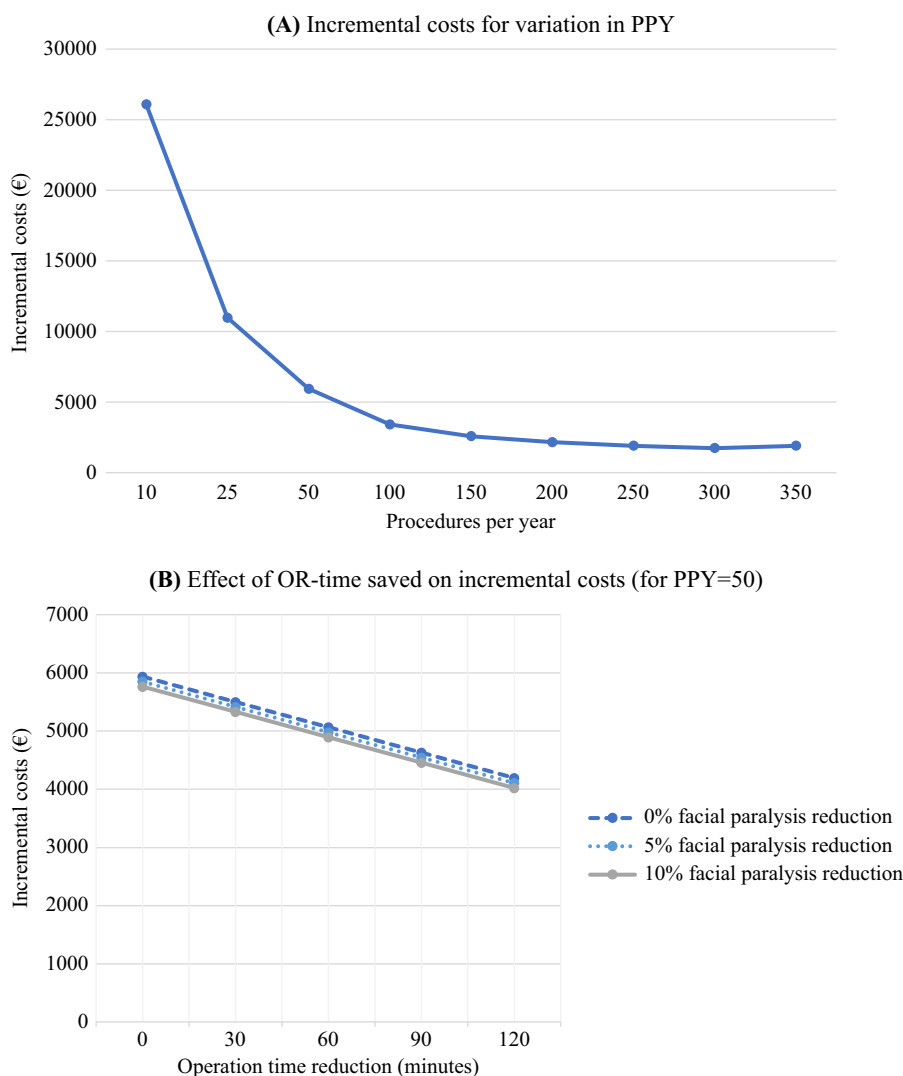


Figure 2. Incremental costs for various numbers of procedures per year, reduced operation time, and facial palsy reduction. (A) Incremental costs for various numbers of procedures per year assuming a purchase price of EUR1,000,000, 0 percent facial palsy reduction, and no OR time saved. (B) Incremental costs for various reduced operation time in combination with various reduced risk of facial palsy, assuming a purchase price of EUR1,000,000 and 50 procedures per year. Analyses for 50 procedures per year, which is the maximum annual volume in the Netherlands.

Table 2. Incremental costs (EUR) or incremental net monetary benefit for various number of procedures per year in combination with saved OR time and 0 and 10 percent risk reduction of facial palsy

(A) Incremental costs (EUR) for various number of procedures per year in combination with saved OR time and 0 percent risk reduction of facial palsy										
OR time saved	PPY	350	300	250	200	150	100	50	25	10
0		1,617	1,737	1,905	2,157	2,577	3,416	5,935	10,972	26,083
30		1,182	1,302	1,470	1,722	2,141	2,981	5,499	10,536	25,647
60		746	866	1,034	1,286	1,706	2,545	5,064	10,101	25,212
90		311	431	599	851	1,271	2,110	4,629	9,666	24,777
120		-124^a	-4^a	164	415	835	1,675	4,193	9,230	24,341
(B) Incremental costs (EUR) for various number of procedures per year in combination with saved OR time and 10 percent risk reduction of facial palsy										
OR time saved	PPY	350	300	250	200	150	100	50	25	10
0		1,446	1,566	1,734	1,986	2,405	3,245	5,764	10,801	25,912
30		1,011	1,131	1,298	1,550	1,970	2,810	5,328	10,365	25,476
60		575	695	863	1,115	1,535	2,374	4,893	9,930	25,041
90		140	260	428	680	1,099	1,939	4,457	9,494	24,605
120		-296^a	-176^a	-8^a	244	664	1,503	4,022	9,059	24,170
(C) Incremental net monetary (EUR) benefit for various number of procedures per year in combination with saved OR time and 10 percent risk reduction of facial palsy										
OR time saved	PPY	350	300	250	200	150	100	50	25	10
0		-1,465	-1,585	-1,753	-2,005	-2,425	-3,264	-5,783	-10,820	-25,931
30		-1,030	-1,150	-1,318	-1,570	-1,989	-2,829	-5,347	-10,384	-25,495
60		-594	-714	-882	-1,134	-1,554	-2,393	-4,912	-9,949	-25,060
90		-159	-279	-447	-699	-1,118	-1,958	-4,477	-9,514	-24,625
120		276^a	156^a	-11	-263	-683	-1,523	-4,041	-9,078	-24,189

^aNegative incremental costs (EUR) or positive INMB (EUR), meaning that the robot saved costs per procedure compared to conventional surgery. INMB, incremental net monetary benefit; OR time, operation time; PPY, procedures per year.

combination with 10 percent reduced risk of facial palsy resulted in incremental costs of EUR 4,021 per procedure. Within the thresholds of this study, the costs did not cross the pivot point.

The results of the analyses for varying the number of procedures per year (10–350) as well as saved OR time (0–120 min) for 0 and 10 percent risk reduction of facial palsy are shown in Table 2A,B. Table 2A shows that the robot saves costs per procedure without reducing the risk of facial palsy, if the robot was used for at least 300 procedures per year in combination with the maximum saved OR time of 120 min. Table 2B shows that the robot saves costs per procedure and will cross the pivot point under the following conditions: 10 percent reduced risk of facial palsy, the robot were rather used for at least 250 procedures per year in combination with the maximum saved operation time of 120 min. In other cases, the robot would result in higher incremental costs compared to conventional TLA.

Table 2C shows almost comparable results as Table 2B, but with INMB as outcome instead of incremental costs. The robot would only result in a positive INMB and will cross the pivot point for at least 300 procedures per year in combination with 120 min saved OR time and 10 percent reduced risk of facial palsy.

Sensitivity Analysis

The sensitivity analysis brings the previous analyses together in one tornado plot (Figure 3). This figure shows that the high number of

procedures per year has the most favorable impact on the incremental costs compared to conventional TLA, followed by low purchase price, shorter OR time, and lower risk of facial palsy, respectively (Figure 3).

Discussion

Our early economic evaluation comprising a decision analytical model and stepwise threshold analysis is a first exploration of the economic consequences of an autonomous surgical robot in relation to its potential benefits compared with conventional TLA. First of all, the results of our study show that using an autonomous surgical robot will result in incremental costs compared to conventional TLA. Furthermore, our study also suggests that the incremental costs of an autonomous surgical robot compared to conventional TLA will be lower if the number of procedures per year using the robot increases, the purchase price of the robot decreases, the saved OR time increases, and/or the risk of facial palsy decreases. A combination of these factors will decrease the incremental costs of a robot even further.

In this study, RoboSculpt Gen 1 was used as an example, but three other robots with the same purpose are currently under development. Dillon *et al.* studied one of these three image-guided surgical robots. The care pathway is comparable to RoboSculpt Gen 1. However, two CT scans are required for the robot studied by

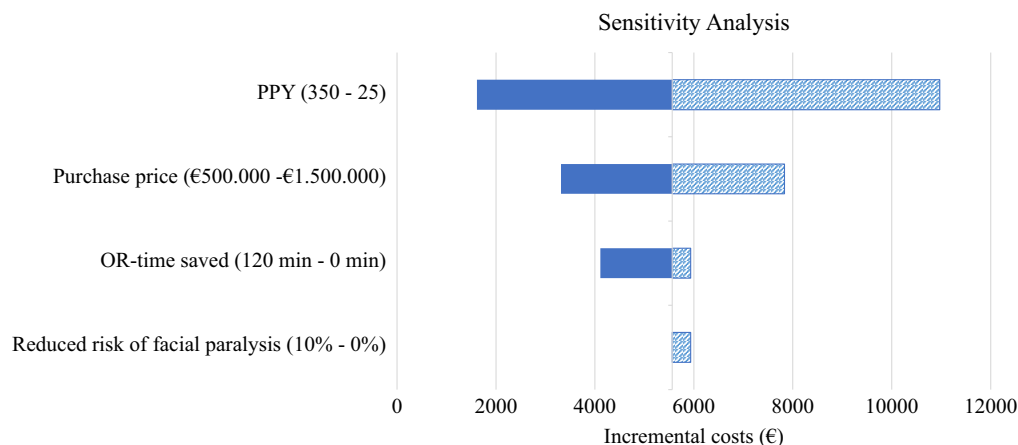


Figure 3. Tornado diagram of the sensitivity analysis. Ordered from high to low impact on incremental costs. Midline is set at the baseline of EUR 5,562 incremental cost per procedure. CI, incremental costs; OR time, operation time; PPY, procedures per year.

Dillon et al.: the first CT scan is made preoperatively for segmentation and the second CT scan is made intraoperatively after placing a positioning frame and is used for registration. This will result in extra incremental costs compared to our model. They tested their robot on five cadavers and showed that the nerves were preserved in all five cadavers. However, it took about 32–57 min to drill a TLA excluding the preparation time (7). The drilling time of this robot is still too high according to our results in order to reduce the incremental costs, especially if the incremental costs increase as a result of the second CT scan required for this robotic procedure. Another autonomous surgical robot is described by Couldwell et al. No results of preclinical tests with this robot were described yet. However, they suggested that their robot can drill a TLA in 2 min and 30 sec (8). If this is achievable, this would be favorable in order to reduce the incremental costs. Finally, Danilchenko et al. tested an autonomous surgical robot, called OTOBOT, on three temporal bone specimens. However, in their study, OTOBOT was used for mastoidectomy and the drilling time of that took about 90 min. They predict that OTOBOT can drill a mastoidectomy within 18 min in the future. They also predicted that OTOBOT may retail for \$500,000. Both predicted factors are favorable for the incremental costs of using their robot.

Our decision model gives valuable information in the early phases of development that various autonomous surgical robots are in, and that can contribute to decision making for further development. It might provide clinicians, policy makers, and developers new insight concerning the financial consequences and viability of these kind of robots (10). No other cost-effectiveness studies about surgical robotics for skull base surgeries are described in the literature. Nonetheless, these kinds of early cost analyses of innovations are recommended by the idea, development, exploration, assessment, and long-term follow-up (IDEAL) collaboration, which suggests modeling studies to predict overall impact on healthcare costs and efficiency (24). Cost failures of expensive innovations are a misfortune, especially in a field like health care that struggles with cost control. During the development phase of innovations, there is still the possibility to adjust and refine a device. The main goal of this kind of early HTA is to explore whether and how an innovation, such as an autonomous surgical robot, is worth the investment in a certain context by capturing a deliberation in the study and to explore how various inputs affect the economic consequences of such an innovation. This kind of study should not be confused with

cost-effectiveness studies where it is important that all inputs and assumptions are as precise as possible. Therefore, this study can contribute to a worthwhile development of the robot resulting in increased chance of successful implementation. Based on our results, we would like to suggest some requirements of applications for autonomous surgical robots and requirements of it in order to reduce the incremental costs as much as possible.

First of all, our analyses suggest that the number of procedures per year has the highest impact on the costs of utilizing an autonomous surgical robot. These robots might have clinically added value for TLA, because this procedure is time-consuming due to the high amount of bone drilling. However, the number of TLA performed per year is low, about 50 per year in the Netherlands. This number is even smaller for each individual hospital performing this procedure. However, it may rise for one hospital in the Netherlands, if the procedure were centralized. However, we expect this number will decrease in the near future due to encouraging results of wait and scan policy (25–27) and stereotactic radiosurgery for vestibular schwannomas (28;29). In order to increase the number of procedures per year using an autonomous surgical robot, other applications including drilling bone away need to be explored. Possible applications for such a robot may be placement of a cochlear implant or spine surgery. Additionally, the number of procedures per year using such a robot can also be increased by centralizing these procedures. By expanding the applications for these kind of robots and centralizing these procedures, this innovation can be prevented from being used inefficiently resulting in unnecessarily high healthcare costs. Moreover, this can also prevent unnecessary procedures being performed with the robot, just to make “good use” of the robot, which also leads to unnecessary high healthcare costs. However, we need to stress that the impact of higher procedure numbers with the robot decreases at a certain point, as the use of an autonomous surgical robot is correlated with fixed costs, such as the markers screws and extra CT scan. To explore the value of autonomous surgical robots for other types of bone removal procedures, we recommend undertaking studies comparable to this study using early decision models for potential other applications for the robot.

In order to decrease the incremental costs of an autonomous surgical robot even more, the use of this robot needs to save a significant amount of OR time for these surgical procedures. Thus, procedures requiring long drilling time would be interesting for this

kind of robot. The extra preparation time that is required when using such a robot must be taken into account when calculating OR time saved and incremental costs could be decreased if preparation was as efficient as possible.

There may be higher opportunity to reduce incremental costs in procedures where there is a high risk of complications, which may be costly to deal with or have high impact on quality of life. Our results showed that the impact of this factor is less compared to the previous two factors. This can be explained by the fact that the complication rates of lateral skull base procedures are already low, and that the impact on quality of life is low (disutility of 0.026 compared to no complications). Moreover, the complications that occur are mainly caused during soft tissue surgery instead of the drilling part of the procedure (13–15), and therefore it is unlikely that an autonomous surgical robot can reduce these complications.

There are a few limitations that need to be mentioned. First of all, we used Dutch prices to estimate the incremental costs of the robot and the results of these analyses may not be applicable in other settings. Therefore, we advise to compare the prices that we used to relevant prices in the setting being assessed. Secondly, as RoboSculpt Gen1 is still under development we had to make assumptions about the costs related to RoboSculpt Gen1. These costs can be different for other robots. Nevertheless, we explored the threshold of these costs resulting in valuable information, for clinicians and developers. Our results show that lower purchase price of a robot leads to decreased incremental costs. Another limitation of our study was that some input for our model was not evidence-based, because this information was not studied yet or available. In order to use as reliable information as possible, we used input based on experts' opinion.

One must realize that not all advantages of an autonomous surgical robot could be expressed in costs, such as ergonomic advantages for surgeons. When the ergonomics of a surgeon can be improved by using an autonomous surgical robot, it might improve the surgeons' health resulting in higher sustainable employability and less medical expenses. However, this factor might not affect the clinical outcome of patients and therefore it is hard to incorporate in a decision model as ours. These kinds of advantages associated with the robot need also to be taken into account for the implementation as potential added value of the robot. Our model did not include the impact on the overall structure and function of the health system in the Netherlands (such as facilities, workforces, policies, and other physical and abstract structures) by the introduction of an autonomous surgical robot. A diagonal approach can be performed to study the impact of an autonomous surgical robot on the direct clinical outcomes including the related costs in combination with the economic consequences of the overall structure and function of the health system (30).

In summary for future research about these autonomous surgical robots, we advise to perform additional early decision modeling studies for other potential applications for these robots in order to explore changes in the economic consequences compared to our study. Additional research is also recommended to obtain more valid information on the drilling time by the robot compared to the surgeon and risk of various complications due to drilling by the robot compared to the surgeon, because these factors also affected the incremental costs of the robot compared to conventional surgery. Furthermore, we advise to also perform a needs assessment in order to explore the added value, for example, the possible improved surgeon's ergonomics and

vitality, and possible disadvantages for various stakeholders related to such an autonomous surgical robot. Additionally, the diagonal approach can be performed to evaluate the impact of such a robot on the overall structure and function of the health system.

Conclusion

Our early economic evaluation comprising a decision analytical model and stepwise threshold analysis suggest that using an autonomous surgical robot for drilling bone away will result in incremental costs compared to conventional surgery. The incremental costs of a robot can be decreased by choosing surgical applications with a high turnover rate, a long OR time that can be saved by using the robot (taking into account the extra preparation time) and a high complication rate caused by drilling correlated with high costs and/or high impact on QOL.

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