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McGill University Health Centre

## Technology Assessment Unit of the McGill University Health Centre (MUHC)

# 532 nm KTP Laser for Vocal Fold Surgery

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**Report prepared for the Technology Assessment Unit (TAU)**

**of the McGill University Health Centre (MUHC)**

**by**

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Use of KTP for laryngeal surgery is still innovative. There are presently no published data to indicate that the KTP laser produces clinically better outcomes or is safer than the presently available CO2 laser.

Unlike the CO2 laser, some KTP procedures can be carried out in the clinic, relieving pressure on the operating room, shortening waiting times, and avoiding the risks associated with inpatient admission

To the extent that this is possible, KTP use would also result in increased efficiency (more clinical acts for the same budget outlay).

## List of abbreviations

| | |
|---|---|
| ENT | Ear, nose, and throat |
| HTA | Health technology assessment |
| KTP | Potassium Titanyl Phosphate |
| MGH | Montreal General Hospital |
| MUHC | McGill University Health Centre |
| PDL | Pulsed dye laser |
| RVH | Royal Victoria Hospital |
| TAU | Technology Assessment Unit |

# EXECUTIVE SUMMARY

## Background

The KTP 532 nm Aura XP is a laser in the green visible light spectrum. In recent years, it has been used for laryngeal surgery. The Technology Assessment Unit (TAU) was requested to evaluate the clinical effectiveness and budget impact of using this technology for vocal fold surgery at the MUHC.

## Method

A systematic literature search was carried out using Pubmed and the health technology assessment (HTA) database of the Centre for Reviews and Dissemination. We estimated the procedure cost of KTP laser therapy in the outpatient clinic and the operating room for vocal fold surgery and compared it with the costs of the $CO_2$ laser currently employed at the MUHC.

## Results: Literature review

No HTAs or systematic reviews of KTP 532 nm laser in ear, nose, and throat (ENT) procedures were identified. We identified 7 articles which reported the use of KTP for treatment of vocal folds, but no studies compared the KTP laser with other technologies.

***Keratosis with dysplasia (office-based procedure):*** In Zeitels 2006 (a), 29 out of 36 procedures (81%) were assessed at 4-8 weeks after surgery using video endoscopic evaluation. Twenty-five (86%) procedures showed a “favourable outcome” (greater than 50% disease regression).

***Recurrent papillomatosis:*** In Burns 2007, 35 of 55 (64%) procedures were evaluated at 1-3 months after surgery. Twenty-eight (80%) of evaluated procedures showed 90% or greater disease regression, indicating that most patients had favourable outcomes at 1 to 3 months after surgery.

***Ectasias and varices:*** Zeitels 2006(b) included 39 patients who were singers, of whom 15 were treated using KTP. The clinical outcomes of PDL and KTP laser treatments were reported together. All patients resumed full vocal activities. All patients with resection of a mass lesion had improvement in mucosal wave function. There were no complications, postsurgical hemorrhages or vocal deterioration. Hsiung et al. report a retrospective review of 14 patients treated with KTP. There were no intraoperative or postoperative complications. All patients recovered full vocal activity within 1 to 2 months. Thirteen out of 14 patients showed excellent clinical outcomes, without recurrence or further hemorrhage.

***Early glottis cancer:*** Zeitels 2008 included 22 patients with early cancer of the glottis. Mean follow, 27 months. Clinical outcomes of both treatments (PDL and KTP

laser) were reported together. All were cancer-free at the end of follow-up. All measures reflected improvement in vocal function.

***Various benign laryngeal pathologies:*** Mallur et al. report a retrospective review of 32 patients (47 procedures) who received office based KTP laser therapy. The indications were: hemorrhagic polyp (n=23), nonhemorrhagic polyps (n=7), vocal process granuloma (n=7), Reinke's edema (n=5) etc. At one month post procedure the lesion size was statistically significantly reduced in all lesion types except polyps.

***Mixed Laryngeal pathologies:*** Burns 2010 et al. report a retrospective review of 710 consecutive endoscopic laryngeal surgical procedures of which 387 (55%) were performed by KTP laser. Importantly, 209 were carried out in the clinic. The authors did not report the clinical outcomes in this study.

***Location of laser procedures:*** In some of these reports KTP procedures were carried out in the outpatient clinic rather than in the OR under general anaesthesia. The overall proportion that might be carried out in this way is uncertain. In the substantial series of Burns et al such procedures constituted 54% of the total.

## Cost analysis

The cost of KTP therapy in outpatient clinic and operating room are $820, and $2,484, respectively. Assuming a turnover of 60 procedures per year, if 50% are conducted in the office, the average cost for all would be $1,652 per procedure, and the annual budget impact $99,121 The operating room and recovery room costs associated with use of the $CO_2$ laser are approximately $1,865 per procedure, and the annual budget impact is about $111,925 for 60 cases.

It is important to note that the net effect of KTP procedures would not be budget saving but rather an increase in efficiency by lowering the use of the operating and recovery rooms.

## Conclusions

- **Use of KTP for laryngeal surgery is still innovative. Approved in Canada in 2011, there is still only one Canadian centre using this technology.**
- **There are seven publications describing the use of KTP, five of which derive from the same group of authors. These indicate that it is a safe, effective technology for the treatment of several laryngeal pathologies.**
- **However, there are presently no published data to indicate that the KTP laser produces clinically better outcomes or is safer than the presently available $CO_2$ laser.**
- **Unlike the $CO_2$ laser, the KTP laser can be used in an office setting for a certain number of cases. Assuming a total of 60 procedures per**

**year, and assuming that with the use of KTP 30 of these could be carried out in the outpatient clinic, the cost per procedure using the $CO_2$ and KTP instruments would be $1,865 and $1,652, respectively. This would diminish pressure on the OR and reduce wait times for this procedure.**

## RECOMMENDATIONS

- **While it may be appropriate that a University Hospital such as the MUHC should take part in the evaluation of a new technology, it would not be appropriate to acquire this technology from the operating budget without further evidence of superiority. Consideration to purchase this technology should be deferred until the following steps have been completed.**
- **The instrument should first be acquired on a temporary basis (rental or loan) during which time it could be used and evaluated by members of the department with particular focus on the following issues :**
  1) **The percentage of patients that can be treated in the outpatient clinic**
  2) **The clinical outcomes (sound/voice assessment, and complications) following use of the KTP laser.**
  3) **The possibility of reusing the glass fiber and the cost of recycling**
  4) **The effect of KTP use on wait times.**
- **With information on these issues and with the benefit of any new evidence that may be available at the time, permanent acquisition of this technology could then be reconsidered.**

# SOMMAIRE


## Contexte

Le laser KTP 532 nm Aura XP utilise la lumière de couleur verte du spectre visible de la lumière. Au cours des dernières années, ce laser fut utilisé pour les chirurgies du larynx. L'Unité d'évaluation des technologies ("Technology Assessment Unit") fut sollicitée pour évaluer l'efficacité clinique et l'impact budgétaire résultant de l'utilisation de cette technologie pour la chirurgie des cordes vocales au CUSM.

## Méthodologie

Une revue systématique de la littérature fut menée à partir de Pubmed et de la base de données (HTA) du "Centre for Reviews and Dissemination". Nous avons estimé les coûts d'une procédure au laser KTP en clinique externe et au bloc opératoire lors de la chirurgie des cordes vocales et avons comparé ces coûts à ceux obtenus lors d'interventions au laser $CO_2$ utilisé couramment au CUSM.

## Résultats. Revue de la littérature

Aucun rapport d'évaluation des technologies (HTA) ou de revue systématique ne fut identifié concernant l'utilisation du laser KTP 532 nm pour des procédures touchant l'oreille, le nez ou la gorge. Par contre, nous avons identifié 7 articles mentionnant l'utilisation du laser KTP pour le traitement des cordes vocales, mais aucune ne comparait le laser KTP à d'autres technologies.

***Kératoses avec dysplasie (procédure exécutée en externe):***

Dans un article publié par Zeitels (2006), on mentionne que 29 procédures parmi 36 (81%) furent évaluées de 4-8 semaines après chirurgie à partir d'une évaluation endoscopique. Vingt-cinq (86%) procédures montraient un "résultat favorable" (une régression de la maladie de plus de 50%).

***Papillomatoses récurrentes:***

Burns (2007) rapporte que 35 procédures parmi 55 (64%) furent évaluées de 1-3 mois après chirurgie. Vingt-huit (80%) procédures évaluées montrèrent une régression de la maladie de 90% et plus, indiquant que la majorité des patients avaient un résultat favorable après 1 à 3 mois, suite à la chirurgie.

***Ectasies et varices:***

Zeitels (2006 b) inclut 39 patients qui étaient chanteurs, dont 15 furent traités à l'aide du laser KTP. Les résultats cliniques des procédures faites à l'aide du laser KTP et du laser PDL (585 nm Pulsed Dye Laser) furent rapportés conjointement. Tous les patients traités recouvrèrent leurs pleines activités vocales et tous les patients ayant eu la résection d'une lésion ("mass lesion") eurent une amélioration de la fonction muqueuse ("mucosal wave function"). Aucune complication ne fut rapportée, ni

hémorragies post-chirurgicales, ni détérioration vocale. Hsiung et al. rapportent une revue rétrospective de 14 patients traités par laser KTP et mentionnent qu'il n'y eut aucune complication peropératoire ou post-opératoire. Tous les patients recouvrèrent leur pleine activité vocale en deçà de 1 à 2 mois après la chirurgie. Treize de ces 14 patients montrèrent d'excellents résultats cliniques, sans récurrence ou autre hémorragie.

***Cancers précoces de la glotte:***

Zeitels (2008) considéra 22 patients dans son étude avec un cancer précoce de la glotte avec un suivi moyen de 27 mois. Les résultats cliniques des deux traitements (lasers PDL et KTP) furent rapportés conjointement. Aucune trace de cancer n'était présente à la fin du suivi et toutes les mesures prises soulignaient une amélioration de la fonction vocale.

***Pathologies bénignes du larynx:***

Mallur et al. firent une revue rétrospective de 32 patients (incluant 47 procédures) ayant subit un traitement au laser KTP au bureau. Les indications étaient: polypes hémorragiques (n=23), polypes non-hémorragiques (n=7), granulome vocal (n=7), oedeme de Reinke (n=5), etc. Un mois après le traitement, la taille de la lésion était réduite de façon statistiquement significative pour tous les types de lésions, à l'exception des polypes.

***Pathologies mixtes du larynx:***

Burns et al. (2010) rapportent une revue rétrospective de 710 endoscopies chirurgicales consécutives du larynx dont 387 (55%) furent faites à l'aide d'un laser KTP. À noter que 209 procédures furent faites en clinique. Les auteurs ne rapportèrent pas les résultats cliniques de cette étude.

***Localisation des procédures laser:***

Dans quelques uns des rapports précédents, les procédures au laser KTP furent faites en clinique externe et non au bloc opératoire, sous anesthésie générale. Le pourcentage global des procédures qui auraient pu être réalisées de cette façon est incertain. Ces procédures constituent 54% des procédures totales mentionnées dans les séries importantes de Burns.

## Analyse des coûts

Le coût d'une thérapie au laser KTP en clinique externe et au bloc opératoire est de 820 $ et de 2 484 $, respectivement. Si l'on présume un achalandage de 60 procédures par année et que 50% de ces procédures sont réalisées en clinique externe, le coût moyen de ces procédures serait de 1 652 $ par procédure, avec un impact budgétaire annuel de 99 121 $. Les coûts de fonctionnement de la salle d'opération et de la salle de réveil associé avec l'utilisation d'un laser $CO_2$ nous

donnons un coût moyen par procédure de 1 865 $, avec un impact budgétaire annuel de 111,925 $ pour 60 cas.

Il est important de souligner que l'impact budgétaire des procédures au laser KTP n'entrainerait pas d'économies mais plutôt une augmentation d'efficacité en abaissant les coûts d'utilisation du bloc opératoire et de la salle de réveil.

## CONCLUSIONS

- **L'utilisation du laser KTP pour la chirurgie du larynx demeure une approche innovante. Approuvée au Canada en 2011, cette technologie n'est utilisée que par un seul centre canadien.**
- **Il y a sept publications décrivant l'utilisation du laser KTP, dont 5 provenant des mêmes auteurs. Ces publications soulignent que cette technologie est sécuritaire et efficace pour le traitement de plusieurs pathologies du larynx.**
- **Cependant, il n'y a aucune donnée publiée indiquant que les procédures au laser KTP entrainent de meilleurs résultats cliniques ou sont plus sécuritaires que les procédures au laser $CO_2$ réalisées actuellement.**
- **Contrairement au laser $CO_2$ alternatives, le laser KTP peut être utilisé sur une base externe pour un certain nombre de cas. Si l'on présume un nombre total de 60 procédures par année et que l'utilisation d'un laser KTP puisse permettre de réaliser 30 procédures en clinique externe, le coût d'une procédure réalisée avec un laser $CO_2$ et un laser KTP serait de 1 865 $ et 1 652 $, respectivement. Ceci diminuerait la pression sur le bloc opératoire ainsi que les temps d'attente pour cette procédure.**

## RECOMMANDATIONS

- **Malgré le fait qu'il serait approprié qu'un hôpital universitaire tel que le CUSM puisse prendre part à l'évaluation d'une nouvelle technologie, il ne serait pas avisé d'acquérir cette technologie à partir du budget d'opération sans plus d'évidence de sa supériorité. L'acquisition de cette technologie devrait être reportée jusqu'à ce que les étapes suivantes aient été complétées.**
- **En première approche, le laser devrait être acquis sur une base temporaire (location ou prêt) de façon à permettre son utilisation et son évaluation par les membres du département avec une attention spéciale sur les points suivantes:**
  1. **Le pourcentage de patients pouvant être traités en clinique externe**
  2. **Les résultats cliniques (évaluation de la voix et complications) du laser KTP**
  3. **Le possibilité de réutilisé la fibre de verre et le coût du retraitement**
  4. **L'impact du laser KTP sur les temps d'attente.**
- **En prenant en considération les réponses aux questions précédentes ainsi que toutes nouvelles données disponibles ultérieurement, l'acquisition permanente de cette technologie pourrait alors être reconsidérée.**

# 532 nm KTP Laser for Vocal Fold Surgery

## 1. BACKGROUND

The KTP 532 nm Aura XP (American Medical Systems) is a laser in the green visible light spectrum. It has been relatively widely used for urologic and dermatologic indications and in 2006 Zeitels et al reported its use for ear, nose, and throat (ENT) surgery[1].

Until recently two instruments have been used for laser ablation of papillomatosis and dysplasia of the vocal cords, the $CO_2$ laser[2] and the 585-nm pulsed dye laser (PDL)[2] . Currently, in the McGill University Health Centre (MUHC) a $CO_2$ laser is employed in operations on the vocal folds. The KTP laser has some theoretical advantages over the other lasers[3;4] which suggest that it might result in less vocal fold damage and scarring. Also, a proportion of KTP treatments can be carried out under local anesthesia in the outpatient clinic, with potential resource saving in use of the operating room. This instrument received approval in Canada in 2011, and at the present time there is only one in use in Canada.

The acquisition of this instrument has been proposed by Dr J Young of the Division of Adult Otorhinolaryngology of the Montréal General Hospital (Head: Dr Karen Kost). On Dec 7th, 2011, the Technology Assessment Unit (TAU) was requested by Mr Gary Stoopler (Administrative Director, Surgical Mission, MUHC) to undertake a review of the efficacy and costs of this technology and to recommend whether or not it should be acquired by the MUHC.

## 2. OBJECTIVES

- To evaluate the effectiveness and safety of KTP laser for vocal fold surgery.
- To estimate the budget impact of using this technology at the MUHC.

## 3. METHODS

### 3.1. Literature search

A systematic literature search was carried out using Pubmed and the health technology assessment (HTA) database of the Centre for Reviews and Dissemination[5]. The following key words were used: (“532 nm” or “532 nanometre”) AND (KTP or "Potassium Titanyl Phosphate" or “potassium-titanyl-phosphate”) AND (vocal or voice or laryngeal or larynx or glottic or papillomatosis or dysplasia). We

also used the website of Aura XP (the producer of Potassium Titanyl Phosphate (KTP) 532 nm laser) to obtain additional publications[6]. We limited our literature search to research studies on human subjects, whose full-texts were published in peer-reviewed journals or in HTA reports from public agencies. Xie carried out the literature search. The eligible articles were reviewed by both authors.

## 3.2. Cost analysis

We estimated the procedure costs of using KTP laser therapy for vocal fold surgery, both in the outpatient clinic and the operating room (OR). We compared this with the cost of using the $CO_2$ laser in the operating room only. The purchasing and maintenance cost of the KTP laser, and the cost of disposable components (Endostat Fiber) were obtained from AMS Canada Inc.[7] We used MUHC surveillance data from the Department of Finance for the estimate of the cost of OR, recovery room and outpatient clinic (primarily personnel cost and supplies)[8]. All costs were expressed in Canadian Dollars 2011[9].

# 4. LITERATURE REVIEW

## 4.1. Health technology assessment reports and Systematic reviews

Although there are a number of systematic reviews and one HTA report of KTP 532 nm for prostatic diseases, no HTAs or systematic reviews of KTP 532 nm laser in ear, nose, and throat (ENT) procedures were identified.

## 4.2. Observational studies

We identified 7 articles which reported the use of KTP for treatment of vocal folds, two for ectasias and varices[10;11],one article each for treatment of keratosis with dysplasia[1], recurrent papillomatosis[1;2], early glottis cancer[12], various benign laryngeal pathology[13], and a retrospective review of the use of KTP in 387 endoscopic laryngeal surgeries in a one-year period (2007-08)[14]. No studies compared KTP laser with other technologies. The details of the literature search and study selection can be found in Appendix 1.

We summarize the results of these 7 studies in this section. More details can be found in Table 1.

### *4.2.1. Keratosis with dysplasia (office-based procedure)*

In Zeitels 2006 (a)[1], 28 dysplasia patients received 36 office-based procedures using KTP. Twenty-nine out of 36 procedures (81%) were assessed at 4-8 weeks after surgery using videoendoscopic evaluation (pretreatment versus posttreatment). Twenty-five (86%) procedures showed a “favourable outcome” (greater than 50%

disease regression). The authors also suggested, though they did not provide any evidence, that KTP therapy overcomes some of the shortcomings of the 585-nm pulsed dye laser (PDL), such as vessel wall disruption and visible extravasation of blood.

### *4.2.2. Recurrent papillomatosis*

Burns 2007[2] included 37 patients and 55 procedures. The authors mention that 15 individuals had two surgeries, 1 individual had 4 surgeries and the remaining 21 individuals did not require further treatment or were treated with KTP in an office-based setting. Thirty-five of 55 (64%) procedures were evaluated at 1-3 months after surgery. Twenty-eight (80%) of evaluated procedures showed 90% or greater disease regression, indicating that most patients had favourable outcomes at 1 to 3 months after surgery. There were no complications of anesthesia or surgery. No patients developed new webbing or synechia. All patients reported improvement of vocal function (self-reported outcome). The authors suggested that KTP showed comparable results with their own previously published article of PDL[15] in eradicating papillomatosis from the glottis surface.

### *4.2.3. Ectasias and varices*

Zeitels 2006(b)[10] included 39 patients who were singers with 40 procedures in 54 vocal folds. All operations were done under general endotracheal anesthesia. The first 24 patients (33 vocal folds) were treated using PDL and the last 15 patients (21 vocal folds) were treated using KTP. The authors reported the clinical outcomes of both treatments together, not independently. All patients resumed full vocal activities. All patients with resection of a mass lesion had improvement in mucosal wave function. There were no complications, postsurgical hemorrhages or vocal deterioration. However, more ecchymosis of the superficial lamina propria (SLP) was observed in the PDL group, with delayed onset of singing for 4 to 5 weeks (authors did not report the number). Nineteen patients (50%) were evaluated for their postsurgical voice. In this voice assessment, the average speaking fundamental frequency (F0) was in the normal range for 17 of 19 patients (89%); and aerodynamic efficacy was normal for 14 patients (74%). The authors concluded that both lasers were effective and relatively safe for the treatment of vascular abnormalities of the vocal folds in singers, but, PDL was associated with higher risks of vessel wall rupture.

Hsiung et al. report a retrospective review of 14 patients who underwent microlaryngeal surgery by KTP laser for microvascular lesions (also called varices) of the vocal fold[11]. All patients were hospitalized for 1 or 2 days. There were no intraoperative and postoperative complications. All patients recovered full vocal activity within 1 to 2 months. Thirteen out of 14 patients showed excellent clinical outcomes, without recurrence or further hemorrhage. Patients were followed for 7 months on average, ranging from 2 to 14 months. In the before and after

comparison, authors found the phonatory functions improved significantly, in the measurements of jitter, shimmer, grade, breathiness and roughness.

### *4.2.4. Early glottis cancer*

Zeitels 2008[12] included 22 patients with early cancer of the glottis. The first 8 patients were treated by PDL and the next 14 were treated by KTP. All procedures were carried out under general endotracheal anesthesia. The mean follow up duration was 27 months. Again, the authors reported the clinical outcomes of both treatments together, not independently. All 22 patients were cancer-free at the end of follow-up. The authors compared vocal function pre-and post-surgery. All measures reflected improvement in vocal function. In particular, there was a statistically significant improvement on measures such as: “average F0 in reading, maximum phonation time, Jitter, Shimmer, maximum F0 range and sound pressure comfortable level”. Authors also pointed out some technical problems with PDL. For example, they report that since the pulse width of PDL is very short and difficult to adjust past approximately 0.5 ms, it can often result in vessel wall rupture whereas KTP is a more precise technology. Data are not provided to support these comments.

### *4.2.5. Various benign laryngeal pathologies*

Mallur et al. report a retrospective review of 32 patients (47 procedures) who received office based KTP laser therapy for benign laryngeal pathology[13]. The authors excluded patients with recurrent respiratory papillomatosis because of the difficulty of assessing disease regression, and patients with incomplete follow-up. The indications were: hemorrhagic polyp (n=23), nonhemorrhagic polyps (n=7), vocal process granuloma (n=7), Reinke’s edema (n=5), and one of each of the following, pseudocyst, leukoplakia, squamous cell carcinoma in situ, and vocal fold hemorrhage. The authors found that the lesion size was statistically significantly reduced between the period before KTP laser therapy and 1 month after KTP in all lesion types but polyp. The authors also compared the pre-KTP lesion size with the smallest lesion size observed during the 1-year follow-up. There was a statistically significant difference for all lesion types except Reinke’s edema.

### *4.2.6. Mixed Laryngeal pathologies*

Burns et al. report a retrospective review of 710 consecutive endoscopic laryngeal surgical procedures carried out in one year[14]. Of these procedures, 387 (55%) were performed by KTP laser, including 209 clinic and 178 operating theatre procedures. The major indications were dysplasia (n=114 (54.5%)) and papillomatosis (n=89 (42.6%) for office-based procedures, and cancer (n=54 (30.35%)), dysplasia (n=52 (29.2%)), papillomatosis (n=38 (21.3%)) and varices or ectasia (n=13 (7.3%)) for OR procedures. The authors did not report the clinical outcomes in this study. These authors have developed a treatment model in which "the initial procedure is performed under general anaesthesia, and recurrent dysplasia is usually ablated in

the clinic under topical anaesthesia". It is this model that will be used in the MUHC. (J Young).

***Location of laser procedures***

In many of these reports KTP procedures were carried out in the outpatient clinic rather than in the OR under general anaesthesia (See Table 1). The overall proportion of procedures that might be carried out in this way cannot be determined. In the largest Series (Burns et al) such procedures constituted 54% of the total.

# 5. COST ANALYSIS

The estimated procedure costs of KTP laser therapy in the outpatient clinic and the operating room are presented in Appendix 2 and are summarized in Table 2.

Since the KTP laser can be used for some cases under local anaesthesia in the outpatient clinic while the $CO_2$ cannot, the relative price difference will vary with the proportion of KTP procedures that can be carried out in the clinic. To estimate the cost consequences of changing from $CO_2$ to KTP laser, we assumed a turnover of 60 procedures per year (Dr. Young had proposed a range from 50-100), and estimated the costs as follows:

- KTP Laser. If 50% procedures are conducted in the clinic and the other 50% in the operating room (OR), the average cost would be $1,652 per procedure, and the annual budget impact for 60 cases, $99,121 (=$820 x 30 + $2,484 x 30).[ If 25% procedures are conducted in the office, the average cost would increase to $2,068 per procedure, and the annual budget impact $124,073= ($820 x 15) + ($2,484 x 45).]
- $CO_2$ Laser. Assuming that the present $CO_2$ laser will not require replacement for at least seven years, and that the maintenance costs of both lasers is the same, the operating room and recovery room costs associated with use of the $CO_2$ laser are approximately $1,865 per procedure, and the annual budget impact would be about $111,925 for 60 cases.
- Thus, a clinic procedure by KTP laser would cost $1,664 (= $2,484 - $820) less than an operating room procedure (see Table 2), and the *net* cost would vary according to the number carried out in the clinic instead of in the operating room. If 22 of the 60 procedures were carried out in the clinic instead of in the operating room the net cost of the change from $CO_2$ laser to KTP laser would be approximately zero.

It is important to note that the apparent saving that would result from lower use of the operating and recovery rooms for KTP procedures would not constitute an actual budget saving because the time gained in the operating and recovery rooms would,

in practice, be used for other purposes. Thus, the net effect would not be budget saving but rather an increase in efficiency.

# 6. DISCUSSION

The use of KTP for laryngeal lesions: In spite of theoretical reasons for the possible superiority of solid-state lasers and the KTP in particular[3;4], available evidence of its efficacy and safety is only of Level 4 (i.e. based on case series with no comparison groups)[16]. None of the articles directly compare the KTP with the $CO_2$ laser (the type that is presently employed at the RVH). Though Zeitels 2008[12] and Zeitels 2006 (b)[10] used both PDL and KTP in their cohorts, when reporting results they combined the two groups, suggesting that they did not think there were significant differences between the two lasers in terms of clinical outcomes.

Of the 7 case series, most provide only incomplete data. For example; Mallur et al 2011[13] did not report how many patients and procedures were excluded due to incomplete follow up; in Hsiung's 2003[11] retrospective study of 14 patients, in only 10 was phonatory function assessed before and after surgery; while Burns et al 2010 did not report clinical outcomes[14]. In three of the remaining four studies a substantial proportion of patients were not evaluated after treatment[1;2;10].

As regards safety, there is agreement that KTP was safer than PDL in 4 articles[1;2;10;12], but no data were provided to support these opinions. However, there is no evidence in any of these reports to indicate that KTP technology is less safe than competing technologies, and it is clear from several that it can be used in the clinic.

Importantly, to the extent that procedures could be performed in the clinic rather than in the OR, acquisition of a KTP laser would expedite treatment and save OR time. For those treated in the clinic, the potential morbidity associated with general anesthesia and the OR would also be avoided.

# 7. CONCLUSIONS

- **Use of KTP for laryngeal surgery is still innovative. Approved in Canada in 2011, there is still only one Canadian centre using this technology.**
- **There are seven publications describing the use of KTP, five of which derive from the same group of authors. These indicate that it is a safe, effective technology for the treatment of several laryngeal pathologies.**

- **However, there are presently no published data to indicate that the KTP laser produces clinically better outcomes or is safer than the presently available $CO_2$ laser.**
- **Unlike the $CO_2$ laser, the KTP laser can be used in an office setting for a certain number of cases. Assuming a total of 60 procedures per year, and assuming that with the use of KTP 30 of these could be carried out in the outpatient clinic, the cost per procedure using the $CO_2$ and KTP instruments would be $1,865 and $1,652, respectively. This would diminish pressure on the OR and reduce wait times for this procedure.**

# 8. RECOMMENDATIONS

- **While it may be appropriate that a University Hospital such as the MUHC should take part in the evaluation of a new technology, it would not be appropriate to acquire this technology from the operating budget without further evidence of superiority. Consideration to purchase this technology should be deferred until the following steps have been completed.**
- **The instrument should first be acquired on a temporary basis (rental or loan) during which time it could be used and evaluated by members of the department with particular focus on the following issues :**
  1. **The percentage of patients that can be treated in the outpatient clinic**
  2. **The clinical outcomes (sound/voice assessment, and complications) following use of the KTP laser.**
  3. **The possibility of reusing the glass fiber and the cost of recycling**
  4. **The effect of KTP use on wait times.**
- **With information on these issues and with the benefit of any new evidence that may be available at the time, permanent acquisition of this technology could then be reconsidered.**

# TABLES

## Table 1 Summary of details of research studies on KTP lasers

| Author | Duration of recruitment | Age (years) | N Patients (% Female) | N Procedures (% In Clinic) |
|---|---|---|---|---|
| Zeitels 2006 (a) [1] | July 2005 to March 2006¶ | NR | 48 (NR) | 72 (100%) |
| Burns 2007[2] | July 2005 to December 2006¶ | 23 - 73 | 37 (43%) | 55 (0%) |
| Zeitels 2006 (b) [10] | 2001 to 2006 | Adult | 15 (54%)* | 15 (0%) |
| Zeitels 2008[12] | 2003 to 2007 | NR | 14 (9%)*# | 14 (0%) |
| Mallur 2011[13] | June 2007 to December 2009 | NR | 32 (NR) | 47 (100 %) |
| Burns 2010[14] | July 1st 2007 to June 30th 2008 | NR | NR (NR) | 387 (54%) |
| Hsiung 2003[11] | January 2001 to March 2002 | 22 - 53 | 14 (57%) | 14 (0%) |

NR: Not reported.

¶: According to the duration of recruitment, we judged that all papillomatosis patients in Zeitels 2006 (a)[1] were also included in Burns 2007[2], so the papillomatosis arm in Zeitels 2006 (a)[1] is not reported in the following paragraph .

*: The percentage of female was calculated from the patients receiving PDL and KTP together, since the authors did not reported the gender of both treatments independently[10;12].

#: Authors reported that 22 cancer patients were included though they reported 21 male patients and 2 female patients in Table 1.

**Table 2 Cost of use of KTP laser in outpatient clinic and operating room, and $CO_2$ laser in operating room (Assumed turnover 60 per year)**

| | **Office procedure KTP** | **Operating room procedure KTP** | **Operating room procedure $CO_2$** |
|---|---|---|---|
| Attributable* cost per procedure | $370 | $370 | $117 |
| Single-use fiber (Endostat) | $365 | $365 | 0 |
| Operating room | -- | $1,104 ($883 * 1.25) | $1,104 ($883 * 1.25) |
| Recovery room | -- | $645 ($215 * 3) | $645 ($215 * 3) |
| OTL outpatient clinic | $85 ($170.6 *0.5) | -- | -- |
| | | | |
| **Cost per procedure** | $820 | $2,484 | $1,865 |

OTL: otolaryngology.

* Attributable = capital costs (KTP= $99,370) amortised over 7 years, plus maintenance costs ($7,000 per year), divided by the projected number of patients per year(60). Assumed: that maintenance costs for $CO_2$ and KTP are identical, and that the service life of existing $CO_2$ equipment is at least another 7 years.

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# APPENDICES

## Appendix 1: Literature search and study selection

### Search 1

Electronic database: Pubmed

Date of the last search: February 10th, 2012

Key words: (“532 nm” or “532 nanometre”) AND (KTP or "Potassium Titanyl Phosphate" or “potassium-titanyl-phosphate”) AND (vocal or voice or laryngeal or larynx or glottic or papillomatosis or dysplasia)

Twenty-three hits were retrieved. After reviewing the abstracts, we excluded 13 studies for the following reasons: studies not on human subjects (n= 5), language not in English or French (n = 2), indications not for the treatment of vocal folds (n = 2), combined therapy (bevacizumab and KTP) (n= 3) and comment (n = 1).

The remaining 10 studies were selected for full-text screening. There were 3 studies were excluded from the review for the following reasons:

- Two reviews articles by Zeitels et al[17;18] did not provide any additional data beyond the 5 individual publications by their group, and neither reviews was a systematic review.
- The indication was the papilloma of the nose and paranasal sinuses in Kaluskar et al.[19]

Finally, a total of 7 articles were identified in this systematic review.

### Search 2

Electronic database: Centre for Reviews and Dissemination, University of York

Date of the last search: February 10th, 2012

Key words: (KTP or "Potassium Titanyl Phosphate")

There were 10 records, but no studies used KTP 532 nm laser for operations of the vocal folds.

## Appendix 2: Cost Analysis of KTP

Capital Costs plus Maintenance costs. The purchase price for the Aura KTP laser is $99,370[7], including a one-year warranty and a small quantity of disposable components, such as 6 pieces of Endostat Fiber[7] worth about $2,190 (= $365 X 6). At the end the first year, there would be an additional annual maintenance cost of $7000[7]. Assuming the service lifespan of the KTP laser is 7 years, additional maintenance over this lifespan would be $7000 X 6 = $42,000. At an annual discount rate of 5%, this would be approximately $35,530.

Therefore, the present discounted value of the capital cost and maintenance cost over 7 years of KTP laser is $99,370 + $35,530 = $134,900. The corresponding equivalent annual cost (EAC), discounting at 5%, is $22,203. For a projected 60 procedures per year using KTP, the cost per procedure would be $370.

Procedure costs. The price of the glass fiber (Endostat Fiber) is $365 per unit. Although these fibers can be reused after cleaning, this is not recommended by the manufacturer. Assuming the endostat fiber is used once only, the approximate equipment cost is $365 per procedure. Both KTP and $CO_2$ laser procedures, when carried out in the operating room (OR) require 1 hour 15 minutes (Range;45min-3hr) [J Young] plus a minimum of 3 hours in the recovery room, some patients requiring admission overnight (K. Kost). KTP procedures conducted in the office, require approximately 30 minutes, and do not normally require post-procedural observation (J Young). The cost of an operating room is $883 per hour, the cost of a recovery room is $215 per hour and the cost of an otolaryngology (OTL) outpatient clinic visit is $170.6 per hour[8]. These costs are for personnel and supplies, and are adjusted for inflation[9].