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Main Article

Double-blind, randomised, controlled study of post-operative pain in children undergoing radiofrequency tonsillotomy versus laser tonsillotomy

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Abstract

Introduction: In the last decade tonsillotomy has come into vogue again, whereas the number of tonsillectomies is decreasing rapidly. Currently, most tonsils are reduced by utilise electrosurgery, radiofrequency or carbon dioxide laser. However, it is not clear whether radiofrequency tonsillotomy is as effective as laser or other surgical techniques in respect of post-operative pain and haemorrhage.

Material and methods: A prospective, randomised, double-blinded, controlled, clinical study was conducted in the otorhinolaryngology department of Ludwig Maximilians University, Munich, Germany. Twenty-six children with tonsillar hypertrophy were included. Exclusion criteria were: history of peritonsillar abscess, previous tonsil surgery, tonsillitis within two weeks, pain before surgery, psychiatric illness, asymmetrical tonsils, chronic analgesic usage, bleeding disorders and other surgical procedures during the same operation. Tonsillotomy was performed on one side with radiofrequency and on the other side with a carbon dioxide laser. All procedures were performed by a single surgeon, under general anaesthesia. A visual analogue scale was used to measure patients' pain on each side, administered by a 'blinded' nurse on the three post-operative mornings and evenings, within the hospital.

Results: There was no difference in post-operative pain scores or haemorrhage, comparing laser versus radiofrequency tonsillotomy. Patient's overall reported pain was very modest compared with post-tonsillectomy pain. No haemorrhage or other adverse effects were observed.

Key words: Tonsillectomy; Laser; Radiofrequency Surgery; Pain; Intraindividual design; VAS; Postonsillotomy

Introduction

Tonsillectomy and tonsillotomy are now the most commonly performed otolaryngology operations. Otolaryngologists throughout history have explored different techniques of tonsil removal.[1] This exploration may have arisen partly from the ongoing need to reduce post-tonsillectomy haemorrhage and pain. Post-tonsillectomy pain is a significant problem which merits continued investigation. It may last for three weeks,[2] and most clinics have adopted strict analgesia regimes to ensure pain control.[3] In addition to classical 'cold' dissection, numerous techniques for tonsil removal and volume reduction have been developed, in order to reduce pain and post-operative bleeding: CO^2 and diode laser,[4] bipolar radiofrequency-induced thermotherapy,[5] coblation,[6] monopolar electrical knife,[7] ultrasonic scalpel,[8] bipolar electrosurgical scissors,[9] argon-supported monopolar needle,[10] and microdebrider.[11]

All these surgical techniques (with the exception of coblation) can be used for tonsillectomy or tonsillotomy. Several studies have demonstrated that the technique of tonsillotomy decreases the risk of post-operative haemorrhage[12] and the duration and severity of post-operative pain by over 50 per cent, compared with tonsillectomy.[13,14] In tonsillotomy, the tonsillar capsule is not breached and the underlying muscle is protected, resulting in less pain. Ericsson[15] and Hultcrantz[16] found that children younger than 15 years with tonsillar hypertrophy, both with and without recurrent infection, benefitted from less invasive tonsillar surgery, e.g. tonsillotomy. According to the English- and German-language literature, most current tonsillotomy procedures utilise monopolar electrosurgery, radiofrequency[17] or carbon dioxide laser.[18]

However, a recent Cochrane review[19] reported there was insufficient data to support claims that radiofrequency was superior to other surgical techniques for tonsillotomy and tonsillectomy. Most relevant trials were not randomised, and several involved the peri-operative co-administration of

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intravenous opiates which may have masked any beneficial effect of the surgical technique on post-operative pain. A general problem is the great variation in assessment techniques used to compare pain between patients.

In the current study, we eliminated inter-individual variation in pain assessment by using an intra-individual study design in which patients were asked to compare their pain on the right and left sides.

Materials and methods

A prospective, randomised, double-blinded, controlled, clinical study was conducted in the otorhinolaryngology department of Ludwig Maximilians University, Munich, Germany, from May 2008 to June 2009.

After institutional ethics committee approval, we selected 30 children aged between three and nine years (mean age, five years) for whom tonsillotomy was planned to treat tonsillar hyperplasia. Consent was obtained from all the included children's parents, following a full discussion of the study, in accordance with the Declaration of Helsinki II. Exclusion criteria were: history of peritonsillar abscess, previous tonsil surgery, tonsillitis within two weeks, pain before surgery, psychiatric illness, asymmetrical tonsils, chronic analgesic usage, bleeding disorders, and other surgical procedures (i.e. adenotomy) planned during the same anaesthetic.

All procedures were performed by the same consultant surgeon (KS). Patients were randomised on the day of surgery, by sealed envelope allocation, regarding which tonsil (left or right) was to be reduced using carbon dioxide laser (Sharplan 20C, Laser Industries, Tel-Aviv, Israel), using 16 W, continuous wave mode and a wavelength of 10 600 nm. For laser surgery, the surrounding tissue was protected with wet swabs. The contralateral tonsil was dissected using bipolar radiofrequency tonsillotomy (LabENT and ProCut; Celon AG Medical Instruments, Teltow, Germany), using 16 W in ProCut mode. The objective in both procedures was to reduce the tonsillar tissue by the same amount: specifically, to remove only the part of the tonsil protruding into the pharynx (Figure 1). Haemostasis was achieved by packing the wounds with a swab (soaked in 0.9 per cent sodium chloride) for 1 minute, followed by punctual bipolar cautery (20 W) if necessary. No local anaesthetic was used. Only the surgeon and the assisting nurse knew which method was used on each side.

On the day of each patient's operation, we noted the time required to complete each procedure, the weight of resected tonsillar tissue, the frequency of bipolar forceps coagulation and any difficulties encountered. All patients' tonsils were documented by digital photography before and after surgery (Olympus XP200 camera with macro objective and ring flash; Olympus Europe GmbH, Hamburg, Germany) (Figure 1). Different persons performed the random number allocation, surgery and data collection, in order to reduce the chance of bias.

Anaesthesia was based on total intravenous remifentanil, preceded in most cases by intravenous sufentanil and propofol. No patient received halothane. The patient's expired carbon dioxide, oxygen saturation and electrocardiographic data were continuously monitored for the duration of anaesthesia.

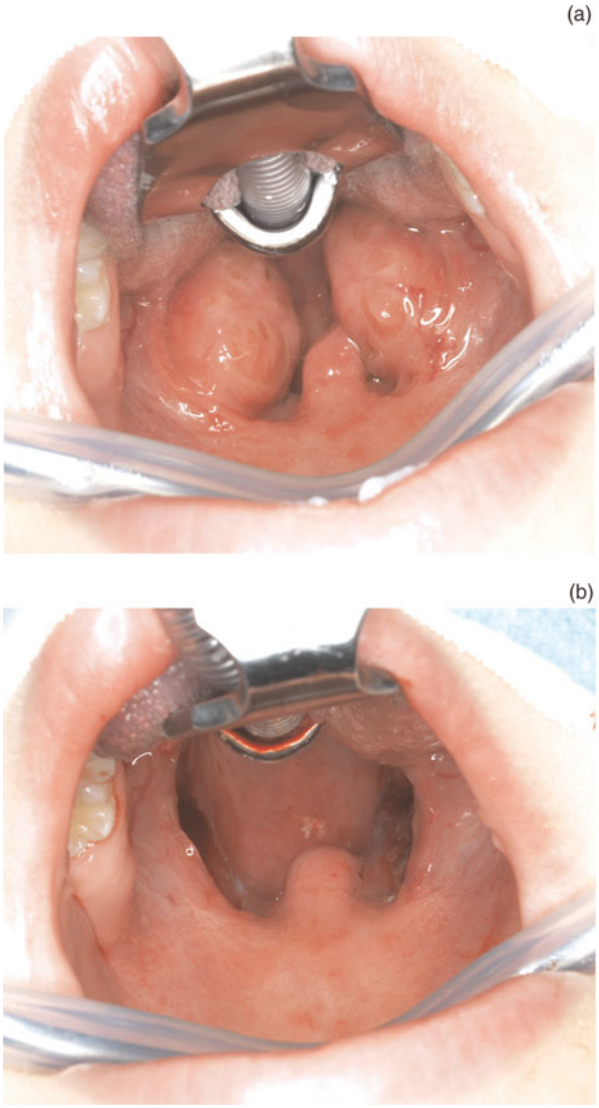

FIG. 1
(a) Pre-operative and (b) post-operative status after laser tonsillotomy on the right side and radiofrequency tonsillotomy on the left side.

Ibuprofen and (as escape medication) metamizol were given to patients on demand. A nurse recorded all drugs used. All other events (i.e. bleeding, dysphagia, severe pain or aspiration) were registered in a patient diary, either by the child's parents or by the child themselves (in the case of older patients).

Pain was monitored using a six-point, picture face, visual analogue scale (VAS) (Figure 2). A happy face equated to no pain, and was allocated a value of zero, while a crying face was allocated a value of 10. Results for each side were registered by a blinded nurse 6 hours after the operation (i.e. day one) and then four times a day (at 0700 (on waking), 0800 (during breakfast), 1700 (during dinner) and 2000 (before the night-shift)), until discharge from hospital on day three. The

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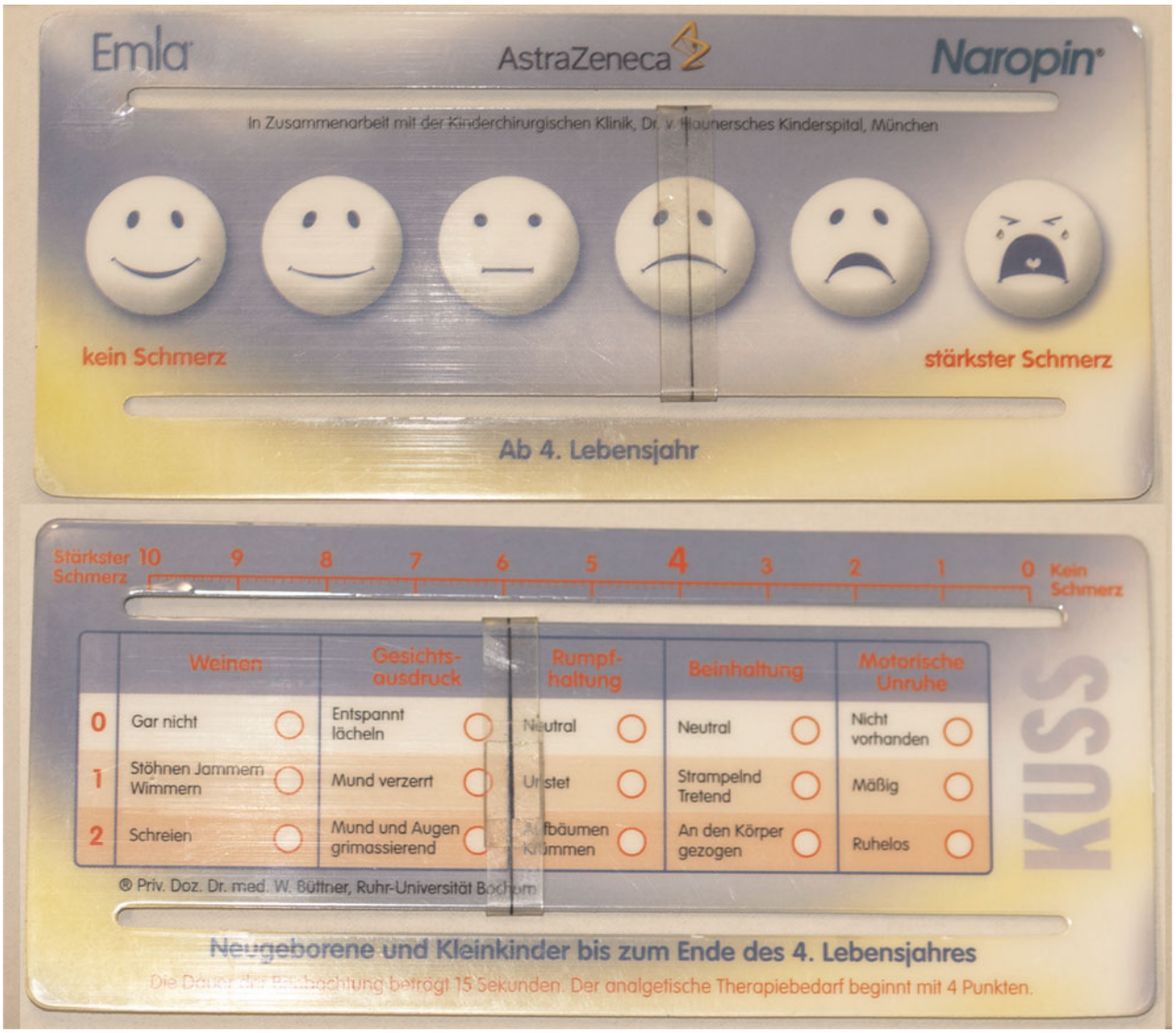

FIG. 2
The picture face visual analogue scale used.

principal surgeon was not involved in pain scoring or data processing until the end of the study.

Statistical analysis was performed using the *t*-test and the Statistical Package for the Social Sciences version 15.0 software (SPSS Ltd, Chicago, Illinois, USA). A p value of ≤ 0.05 was considered statistically significant. The anticipated number of patients was calculated with nQuery Advisor version 6.0 software, using the following parameters: p value, 0.05; power, 80 per cent; difference in VAS, 1; standard deviation, 2; and a nonchained, two-sided *t*-test. Visual analogue pain scores were plotted versus time and the area under the curves calculated. Using these parameters, the predicted number of patients required was 26. For safety reasons (i.e. to allow for drop-outs), we included 30 patients.

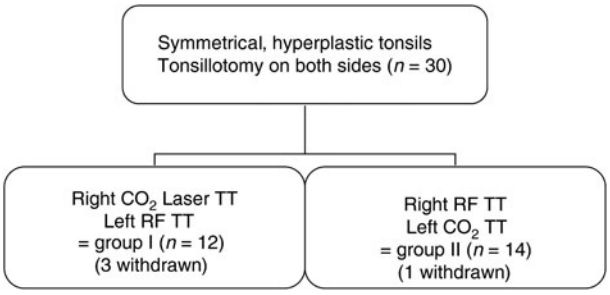

FIG. 3
Patients included in the two study groups. TT = tonsillotomy; RF = radiofrequency

Results

Figure 3 shows the participating patients. Four patients were withdrawn from the study, for the following reasons: intra-operatively detected tonsillar asymmetry of more than 10 per cent ($n = 2$), incorrectly completed diary ($n = 1$) and withdrawal of patient consent ($n = 1$).

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Figures 4 and 5 compare the post-operative VAS pain scores reported for the laser tonsillotomy and radiofrequency tonsillotomy sides. There was no statistically significant difference in VAS scores, comparing the laser tonsillotomy sides and the radiofrequency tonsillotomy sides ($p = 0.37$, $n = 26$ patients). Even when swallowing liquids or eating, there were no significant intra-individual pain score differences between the laser and radiofrequency sides. Of the 26 patients completing the study, three required no analgesia, 16 were content with paracetamol suppositories and seven were content with ibuprofen liquid; no patients required metamizol or opioids.

Post-operative bleeding was not observed. Bipolar forceps coagulation for intra-operative haemostasis was used more frequently for the radiofrequency tonsillotomy sides (mean, 1.88 times per operation; standard deviation (SD), 1.09), compared with the laser tonsillotomy sides (mean, 0.63 times per operation; SD, 1.07) (Figure 6).

The mean time for completing the procedure (including preparing the system, protecting surrounding tissue and haemostasis) was significantly shorter for the radiofrequency tonsillotomy sides (3.9 minutes) than for the laser tonsillotomy sides (8.2 minutes).

The mean weight of removed tonsillar tissue was nearly equal for both methods (laser tonsillotomy, 1.89 g, SD 0.70; radiofrequency tonsillotomy, 1.91 g, SD 0.77).

In one patient, an electrocardiogram malfunction was observed when using the radiofrequency probe. This malfunction stopped immediately after ceasing the radiofrequency procedure. There were no other adverse effects monitored or described in this patient's diary.

All removed tonsillar tissue was preserved for histopathological assessment. In 48 out of 52 specimens (92 per cent), subacute inflammation and fibrosis of the crypts was detected. No tonsil was removed to the base of the crypts, as this is not the purpose of a tonsillotomy (compared with tonsillectomy). The coagulation zone in the laser group was approximately 0.3 mm, compared with 0.1 mm in the radiofrequency group (Figure 7).

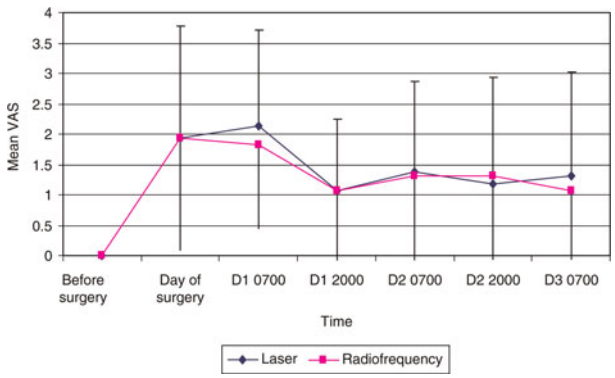

FIG. 4

Patients' ($n = 26$) visual analogue scale (VAS) pain scores for sides undergoing laser tonsillotomy and radiofrequency tonsillotomy, versus time (whiskers indicate standard deviations).

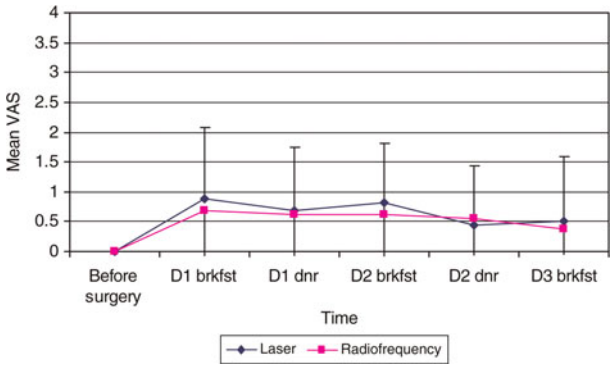

FIG. 5

Patients' ($n = 26$) visual analogue scale (VAS) pain scores during swallowing, for sides undergoing laser tonsillotomy and radiofrequency tonsillotomy, versus time (whiskers indicate standard deviations).

Discussion

Electrosurgical devices work with high frequency alternating current at frequencies between 100 kHz and 4 MHz. During electrosurgical cutting, small electrical arcs are generated between the electrode and the tissue which cause a quick temperature increase and immediate tissue vaporisation. Medical lasers usually work with invisible light in the infrared spectrum. Absorption of the laser radiation also causes a temperature increase in the tissue. When using laser wavelengths with very small penetration depths (e.g. CO_2), the temperature increase is also very fast, achieving immediate vaporisation. Moving the electrosurgical electrode or the laser beam will result in an incision that can be used to resect tissue.

In a similar study, Adnan *et al.* found that radiofrequency tonsillectomy compared favourably to laser tonsillectomy in terms of reduced post-operative pain, operative duration and blood loss; furthermore, tonsillar fossae healing was also improved.[20] These results were achieved by showing statistically significant differences between the two methods used in the same patient.

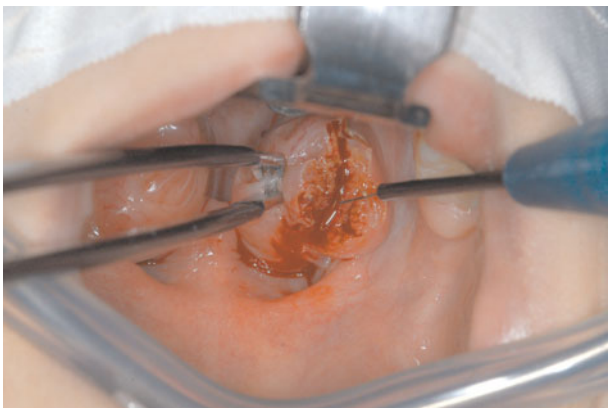

FIG. 6

Intra-operative photograph showing use of the radiofrequency tonsillotomy probe on the right tonsil. There is more bleeding from small vessels, compared with the laser technique.

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FIG. 7
Surgically removed tonsillar tissue: left tissue removed by laser tonsillotomy, right tissue by radiofrequency tonsillotomy.

The present study observed no difference in post-operative pain between laser tonsillotomy and radiofrequency tonsillotomy, during patients' first three days after surgery. Overall, post-tonsillotomy pain was very minor compared with tonsillectomy. A strict pain control regime was not needed. Most children were pain-free with paracetamol suppositories, the preferred analgesia, although the older children favoured ibuprofen liquid twice daily. Interestingly, patients reported lower pain levels during eating and drinking, possibly due to distraction.

The VAS with six-point picture faces has been shown to be a valid and reliable method of pain measurement, with very good test–retest reliability in children.[21] Assessment is an essential but challenging component of any pain management plan. However, pain is a multidimensional phenomenon. Furthermore, it is subjective; therefore, there is no objective measure which can capture every aspect of the pain experience.[22] Because of the wide range of inter-individual pain sensations, the SDs for this parameter in our study were very high.

However, despite the fact that our pain data were generated from the difference between the left and right sides, rather than an assessment of overall pain, our results show no significant difference between the two tonsillotomy techniques. In a previous study, we found that even small children could easily discriminate between pain on the right and left side.[3] This may be due to the nature of typical post-tonsillectomy pain, which radiates laterally into the middle ear due to the effect on the glossopharyngeal nerve.[23] This enables the use of an intra-individual study design in which patients act as their own controls,[24] which reduces the problems caused by inter-individual variation in pain perception, and by bias due to peri- and post-operative administration of analgesics. The use of an intra-individual study design in a clinical trial was first described in 2004.[25] This design is an appropriate research method for bilateral operations such as tonsillectomy or ear procedures.

Previous authors have also observed that every surgeon (particularly beginners), whether left- or right-handed, prefers to operate on one side more than the other. Most right-handed surgeons prefer to operate on the right side, and are faster and more accurate on this side.[3] Therefore, in the present study it was important to apply both methods on both sides in equal numbers, and by the same surgeon.

Although there was no significant difference in reported pain between the two methods, there was a statistically significant difference in intra-operative haemorrhage. Bipolar forceps coagulation was required three times more frequently for radiofrequency tonsillotomies than for laser tonsillotomies, because of increased bleeding from small vessels (see Figure 7). Histopathological findings indicated that the tissue damage caused by high frequency radiofrequency surgery was more superficial, and that the lateral heat reaching the surrounding tissue was less, compared with laser surgery. Therefore, the coagulation effect of the radiofrequency probe was not as efficient as that of the laser. This could have been balanced by reducing the laser power or increasing the radiofrequency tonsillotomy power, as well as by using cutting electrodes of larger diameter.

- **Several studies have demonstrated that the technique of tonsillotomy decreases the risk of post-operative haemorrhage as well as the duration and severity of post-operative pain, compared with tonsillectomy**
- **This prospective, randomised, controlled study compared the outcomes of radiofrequency tonsillotomy and carbon dioxide laser tonsillotomy**
- **There were no differences in post-operative pain scores or haemorrhage, comparing laser and radiofrequency tonsillotomy; patients' overall reported pain was very modest compared with post-tonsillectomy pain, and no haemorrhage or other adverse effects were observed**

Radiofrequency tonsillotomy took about half the time of laser tonsillotomy, mainly because of the wet protection layers that had to be placed behind the tonsil and around the patient's mouth and eyes for the laser procedure (Figure 7). Such protection layers are obligatory when using lasers in the head and neck area. Otherwise, there is a high risk of accidental burns on intubation tubes and the surrounding tissue. In addition, protective eye glasses are mandatory for the whole operating team during laser surgery.

In this study, we observed no adverse effects of either tonsillotomy method used.

We intend to undertake long term follow up (i.e. one to three years) of our patients, to monitor post-operative complications (e.g. tonsillar regrowth and recurrent infection) and patients' quality of life.

Conclusion

The intra-individual design of this study allowed direct comparison of laser tonsillotomy and

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radiofrequency tonsillotomy. No difference was found in patients' post-operative pain or post-operative haemorrhage, comparing these two procedures. Compared with the carbon dioxide laser, the radiofrequency equipment is more easily transportable and does not require a special surgical environment. Furthermore, handling, manoeuvring and adjustment of radiofrequency instruments are easier, compared with the laser probe.

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