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MAIN ARTICLE

Hacettepe cartilage slicer: a novel cartilage slicer and its performance test results

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Abstract

Objective: This study investigated the performance of a cartilage slicer device referred to as the 'Hacettepe cartilage slicer'.

Methods: Forty-one cartilage pieces were harvested from eight fresh frozen human ears and measured in thickness with a digital micrometer. These pieces were randomly sliced using four different thickness settings and two different types of blades. The thicknesses of the slices and remaining pieces were measured also. Scanning electron microscopy was utilised to determine the surface smoothness of the slices.

Results: Thickness results showed a proportional increase with the increasing thickness setting, with a ±0.1 mm margin of error. The measurements showed that over 95 per cent of the slices' structural integrity was preserved. Although both blades provided satisfactory results, scanning electron microscopy revealed that the slices cut with a single bevel blade had superior surface smoothness.

Conclusion: To our knowledge, the current study is the first to evaluate the performance of a cartilage slicer device. Based on the thickness results, the Hacettepe cartilage slicer fulfilled its design goals: to consistently produce slices at the intended thickness with a ±0.1 mm tolerance, and to preserve over 95.3 per cent of cartilage thickness thereby ensuring undamaged, strong cartilage slices.

Key words: Tympanoplasty; Myringoplasty; Ear Cartilage

Introduction

Cartilage is often preferred as a tympanic membrane graft material because of its high success rate and comparable audiological results to those of temporalis muscle fascia.[1,2] Closure rates of up to almost 100 per cent have been documented, even with large perforations.[3] Aside from tympanic membrane closure, cartilage grafts can also be used for reconstructing canal walls, closing various defects and covering total ossicular replacement prostheses.

An acoustic analysis of cartilage pieces at different thicknesses in an experimental setup, using a laser Doppler interferometer, estimated better acoustic gain if the cartilage graft was thinner than 0.5 mm.[4] Other studies revealed that various tympanic membrane closure techniques need multiple overlapping thin cartilage pieces.[5,6] However, hand slicing a harvested cartilage into thin slices with a homogeneous thickness is extremely difficult. This difficulty has prompted surgeons to employ devices for this purpose.

Cartilage has become the graft material of choice in our institution for the reconstruction of tympanic membrane perforations. Our growing experience in cartilage tympanoplasty has led to the design of a cartilage slicer, referred to as the 'Hacettepe cartilage slicer'. This slicer has some key features, including a durable unibody design, the ability to slice cartilage without damage, ease of use, adjustable cartilage thickness options, and the ability to use standard surgical blades, which is in turn associated with low cost and practicality. This study investigated the performance of the cartilage slicer device.

Materials and methods

Design process

During the design process, the concept of the Hacettepe cartilage slicer was modelled three-dimensionally, and a beta prototype was built and tested. The imperfections were refined and an alpha prototype was built out of a surgical grade stainless steel alloy using precise computerised tools. The alpha prototype yielded satisfactory results and the current cadaver study was carried out. A patent application was also filed.

The preliminary results of this study were presented orally at the 4th National Otology Neuro-otology Congress, 21–24 April 2016, Antalya, Turkey, and at the 10th International Conference on Cholesteatoma and Ear Surgery, 5–8 June 2016, Edinburgh, Scotland, UK.
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Mode of operation

To slice a harvested cartilage, the surgeon raises up the upper part of the slicer, places the piece of cartilage on the cartilage plate, which has a high friction coating, and closes the upper part. When the upper part is closed, the vertically movable supporting plates poke out of the upper surface, revealing the shape of the cartilage piece. An adjustment wheel is used to choose a thickness setting, with 0.1 mm intervals. The surgeon then places their finger on the supporting plates, locates the blade in the blade channel and cuts horizontally. While the blade is cutting through the cartilage, the corresponding supporting plates move upwards, both to give tactile feedback, showing the position of the advancing blade and to protect the cartilage from any damage (Figure 1).

After the slicing is complete, the upper part can be opened and the slice removed, or the wheel can be adjusted and another slice cut (Figure 2, taken from the supplementary video available on *The Journal of Laryngology & Otology* website (Appendix 1)).

This system has been designed for single bevel blade use, but standard surgical scalpels with double bevel cutting edges could be used as well; however, less accurate slice thickness and inferior surface smoothness should be expected.

Cadaver study

In order to objectively test the performance of the Hacettepe cartilage slicer, a phase 0 clinical trial was planned and the approval of Hacettepe University Non-interventional Clinical Research Ethics Board was obtained (GO16/19-07).

A professionally sharpened multiuse dermatome blade with a single bevel 'chisel type' cutting edge and a number 20 disposable surgical scalpel blade (Aesculap, Tuttlingen, Germany) with double bevel cutting edges were used during the experiment. The disposable blades were replaced after every four cuts in order to maintain a standard level of sharpness. Four different thickness settings were tested for each blade type.

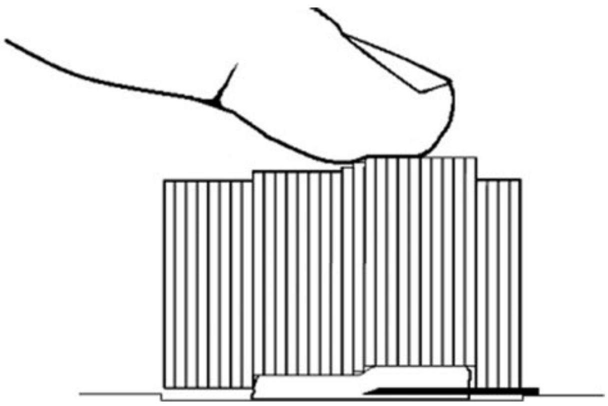

FIG. 1
The upwards movement of the supporting plates compensating for the thickness of a single bevel blade.

FIG. 2
A still image of the Hacettepe cartilage slicer, taken from the supplementary video (Appendix 1).

The certified Digimatic 0–25 mm digital micrometer (Mitutoyo, Kawasaki, Japan), with 0.001 mm claimed sensitivity, was used to measure cartilage thickness. The micrometer had two circular measuring surfaces of 8 mm diameter and a torque limiter to apply a standard pressure to the specimen.

A scanning electron microscope (SEM-ASID 10; Jeol, Tokyo, Japan) was utilised to evaluate the surface smoothness of the cartilage slices; routine protocols were applied. Four slices were cut, with two different blades, at different thickness settings chosen randomly. These were fixed in 2.5 per cent glutaraldehyde for 24 hours, washed in phosphate buffer (pH 7.4), post-fixed in 1 per cent osmium tetroxide for 1 hour and re-washed in phosphate buffer (pH 7.4). The slices were subsequently dehydrated in increasing concentrations of acetone and subjected to critical point drying. The slices were then mounted on metal stubs with a double-sided adhesive band, and sputtered with a 100-Angstrom thick layer of gold palladium using sputter apparatus (Bio-Rad, Hercules, California, USA). Electron micrographs were subsequently taken.

In total, 41 tragal or conchal cartilage specimens were harvested from 8 fresh frozen cadavers. The harvested specimens were initially tagged with a code, measured in terms of thickness, and then sliced randomly using one of the two blades and four thickness settings. Hence, eight groups were created. The thickness of each slice was measured by an independent researcher, with no bias regarding the thickness setting, and the result was recorded with a tag code. Subsequently, the thickness of the remaining cartilage was measured and recorded. Once the experiment had been completed, the results and thickness settings were matched using the tag codes, and evaluated. Four random slices cut with different blades at different thicknesses were photographed with scanning electron microscopy.

Results

The thicknesses of the slices cut with the single bevel blade are shown in Figure 3. The thicknesses ranged between 0.15 and 0.66 mm. The average difference between the median values of the thickness settings was found to be 0.11 mm.

The thicknesses of the slices cut with the double bevel blade are provided in Figure 4. The thicknesses ranged between 0.33 and 0.71 mm. The average difference between the median values of the thickness settings was found to be 0.06 mm.

In order to assess whether the Hacettepe cartilage slicer could cut slices without damage, the sum of thicknesses of each slice and its remaining part were compared to the thickness of the original harvested piece. This revealed that the single bevel blade could preserve 98.4 per cent of the original thickness on average, while the double bevel blade could preserve 95.3 per cent.

Figure 5 shows a scanning electron microscopy photograph of a slice cut with a single bevel multiuse dermatome blade. Note the considerable smoothness of the surface (the image was focused all around the frame).

Figure 6 shows a scanning electron microscopy photograph of a slice taken with a double bevel disposable number 20 blade. Note that the surface has microscopic roughness, with loss of focus at some areas because of slight differences in thickness throughout the slice.

Discussion

Cartilage has been used as a tympanic membrane reconstruction material since 1953.[7] However, there has been a growing interest over the last decade in light of its high closure rates, even with difficult cases such as Eustachian tube dysfunction, and similar audiological results to those of temporalis muscle fascia have been documented.[1–3,8]

Compared with temporalis muscle fascia, cartilage has higher structural strength, and greater resistance against retraction and infection, which makes it ideal for Eustachian tube dysfunction, atelectasis and chronically infected ears.[1,5,8,9] Its resistance against ischaemia makes cartilage a good choice for smokers and revision cases where temporalis fascia may fail.[8] Although some chondrocyte degeneration occurs over time, especially towards the centre of large perforations, cartilage matrix remains intact, and retains most of its structural support and elasticity.[1] Therefore, cartilage grafts may have higher closure rates than temporalis fascia for large perforations.[2,10] Moreover, being an elastic and pliable material, cartilage is easier to shape and use. These advantages make cartilage a suitable graft material, especially for cases of revision, atelectasis, large perforations and chronic Eustachian tube dysfunction, and smokers.

The only major pitfall of cartilage as a tympanic membrane reconstruction material is the possibility of it hiding a cholesteatoma or a middle-ear (tympanic cavity) pathology.[6] However, the occurrence of this risk has become insignificant given the high sensitivity of rapidly developing imaging modalities such as non-echo planar imaging sequences of magnetic resonance imaging.[11]

A thick harvested cartilage seems to be disadvantageous as a tympanic membrane graft material, as it is bulky and opaque. However, it becomes advantageous once the cartilage is sliced to the desired thickness, and is then capable of occupying three or even four times the surface area of the original harvested piece. The average tragal cartilage thickness, measured intra-operatively using digital calipers, was reported as being between 0.879 and 1.432 mm, depending on patients' age and sex.[12]

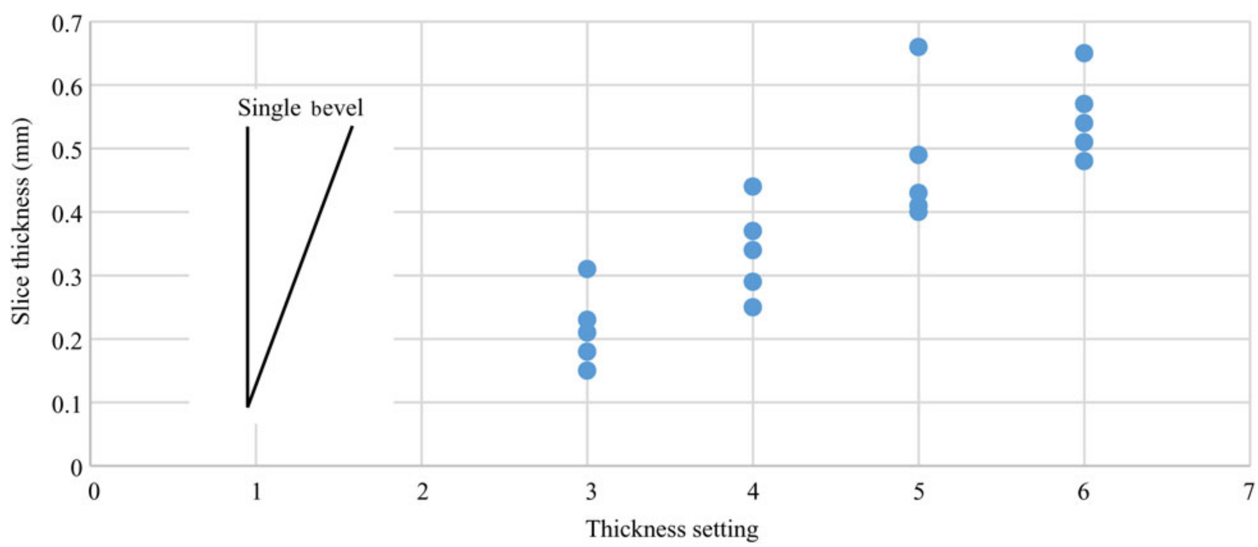

FIG. 3
Thickness results with the multiuse dermatome blade with a single bevel cutting edge.

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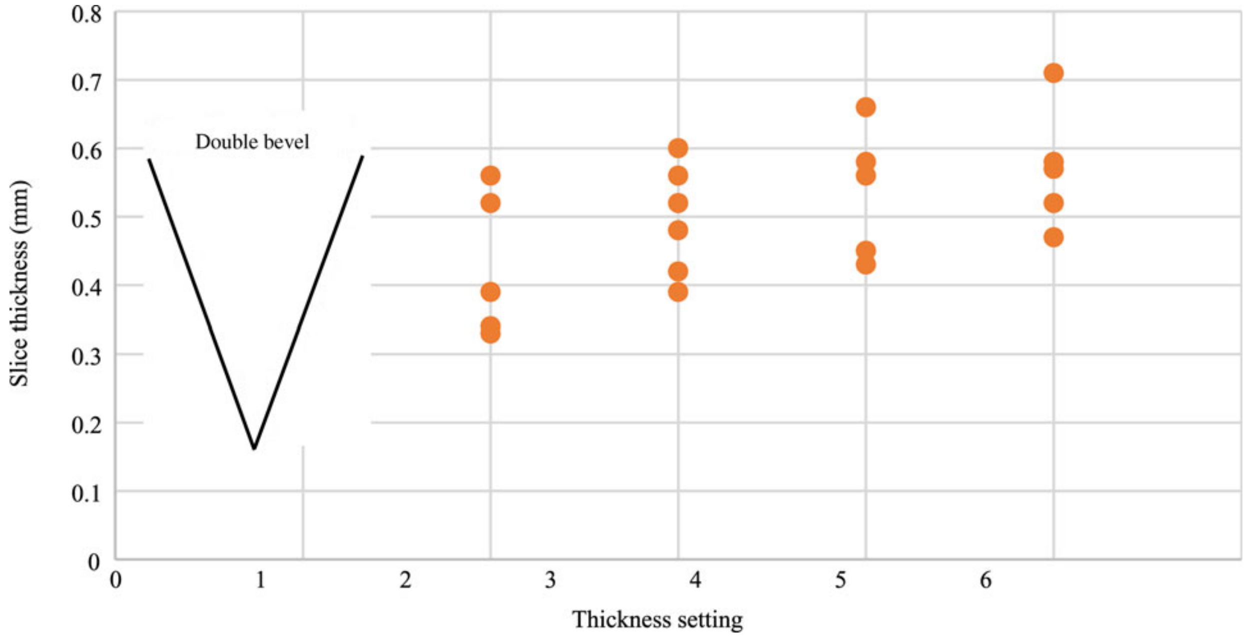

FIG. 4
Thickness results with the disposable number 20 scalpel with a double bevel cutting edge.

A micrometer with wide circular measuring surfaces (instead of the sharp edges of calipers) and a torque limiter to apply a standard pressure (instead of manually applied pressure) were considered to provide more reliable results, and were thus preferred for this study. However, although the pressure of the micrometer was consistent throughout the experiment, any pressure may have affected thickness results.

When a single bevel blade was used, all the remaining cartilage that was over the cutting edge was pushed upwards, which was compensated for by upper movable supporting plates, and a nice slice with equal thickness was left beneath the blade (Figure 1).

In order to hold the cartilage piece in place and enhance the slicing accuracy, a friction layer had been added to the cartilage plate. Inevitably, the thickness of that coating (0.07 mm) caused misalignment, and each thickness setting resulted in slices that were 0.07 mm thinner than their nominal values (Figure 3). For example, the median value was 0.43 mm when the fifth setting was used. The average difference between the median values of each thickness setting was 0.11 mm with the single bevel blade and 0.06 mm with the double bevel blade. This indicates that more linearly increasing slice thicknesses could be achieved with the single bevel blade than with the double bevel blade, taking into consideration that the adjustment wheel elevated the cartilage plate 0.1 mm with each increasing setting. Moreover, scanning electron microscopy results (Figure 5) revealed a significantly smoother surface with the single bevel blade.

When a number 20 surgical blade (0.4 mm thick and double bevel) was used, the cutting edge met the cartilage 0.2 mm higher than a single bevel blade because

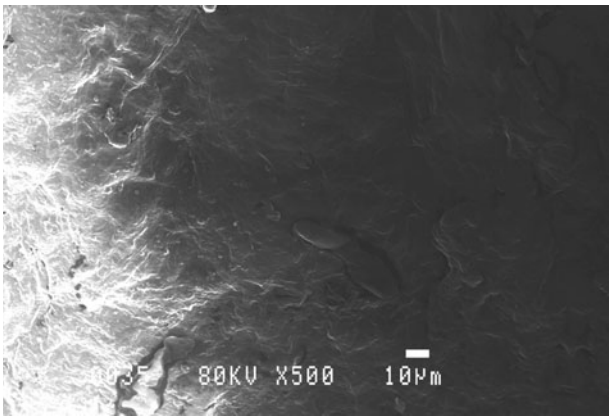

FIG. 5
Scanning electron microscopy photograph of a slice cut with a single bevel blade (×500 magnification).

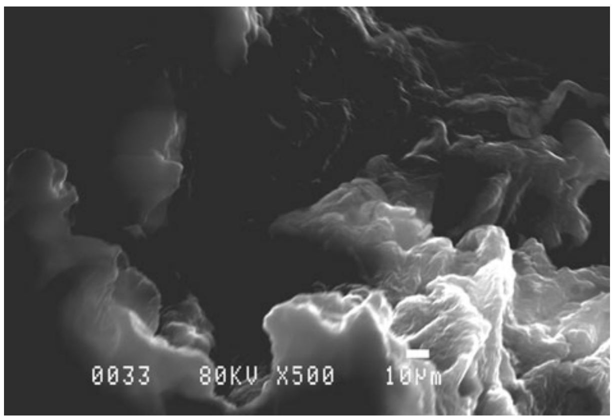

FIG. 6
Scanning electron microscopy photograph of a slice cut with a double bevel blade (×500 magnification).

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of the half thickness of the blade. Taking the 0.07 mm thick friction coating in consideration, the 0.2 mm higher cutting edge should have given 0.13 mm thicker slices than the thickness setting. In fact, the median values of each thickness setting were 0.14 mm thicker than the thickness setting (Figure 4), which was concordant with our expectations. When the blade was passed through the cartilage, it is believed that the lower half of the cutting edge acted as a ramp and pushed the blade upwards. The blade channel was only slightly wider than the thickness of the blade, so, after a fraction of a millimetre, the upwards movement of the blade was limited by the blade channel. After this point, the blade must have moved horizontally with a slightly oblique orientation, which might have hindered the proper contact of the cutting edge to the cartilage and caused a bubble-like separation cavity because of the elastic nature of the cartilage. This cavity might have led to a coarse, shearing-off type separation between the slice and the remaining cartilage. The thicker the slice, the higher the error observed associated with this effect. The median values of the thickness settings and the differences between them indicate that, after the fourth setting, the results tended to accumulate at the lower half of the distribution and the cartilage separated from its half thickness. Thus, both the median values and the differences between thickness settings decreased. The scanning electron microscopy photographs (Figure 6) support this explanation and reveal microscopic roughness across the slice surface.

- **A reliable, surgical tool to slice autologous cartilage into undamaged, smooth slices at any desired thickness is advantageous for otologists**
- **To our knowledge, the current study is the first to evaluate the performance of a cartilage slicer device**
- **Based on thickness results, the Hacettepe cartilage slicer fulfils its design goals**
- **The slicer consistently produced slices at the intended thickness with a ±0.1 mm tolerance**
- **In addition, it preserved over 95.3 per cent cartilage thickness, ensuring undamaged, strong cartilage slices**

When the sum of thicknesses of each slice and its remaining counterpart was compared to the thickness of the original harvested piece, it was observed that 98.4 per cent of cartilage thickness was preserved, which fulfils the design goal. This is considered a major advantage for a cartilage slicer, as it ensures the cartilage slice is structurally intact. Although controlled tests have not been conducted, it is believed that if a piece of cartilage is fixed from both sides, as in a vice and cut (as with most of the commercially available cartilage slicers), the cartilage might get squashed to some degree with the passing of the blade and lose its structural strength.

Based on the thickness results, the Hacettepe cartilage slicer fulfils the design goal, namely to reliably produce consistent slices at the intended thickness with a ± 0.1 mm tolerance. A single bevel blade offers even better results.

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Appendix 1. Supplementary video material

A short video demonstrating the mode of operation of the Hacettepe cartilage slicer is available online at *The Journal of Laryngology & Otology* website, at https://doi.org/10.1017/S0022215117000846.

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