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Quantifying Osteotome Sharpness: Comparing the Major Manufacturers

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Abstract

Objective. (1) To develop a method for quantification of osteotome sharpness in a rhinoplasty model, using artificial bone; (2) to demonstrate changes in osteotome sharpness over multiple uses; and (3) to compare osteotomes from different manufacturers in terms of sharpness and cost.

Study Design. Prospective surgical model.

Setting. Academic hospital and engineering research facility.

Methods. Osteotomes were used to make 4-cm cuts through 4-mm wedges of artificial bone. Sharpness was assessed at baseline and following 1, 4, 7, and 10 uses by measuring the load required to cut a #2 Prolene suture. Changes in sharpness from baseline were measured over time, and comparison of manufacturers was performed using analysis of variance (ANOVA). Cost per use was computed for each osteotome.

Results. Five osteotomes were tested (Biomet, Black & Black, Miltex, NexEdge, Storz). At baseline, the Storz osteotome was sharpest (1.74 lb, $P < .001$), followed by Miltex and Biomet (2.50 lb, 2.68 lb) and NexEdge and Black & Black (3.48 lb, 3.40 lb). All osteotomes except NexEdge ($P = .098$) demonstrated significant decreases in sharpness over time ($P = .02$ to $P < .001$), although relative changes and absolute sharpness varied greatly. ANOVA demonstrated Storz to be significantly sharper at all time points ($P < .001$). Storz and Miltex were superior in cost-per-use analysis.

Conclusion. Sharp osteotomes are important in cosmetic and functional rhinoplasty. Instruments may appear the same but can be quite dissimilar in efficacy and cost. Indeed, relative efficacy has not been previously tested. Quantitative analysis performance and cost-effectiveness analyses are reported here and can assist the surgeon in selection and maintenance of instruments.

Keywords

rhinoplasty, osteotome, osteotomy, cost-effectiveness, instrument maintenance

Maintenance of fine surgical instruments is a critical aspect of rhinoplasty. Osteotomes are essential tools in rhinoplasty and are used in dorsal hump reduction and medial and lateral osteotomies. It is widely understood that use of carefully maintained osteotomes, with sharp, even cutting surfaces, enhances precision and minimizes trauma.[1-4] Microfractures and large segmental fractures of the bone can occur when using a dull osteotome, as the force of the mallet strike is disseminated rather than focussed at the cutting surface.[1] Skipping of the blade during a cut is also more common with a dull blade and may cause soft-tissue injury to the overlying skin envelope, the nasal mucosa, or both.[2,3] This risk is proportional to dullness, as relatively greater force must be applied to allow the blade to cut. There are clearly many reasons to ensure the sharpness of surgical instruments.[1]

Currently, there is no evidence-based guideline to compare the relative sharpness of osteotomes. Purchasing and instrument care practices vary widely, including surgeons who bring their own instrument sets to the operating room, those who religiously sharpen their instruments after each procedure, and those who must use central supply–based sets regardless of condition and maintenance. At present, surgeons generally rely on qualitative feedback (ie, ''feel'') as the sole indicator of the quality of a blade, the right time to sharpen the instruments, and the need to purchase replacements.[5]

In this study, we expand on our previously reported method for quantifying the sharpness of osteotomes using a reliable, reproducible, and precise technique.[5] Further, we develop a

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Table 1. Cost Analysis Data, Including Purchase Price and Estimated Cost-per-Use under 2 Dullness Thresholds

	Purchase Price, $	Cost-per-Use (>3.5 lb), $	Cost-per-Use (>2.5 lb), $
Biomet	112	11	112
Black & Black	155	155	155
Miltex	151	12	151
NexEdge	325	81	325
Karl Storz	272	16	25

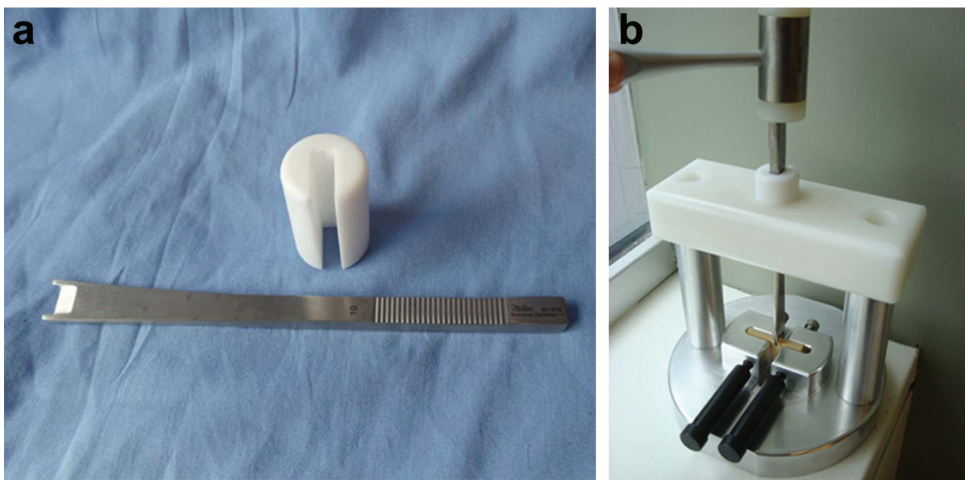

Figure 1. (a) Custom-milled osteotome holder, with double-guarded Cinelli osteotome. (b) Custom-milled artificial bone holder and with attached osteotome holder, as set up for perpendicular osteotomies.

surgical model to expand the analysis of these instruments. This model is then employed in a quantitative analysis of osteotome sharpness over time and in a comparison of osteotomes from different surgical instrument manufacturers. Finally, we use these data to look at relative costs.

Materials and Methods

Study Design

This study received an exemption approval from the institutional review board of the University of Pennsylvania, as no patients were treated and no human tissues were used. We devised a prospective study to quantify the relative sharpness of osteotomes from multiple manufacturers at baseline and following multiple simulated osteotomies. All experiments were undertaken at the University of Pennsylvania Mechanical Testing Central Facility in the School of Engineering and Applied Science.

Materials

Five new, double-guarded, 10-mm Cinelli osteotomes were purchased from 4 manufacturers: Biomet (Lorenz Surgical, Jacksonville, Florida), Black & Black Surgical (Tucker, Georgia), Miltex (Integra, York, Pennsylvania), NexEdge (Black & Black, Tucker, Georgia), and Karl Storz (Tuttlingen, Germany). Purchase prices are listed in **Table 1**. To simulate osteotomies in a reproducible manner with minimal variability, we employed identical 4-mm-thick, symmetric, smooth #40 density wedges of artificial bone (Sawbones; Pacific Research Laboratories, Vashon, Washington).

Osteotomy Model and Sharpness Quantification

To generate standard, reproducible osteotomies using the different blades, we created a custom-milled holder for both the osteotome[5] (**Figure 1a**) and the artificial bone (**Figure 1b**). This holder permitted a reproducible, perpendicular cut of 4 cm through the artificial bone. Cuts were made in traditional fashion, using the ''tap-tap'' method of applying force with a surgical mallet to the end of the osteotome handle. All cuts were performed by the same surgeon (M.B.A.), with the same mallet, using a level of force commensurate with surgical procedures performed on actual patients. This force was measured, also using the Instron, and was found to be between 33 lb and 52 lb (mean, 41 lb). It is important to note, however, that this is dynamic force—representing the maximum force applied during a kinetic process—and is thus different than the static force applied in the sharpness assay.

Quantification of osteotome sharpness was performed as previously reported.[5] Briefly, an Instron Universal Tester (model 4206; Instron, Norwood, Massachusetts) equipped with 100-N load cell was used. A specific holder for the osteotome handles was custom milled and constructed by a

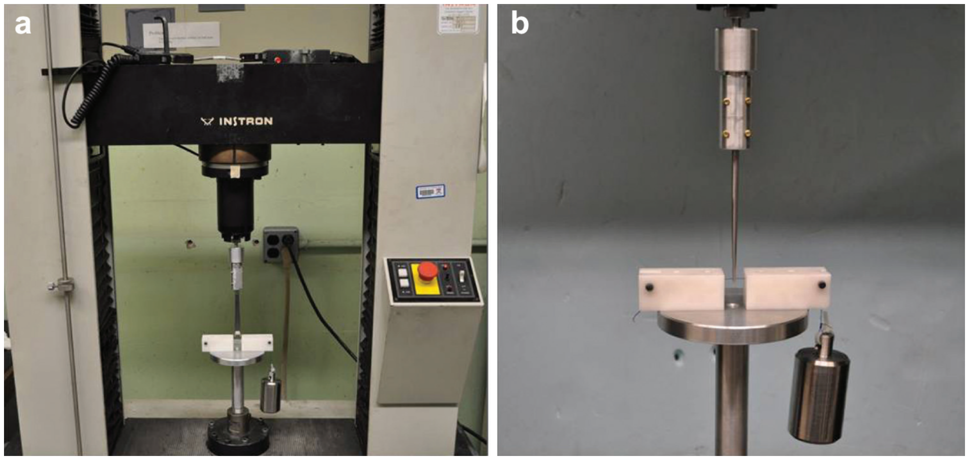

Figure 2. (a) Experimental setup for osteotome sharpness quantification. (b) Close-up photo of osteotome, suture, and counterweight system.

biomedical machinist. In addition, a holder for a #2 (5.0 metric) monofilament polypropylene suture (Prolene; Ethicon Inc, Somerville, New Jersey) was made. The suture was fixed at one end and then attached at the other to a standard 370-g weight, thus applying constant tension. For each trial, the osteotome was advanced slowly against the suture, with constant increase in force, until the suture was severed and the weight released (**Figure 2**). The software accompanying the Instron developed a force-versus-displacement curve throughout the trial; the force at the instant when the suture is cut drops to zero as the weight is released. We recorded the force immediately preceding this event as the force needed to cut the suture, which is inversely proportional to the sharpness of the blade.

Statistical Analysis and Cost-Effectiveness

The sharpness value at each time point for each osteotome was determined by averaging 3 trials. For sharpness comparison at baseline, a between-subject Student *t* test was employed. Analysis of changes in sharpness for each individual osteotome over time was completed using within-subject Student *t* tests. Comparison of sharpness data among all instruments tested, across all time points, required a multiway analysis of variance (ANOVA).

Cost-effectiveness was estimated as cost per use using the purchase price for each osteotome and the number of uses before reaching a dullness threshold. Analyzing the sharpness data, we chose to examine 2 levels of force as dullness cutoffs: 2.5 lb and 3.5 lb. These levels were chosen relative to the baseline measures obtained and correspond to 5% to 10% of the force of a ‘‘tap’’ during mallet strikes in the surgical model. For osteotomes that did not cross a particular threshold within 10 uses, a best-fit analysis was applied to the sharpness data, and the curve with the highest correlation (*r* coefficient) was selected. The point at which the curve crossed 3.5 lb was then extrapolated.

In all cases, 2-tailed analysis was used and a P value $<.05$ was considered significant. Statistical analyses were performed using Excel (Microsoft, Redmond, Washington) and SPSS (IBM, Armonk, New York).

Results

Baseline testing of each osteotome demonstrated the Karl Storz blade as the sharpest (1.74 lb) and significantly different than the remaining four ($P < .001$). The Miltex (2.50 lb) and Biomet (2.68 lb) blades followed and were similar in sharpness ($P = .16$). Finally, the least sharp were the Black & Black (3.40 lb) and NexEdge (3.48 lb) osteotomes; these were also very similar ($P = .49$).

Results of sharpness quantification after 1, 4, 7, and 10 osteotomies are shown in **Figure 3**. All osteotomes except for NexEdge demonstrated a significant loss of sharpness from baseline over time ($P = .10$). This occurred after 1 use for the Storz and Miltex blades, after 4 uses for the Biomet blade, and after 7 uses for the Black & Black blade ($P = .02$ to $< .001$). The Storz osteotome was the sharpest at each time point. Multiway ANOVA revealed that the Storz osteotome was significantly different than the other four ($P < .001$).

Cost-effectiveness was estimated as cost per use using the purchase price for each osteotome and the number of uses before reaching the dullness threshold (**Figure 3**). Cost data are presented in Table 1. Using the 3.5-lb dullness cutoff, cost per use was lowest with the Biomet, Miltex, and Karl Storz osteotomes. With a more stringent cutoff of 2.5 lb, cost per use was much higher for all blades. The lowest cost at this threshold was the Karl Storz instrument (**Table 1**).

Conclusions

Instrument selection and maintenance is an important but easily overlooked aspect of developing a successful surgical practice. In this study, we highlight the importance of these issues using osteotomes as an example. Predictable movement and precise control in dorsal reduction and osteotomy placement is key to a good rhinoplasty result.[4] An osteotome that is dull requires a more forceful mallet blow to cut.[6,7] Because the bone of the dorsal hump is thicker where

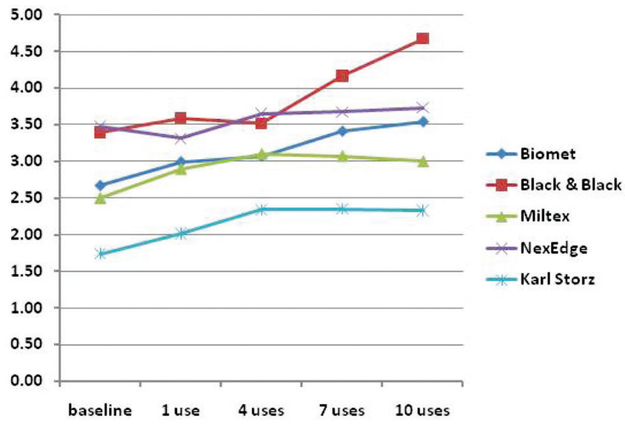

Figure 3. Results of sharpness quantification of each blade at baseline and following 1, 4, 7, and 10 osteotomies.

the nasal bones meet in the midline (more superficial) and thinner laterally, a dull osteotome may skew toward an area of lesser resistance, resulting in overresection and a scooped-out appearance. With medial and lateral osteotomies, greater force applied to a dull osteotome may be more difficult for the surgeon to control and may lead to wider dissemination of force. This would result in unintended and destabilizing microfractures or larger fracture lines that extend beyond the desired cut.[4] Furthermore, a dull osteotome increases the potential for collateral soft-tissue damage when the blade catches or skips.[4,5]

In this study, we compare the baseline sharpness, durability, and cost-effectiveness of 5 brands of osteotomes from 4 major manufacturers. The goal of this study was to explore a method of quantitative comparison of available surgical instruments. Furthermore, we sought to expand on our previous work[5] by adding an element of surgical simulation and a concomitant test of durability. This was achieved using a prospective osteotomy model, using standardized materials and reproducible conditions to ensure both the accuracy and fairness of our conclusions.

Our results reveal a breadth of sharpness in the osteotomes available. In addition, the durability of these instruments was variable. At baseline, the Karl Storz osteotome was significantly sharper than the others tested (**Figure 3**). This was also true at each time point as the osteotomes were used, as proven by multiway ANOVA. Although all of the blades except the NexEdge showed a significant decline in sharpness from baseline during the study, plotting the absolute sharpness at each point demonstrates clear differences between the available instruments (**Figure 3**).

We believe that changes in osteotome sharpness in our model, over a relatively brief use, are indicative of both the durability and expected clinical life span of a particular instrument. It is always possible to make a more forceful mallet strike. However, we strongly believe that this practice—compensating for a dull instrument with increased force—exposes the patient to undue risk and leads to inferior outcomes. Furthermore, we consider the focus of this study to be the surgical model, and we have shown that it is possible to create a reproducible method for testing surgical instruments in a laboratory setting.

Last, the relationship of osteotome performance and initial cost or cost-effectiveness was not linear or proportional. Initial purchase prices varied widely (**Table 1**). Using a dullness threshold derived from the baseline measurements, we determined the cost per use of each osteotome as a means of estimating cost-effectiveness. This analysis showed that 3 osteotomes lasted 10 or more uses before crossing the threshold: Biomet, Miltex, and Storz. Of these, the Biomet and Miltex osteotomes had nearly identical cost per use ($11 to $12), while the Storz osteotome was slightly more expensive ($16 per use). Although the dullness thresholds chosen were somewhat arbitrary, it is worth noting that the Miltex and Storz osteotomes did not cross the dullness threshold within our data collection; rather, cost-effectiveness analysis for these instruments required extrapolation from best-fit curves, thus allowing the possibility that the number of uses was underestimated. Cost per use for these osteotomes, therefore, may be lower than reported. Conversely, when a lower threshold is used (ie, 2.5 lb), cost per use is significantly higher for all but the Storz instrument ($25; **Table 1**).

Regarding cost, it is important to consider that, under any reasonable force threshold, the cost per use of the osteotomes tested in this study compares favorably to other nasal surgical disposables such as sutures, soft-tissue shavers for sinus surgery, PDS absorbable plates, and synthetic hemostatics. The subject of cost is complex and is not the focus of this report. Rather, the cost-per-use information represents an estimate, and the role of cost versus benefit must be left to the individual surgeon and health care system when analyzing the relative efficacy of available materials and equipment.

As a final note, if the reader questions the clinical relevance of the observed significant differences in osteotome sharpness between manufacturers, these instruments may be considered equivalent based on our data. In this scenario, one could then choose among osteotomes with equal performance based on other factors, such as purchase price.

Most surgical instruments are made from stainless steel, with a variety of alloys, specialized coatings, and other methods used to reinforce or augment certain aspects. As a response to surgeons' growing interest in instrument quality, manufacturers have begun to experiment with different materials in order to produce an osteotome that is sharper, stronger, and more durable. The NexEdge osteotome, for example, contains a tungsten-carbide alloy; this may have contributed to its maintenance of baseline sharpness throughout the study (**Figure 3**). The senior author currently uses Storz osteotomes, tracking the number of uses and typically discarding an osteotome between 8 and 10 uses. In most cases, the senior author detects no difference in the feel of the Storz osteotome between the first and seventh uses.

The judgment of the operating surgeon is an important factor in determining which instruments should be used and when they should be sharpened or replaced. The surgeon has several options in addressing a dull instrument.[1,5,8,9] In the case of osteotomes, the surgeon may sharpen with a whetstone or send them out for professional sharpening. In our previous work, we showed that these actions led to persistently dull osteotomes, from either inadequate sharpening (persistent dullness) or removal of too much metal from the cutting surface (oversharpening).[5] A final option is to consider osteotome disposable. Using the durability and cost-effectiveness analysis provided in this study, we encourage rhinoplasty surgeons to strongly consider this alternative.

Rhinoplasty has been performed successfully by experienced surgeons for years with osteotomes that they have maintained in various ways. The measured differences in our study may or may not be clinically significant. The senior author now treats osteotomes as a limited reuse instrument; however, this decision ultimately rests with each operating surgeon. Other surgeons may not find this useful or necessary. Although there are potential avenues for creating surgical instruments for single use or with a specifically defined life span, we do not know of any commercially available osteotomes marketed as such at this time.

In conclusion, surgical instruments can be compared quantitatively. In the case of osteotomes, differences in sharpness can have real consequences for rhinoplasty outcomes. Making wise decisions about instrument purchasing has never been more important.

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Author Contributions

Evan R. Ransom, study design, data collection, statistical analysis, manuscript writing, manuscript preparation and submission; **Marcelo B. Antunes**, study design, data collection; **Jason D. Bloom**, study design, manuscript writing; **Daniel G. Becker**, study concept, supervising research mentor/senior author.

Disclosures

Competing interests: Daniel G. Becker is a consultant to Ethicon on the PDS flexible plate.

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