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Blood Loss Reduction During Surgical Correction of Adolescent Idiopathic Scoliosis Utilizing an Ultrasonic Bone Scalpel

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Abstract

Study Design: Retrospective review of prospectively collected data.
Objectives: To evaluate blood loss associated with posterior spinal fusion in adolescent idiopathic scoliosis patients performed with and without the use of an ultrasonic bone scalpel (UBS).
Summary of Background Information: After using an ultrasonic-powered bone-cutting device with recent Food and Drug Administration approval for use in the spine, the authors perceived a reduction in bone bleeding associated with the cut boney surfaces.
Methods: The first 20 patients with adolescent idiopathic scoliosis who underwent posterior spinal fusion using the UBS by a single surgeon were compared with 2 control groups: 1) the 20 most recent prior cases of the same surgeon before beginning use of the bone scalpel; and 2) 20 cases of the same surgeon before using the bone scalpel matched based on Cobb angle magnitudes. Both cases and controls had Ponte-type posterior apical releases; none had an anterior procedure. Patient demographic and surgical data were analyzed using analysis of variance ($p < .05$).
Results: Preoperatively, the UBS group was similar to both control groups in terms of primary and secondary curve magnitudes, number of levels fused, number of levels with Ponte release, antifibrinolytic use, and patient age ($p > .05$). The UBS group had significantly less estimated blood loss (EBL) (550 ± 359 mL), Cell Saver blood transfused (94 ± 146 mL), and EBL per level fused (48 ± 30 mL) than the most recent controls (EBL: 799 ± 376 mL; Cell Saver: 184 ± 122 mL; EBL/level fused: 72 ± 28 mL) and Cobb-matched controls (EBL: 886 ± 383 mL; Cell Saver: 198 ± 115 mL; EBL/level fused: 78 ± 30 mL) ($p < .05$). Surgical times were equivalent and there were no dural tears in any group.
Conclusions: The use of an ultrasonic bone scalpel to perform the bone cuts associated with facetectomies and apical Ponte-type posterior releases resulted in significantly less bleeding compared with cuts made with standard osteotomes and rongeurs, limiting overall blood loss by 30% to 40%.

Keywords: Adolescent idiopathic scoliosis; Ultrasonic bone scalpel; Blood loss

Introduction

Blood loss during surgical correction of adolescent idiopathic scoliosis (AIS) can be variable. Studies in the literature often demonstrate a standard deviations of estimated blood loss (EBL) exceeding 50% of the reported group average [1,2]. Methods to reduce average blood loss,

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variability in blood loss, and excessive blood loss are of great interest to the pediatric spinal surgeon.

Use of ultrasonic devices for cutting bone is not a new development [3,4]. However, with refinement of designs, usage within surgical specialties has increased recently [5-9]. Ultrasonic bone scalpels (UBS) on the market are intended to efficiently cut bone, but spare soft tissue. The use of an UBS has been documented for numerous procedures including laminoplasty, spinal osteotomies, and craniofacial and orthognathic surgery [5,7,8,10,11]. The bony surface is cut by the repeated impact of the oscillating blade of the bone scalpel. Soft tissue remains relatively unaffected because of its elastic nature, which allows it to deform and absorb the impact of the blade [12]. The device uses saline irrigation delivered at the cutting blade when activated, which provides cooling to the blade. The friction between the bone scalpel blade and the bone is believed to reduce blood loss by sealing the cut bone through the heat emitted from the mechanical energy created by the rapid, repetitive movement of the scalpel [13].

The literature on the use of the UBS in spinal surgery for pediatric patients is limited. Hu et al. [8] reported on 128 cases in which the UBS was used to perform any type of osteotomy. The average age of the patients was 58 years (range, 12−85 years) and diagnoses varied. The authors reported the bone scalpel as overall safe and effective, with only 2 (of 11) instances of dural injury directly related to the use of the bone scalpel. A significant absence of bleeding was noted, with an average EBL of 425 mL, although a comparison group was not included. Similar findings were reported by Al-Mahfoudh et al. [6], who reported on 937 patients undergoing spinal surgery, 62 of which procedures used the UBS. In their series, most cases were for spinal degenerative disorders; the bone scalpel was used for laminotomies. There was 1 dural tear associated with use of the bone scalpel. A trend toward lower blood loss was noted.

These previous studies report similar results, and conclude that the bone scalpel is safe and effective in performing a variety of operations, although a learning curve may exist. An observed decrease in intraoperative bleeding associated with the use of the bone scalpel has been noted [8]; however, empirical evaluation of this claim is needed. To the authors' knowledge, there have been no studies reporting on the use of the bone scalpel in spinal surgery for pediatric patients with a single diagnosis. Because previous studies have found that blood loss can vary by diagnosis [9,14], the researchers thought it important to restrict this variable to a common diagnosis: AIS. In addition, many of the existing studies lack a control group to more clearly evaluate the effects of the bone scalpel on specific surgical outcomes. The purpose of the current study was to evaluate EBL in patients with AIS who underwent a posterior spinal instrumentation and fusion procedure with and without the use of the UBS.

Materials and Methods

The authors conducted a retrospective review of data collected prospectively as part of a larger study on the surgical treatment of AIS. All patients had a diagnosis of AIS and underwent posterior spinal fusion and instrumentation (PSF) with pedicle screw fixation by a single surgeon between 2009 and 2012. In 2011, an UBS was approved by the Food and Drug Administration for use in the spine (Misonix, Inc., Farmingdale, NY) became available at the researchers' institution for routine operating room use. The first 20 patients who underwent PSF with the use of the UBS were compared with 2 controls groups: 1) the 20 most recent prior AIS cases of the same surgeon before beginning use of the bone scalpel, and 2) 20 AIS cases of the same surgeon prior to using the bone scalpel, matched based on Cobb angle magnitudes. The descriptives (mean ± standard deviation) of the thoracic and lumbar Cobb magnitudes within the UBS group were calculated. Patients who underwent surgery before the availability of the UBS were then screened starting with the most recent and working backward. Patients were selected for the Cobb-matched group (CMC) if their thoracic and lumbar Cobb fell within 1 standard deviation of the mean of the UBS group. The most recent control (MRC) group was used to help control for any changes in surgical technique that may have occurred over the 3-year period in which the surgeries occurred. The Cobb-matched controls spanned over a longer period but were used to control for differences in patient and/or curve characteristics. Both the bone scalpel patients and the 2 control groups had Ponte-type apical posterior releases. Patients who underwent an anterior procedure were excluded. Antifibrinolytic agent used and intraoperative red cell salvage (Cell Saver, Haemonetics Corp., Braintree, MA) were recorded.

Inferior articular process facetectomies were performed with cuts made in similar orientation and size among the 3 groups. In the thoracic spine, 2 perpendicular cuts were made: 1 transverse and 1 longitudinal (Fig. 1A). In the lumbar spine, a single oblique cut was made from the inferior pars intra-articularis laterally to the inferior lamina medially. When the cuts were made with the UBS, 2 Frazier suction tips were used to remove the irrigating fluid to maintain visualization. These same bone cuts were made with a 1-cm osteotome and mallet in each control group.

Ponte osteotomies, a technique originally designed to correct hyperkyphosis, was used in these scoliosis patients to create a posterior release to facilitate restoration of thoracic kyphosis. At the released levels in both the UBS and the control groups, the spinous processes were removed with a rongeur (Fig. 1B). The ligamentum flavum was removed with a narrow Leksell rongeur (Fig. 2A) and the superior articular facet was removed with Leksell and/or Kerrison rongeurs (Fig. 2B). Hemostasis was achieved with Gelfoam (Pfizer, New York, NY), with or without Floseal (Baxter, Deerfield, IL). In the

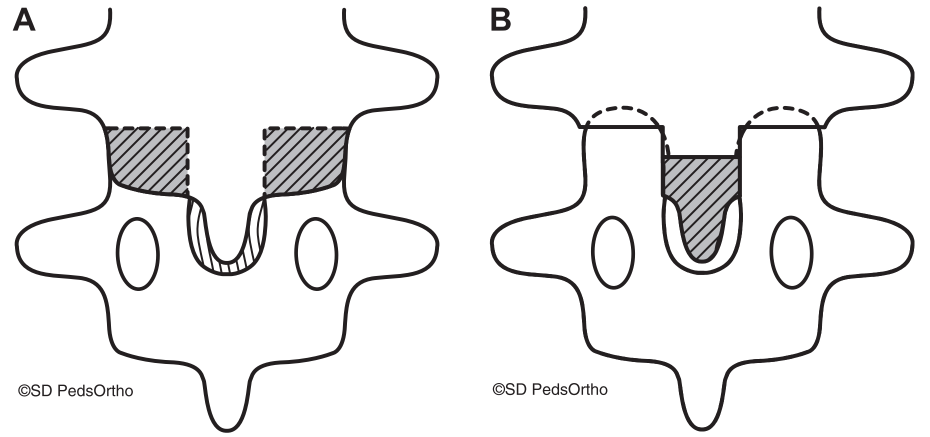

Fig. 1. (A) Bone scalpel or osteotome cuts of inferior articular processes. (B) Removal of spinous process (interspinous ligaments).

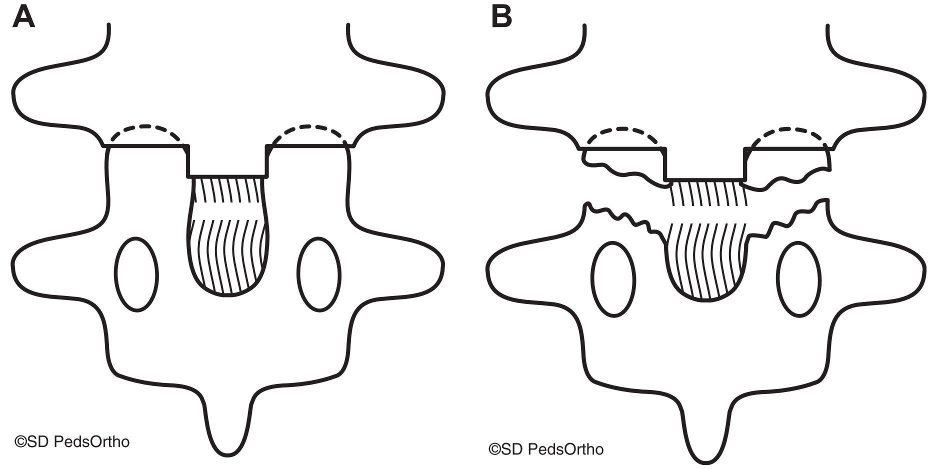

Fig. 2. (A) Standard Ponte technique: the ligamentum flavum was divided with a narrow rongeur. (B) Standard Ponte technique: removal of the superior articular facet with sequential bites with Leksell and/or Kerrison rongeurs.

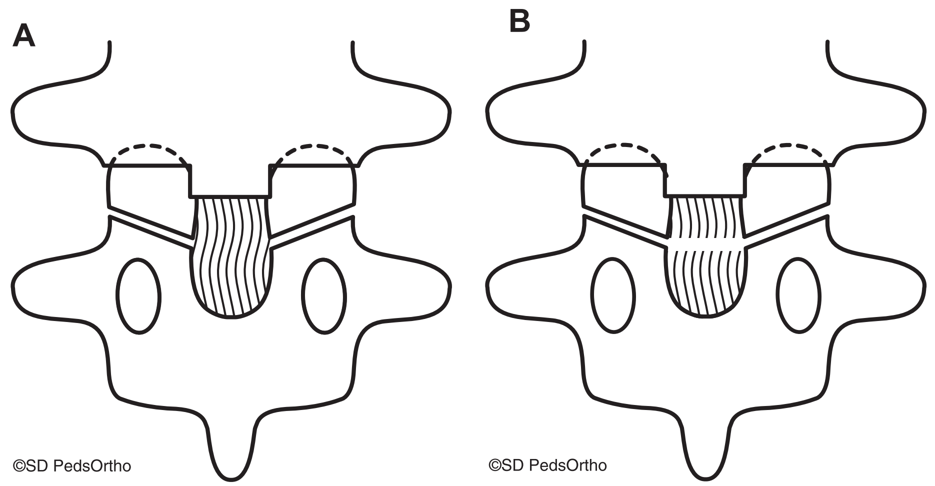

Fig. 3. (A) Bone scalpel Ponte technique. After removal of the spinous process, the superior articular process is cut with the ultrasonic bone scalpel, preserving the ligamentum flavum. (B) Bone scalpel Ponte technique. Just before rod insertion, a cut of the ligamentum flavum was made with rongeurs, completing the release.

UBS group, the spinous process was removed as in the control groups, but at this point the ligamentum flavum was left intact. The superior articular processes were osteotomized just superior to the pedicle using the bone scalpel (Fig. 3A). The superior articular processes were left in situ. Just before rod insertion, the ligamentum flavum was cut with a narrow rongeur (Fig. 3B).

Preoperative and perioperative data were queried from the prospectively collected database and reviewed. The researchers analyzed patient demographic and surgical data using analysis of variance. Data were checked for normality and homogeneity of variances before application of analysis of variance techniques. Analyses were performed using SPSS, version 12 (SPSS, Inc., Chicago, IL). Alpha was set at $p < .05$ to declare significance.

Results

Table 1 lists patient demographic data. Preoperatively, the UBS group was similar to both CMC and MRC groups in terms of age at time of surgery, primary and secondary curve magnitudes (Table 1), number of levels fused, and number of Ponte releases (Table 2) ($p > .05$). All patients received a tranexamic acid as an antifibrinolytic agent intraoperatively.

Ultrasonic bone scalpel group versus most recent control group

The average age of the subjects was 15 ± 3 years in the UBS group and 14 ± 2 years in the MRC group ($p = .67$). There were no differences in preoperative major or minor Cobb angles (Table 1). Operative time was similar for both groups (UBS: 247 ± 62 minutes; MRC: 233 ± 42 minutes; $p = .41$). The UBS group had an average of 11.5 levels fused (median, 12 levels) and 5.5 levels released (median, 5). The MRC group had an average of 11.0 levels fused (median, 11) and 5.2 levels released (median, 5) ($p > .05$). The UBS group had significantly less EBL (550 ± 359 mL) than the MRC group (799 ± 376 mL; $p = .039$), as well as less Cell Saver blood transfused (94 ± 146 mL vs. 184 ± 122 mL, respectively; $p = .042$). Blood loss expressed as a percentage of the estimated blood volume trended toward significance, with the UBS group losing 15% ± 9% versus 23% ± 14% ($p = .07$) in the MRC group. Estimated blood loss per level fused was significantly less in the UBS group (48 ± 30 mL) than in the in the MRC group (72 ± 28 mL; $p = .01$). Similarly, EBL per level released was significantly less in the UBS group (100 ± 50 mL vs. 163 ± 71 mL, respectively; $p = .03$). When normalizing for the degrees of deformity within the thoracic Cobb, the UBS group had an EBL of 10.6 ± 7 mL per degree of thoracic deformity, which was significantly less than that in the MRC group (15.6 ± 6.3 mL per degree of thoracic deformity; $p = .02$).

Ultrasonic bone scalpel group versus Cobb-matched controls

The ages of the 2 groups were similar (Table 1). The UBS group had an average thoracic Cobb angle of 53° ± 9° and an average lumbar Cobb angle of 38° ± 12°; as expected, this was similar to that of the CMC group, which had an average thoracic Cobb of 54° ± 10° and a lumbar Cobb of 35° ± 13° ($p > .05$). Surgical time was similar between groups as well (247 ± 62 minutes vs. 229 ± 30 minutes; $p = .25$). The UBS group had an average of 11.5 levels fused (median, 12 levels) and 5.5 levels released (median, 5 levels). The Cobb-matched controls had an average of 11.3 levels fused (median, 11 levels) and 5.5 levels released (median, 6 levels) ($p > .05$). Estimated blood loss was significantly less in the UBS group (550 ± 359 mL) than in the CMC group (886 ± 383 mL) ($p = .007$). Percent estimated blood volume lost was

Table 1
Preoperative variables for bone scalpel and control groups.

	Bone scalpel	Most recent controls	p value	Cobb-matched controls	p value
Age, years	15 ± 3	14 ± 2	.671	14 ± 2	.227
Thoracic Cobb (degrees)	53 ± 10	51 ± 12	.508	54 ± 10	.869
Lumbar Cobb (degrees)	38 ± 12	33 ± 14	.251	35 ± 13	.445

Table 2
Surgical data for bone scalpel and control groups.

	Bone scalpel	Most recent controls	p value	Cobb-matched controls	p value
Levels fused, n	11.5 ± 1.1	11.0 ± 2.0	.547	11.3 ± 1.3	.589
Levels released, n	5.5 ± 1.1	5.2 ± 1.6	.499	5.5 ± 1.2	.90
Surgical time, minutes	247 ± 62	233 ± 42	.41	229 ± 30	.25
EBL, mL	550 ± 359	799 ± 376	.039	886 ± 383	.007
Cell Saver transfused, mL	94 ± 146	184 ± 122	.042	198 ± 115	.017
EBL/levels fused, mL	48 ± 30	72 ± 28	.01	78 ± 30	.003
EBL/levels released, mL	100 ± 50	163 ± 71	.003	178 ± 116	.009

EBL, estimated blood loss.

significantly less in the UBS group than in the CMC group (15% ± 9% vs. 27% ± 15%, respectively; p = .007). Cell Saver blood transfused was also significantly less in the UBS group (94 ± 146 mL vs. 198 ± 115 mL, respectively; p = .017). The UBS group had significantly less blood loss than the CMC group for each level fused (48 ± 30 mL vs. 78 ± 30 mL, respectively; p = .003) and for each level released (100 ± 50 mL vs. 178 ± 116 mL, respectively; p = .009). When normalizing for degrees of deformity within the thoracic Cobb, the UBS group had an EBL of 10.6 ± 7 mL per degree of thoracic deformity, which was significantly less than that in the CMC group (16.5 ± 6.7 mL per degree of thoracic deformity) (p = .01).

There were no dural tears in any of the 60 patients analyzed. The facetectomies and Ponte osteotomies were performed successfully in all cases. No complications were directly related to the use of the bone scalpel or osteotomes. One patient in the bone scalpel group experienced changes in vision postoperatively, but had a magnetic resonance imaging scan within normal limits and the issue resolved within 1 week postoperatively. No perioperative complications were noted in either control group.

Discussion

The use of an UBS to perform bone cuts associated with facetectomies (both inferior and superior articular processes) during corrective spine surgery for AIS resulted in significantly less bleeding compared with cuts made with standard osteotomes and rongeurs. The cut surfaces of the bone were ‘‘sealed’’ and there was less manipulation within the epidural space (visually reducing epidural bleeding), thus limiting overall blood loss by 30% to 40%. These findings are consistent with previous studies that reported less boney bleeding with the use of the bone scalpel in various populations and surgical procedures [6,8]. In addition, the current study found no dural tears in any patients in the bone scalpel or control groups. Previous studies reported dural tears with use of the bone scalpel in 1.6% to 18% of patients [6,8,12], which is likely the result of differences in the procedures performed and the older age of the patients in these prior studies.

The use of Ponte osteotomies has been previously documented to be associated with increased intraoperative blood loss. Zheng et al. [15] found that idiopathic patients undergoing a PSF with Ponte osteotomy-style posterior releases had significantly greater EBL and operative time than idiopathic scoliosis patients undergoing PSF with simple posterior soft tissue release. Similarly, Halanski and Cassidy [16] compared AIS patients with main thoracic curves who underwent a PSF with multilevel Ponte osteotomies with a similar cohort who underwent a PSF with inferior facetectomies, and found that operative time per level and EBL per level were greater in the osteotomy group. Thus, the current study included only patients who had multilevel osteotomies and evaluated the use of the UBS in performing facetectomies and/or Ponte osteotomies compared with performing this portion of the procedure with an osteotome and rongeurs. When examining the EBL per level released, the bone scalpel group showed significantly less EBL than the osteotome/rongeur control groups. The indication and benefit of Ponte osteotomies in AIS surgery remain debated in the literature [16-18], and it is unclear whether the benefit in reduced bleeding seen with the UBS would exist if only the inferior facetectomy cuts were performed with this device. The purpose of the current report, however, was not to assess the benefit, if any, of Ponte osteotomies in the 3-dimensional correction of AIS.

The influences on intraoperative blood loss during spine surgery are multifactorial. Diagnosis, sex of the patient, weight, body mass index, bone density, preoperative hemoglobin, preoperative Cobb angle, surgical approach, operative time, and number of levels fused have all been shown to be associated with intraoperative blood loss [1,9,14,15,19-22]. Many of these factors are out of the surgical team's control; however, among those able to be manipulated by the surgeon, operative time and number of levels fused appear to be the most significant predictors of intraoperative blood loss [20,23]. Guay et al. [23] studied factors important in determining intraoperative blood loss in idiopathic scoliosis patients and concluded that the number of levels fused was the most significant factor in predicting EBL. The current authors sought to control for as many of these potential factors as possible by using 2 control groups (1 controlling for temporal changes in surgical procedures and the other controlling for curve magnitude which can indirectly affect levels fused, operative time, etc.). Patients undergoing an anterior approach were excluded. Although the median levels fused were 1 level longer (12 levels) in the bone scalpel group than in both control groups, the overall EBL was less in the bone scalpel group.

A limitation to the present study is that it is retrospective in nature. Patients were not randomized to the bone scalpel and control groups, which may have increased the potential for selection bias. However, in an attempt to reduce this bias, the 2 different control groups were used and EBL was normalized to the number of levels fused, levels released, and Cobb magnitude to normalize for the variability potentially associated with these factors. Another limitation is the relatively small sample size. However, a significant difference was observed between the bone scalpel group and both control groups consistently across all outcome variables. Also, despite the overall reduction in average blood loss, the variability of EBL in this patient population was still relatively high in the bone scalpel group. Further efforts to limit blood loss and reduce variability are needed. An assessment of surrounding tissue also was not done in this study. Previous work has demonstrated reduced risk of damage to surrounding tissues and structures [10,11]. However, Sanborn et al. [12] showed that in the ultrasound osteotome group, 6 of 8 specimens demonstrated reactive and reparative changes compared with 2 of 4 specimens in a control group. The clinical significance of these findings is unknown, and those authors suggested that long-term research is warranted to determine the impact of this reaction on the formation of scar tissue.

An additional potential benefit of the bone scalpel technique for performing Ponte osteotomy of the superior articular facets is the ability to maintain the ligamentum flavum during a greater proportion of the surgery. Limiting the time in which the spinal canal is "open" may limit the risk of inadvertent placement of instruments (e.g., suction tip) into the spinal canal. The superior articular processes can be cut with the bone scalpel without the need to divide the ligamentum flavum. This is not as easily accomplished when rongeurs are used and entry into the epidural space with the rongeur is required.

In an attempt to reduce blood transfusions and related complications, numerous means to limit blood loss during spinal corrective surgery for AIS have been employed and appear effective, including the use of antifibrinolytic agents and red cell salvage [24,25]. It is reasonable to believe that if methods exist to safely reduce bleeding without compromising the integrity of the surgery, these methods should be considered. As with any new method or procedure, there is a learning curve associated with the use of the UBS [12,26]. However, when used properly, the UBS can be a safe and effective means for performing facetectomies, with the added benefit of decreased blood loss owing to cauterization of the cut bone.

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