Minimizing Tourniquet Pressure in Pediatric Anterior Cruciate Ligament Reconstructive Surgery

A Blinded, Prospective Randomized Controlled Trial

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Background: Tourniquet cuff pressures in pediatric patients are commonly set at standard pressures. Recent evidence on adult subjects has shown that safer and more effective cuff pressures can be achieved by measuring limb occlusion pressure (LOP) and using a wide contour cuff. There is little evidence validating these techniques in children. The primary objective of this study was to evaluate if a difference in tourniquet cuff pressure can be achieved in a pediatric population using a wide contour cuff in conjunction with measured LOP when compared with a standard cuff and pressure.

Methods: Subjects aged 10 to 17 years that underwent anterior cruciate ligament repair were included and randomized into either the control group or the experimental LOP group using variable block randomization. The tourniquet cuff was inflated to 300 mm Hg in the control group or to the recommended tourniquet pressure based on LOP measurement in the LOP group. The surgeon was blinded to cuff selection, application, and pressure throughout the surgical procedure. Immediately after the surgical procedure, the surgeon rated the quality of the bloodless field on a visual analog scale. This study was powered as an effectiveness trial, and intention to treat analysis was used.

Results: After a planned interim analysis at midpoint, complete data were recorded for 11 (control group) and 10 (LOP group) patients. The quality of the surgical field was not different between the groups ($P = 0.053$). There was a statistically significant difference in the mean cuff pressure between the control (300 mm Hg) and the LOP (151 mm Hg) groups ($P < 0.001$). We ran the same analysis comparing the LOP data with the hypothetical control data of 250 mm Hg, and our results remained statistically significant ($P < 0.001$).

Conclusions: The use of an automatic LOP measurement with the use of wide contour cuffs can significantly reduce mean tourniquet cuff pressures in pediatric patients compared with the typical practice of 300 or 250 mm Hg without compromising the quality of the surgical field.

Level of Evidence: Level 1, prospective randomized controlled trial.

Key Words: tourniquet cuff pressure, pediatric, anterior cruciate ligament, randomized controlled trial

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Tourniquets are commonly used in surgery to establish and maintain a bloodless surgical field, allowing the surgeon to work with greater technical precision and safety. The widespread use of tourniquets in orthopedic surgery involving adults and children is not without risk: the surgical literature includes numerous reports of injuries and hazards associated with tourniquet overpressurization and underpressurization.[1–7] The risk of tourniquet-related injuries can be reduced by minimizing tourniquet inflation time, by using automatic tourniquet instruments and cuffs that allow pressure to be accurately delivered, controlled, and monitored, and by maintaining tourniquet cuff pressure near the minimum level required to stop blood flow during surgery.[5,7–10]

Tourniquet cuff pressures in pediatric patients are commonly set at standard pressures based on experience or on heuristic formulations such as systolic blood pressure plus a standard margin or multiple.[1,4] However, there is little evidence validating these techniques. Physiological and anatomical characteristics or age of the individual patient is not taken into account, which can result in cuff pressures that are too high, increasing the risk of tourniquet-related injuries or too low, compromising the quality of the surgical field with breakthrough bleeding.[11]

Recent surgical literature on adult subjects has shown that safer and more effective cuff pressures can be achieved by measuring limb occlusion pressure (LOP) and using a cuff that is designed to fit any of a wide range of limb contours.[11–15] Limb occlusion pressure is the minimum pressure required in a tourniquet cuff to occlude arterial blood flow into a patient's limb past a specific tourniquet cuff at a specific time. Limb occlusion pressure accounts for the anatomical and physiological characteristics of the patient's limb and

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the physical characteristics and fit of the specific cuff used.[11] Limb occlusion pressure may be determined manually by slowly increasing tourniquet cuff pressure until distal arterial pulsations cease, as indicated by a Doppler stethoscope.[1,12,13,15] More recently, an automated plethysmographic system has been developed and shown to have an accuracy similar to the Doppler method.[11,16,17] Previous studies on adult[11,12,14,15] and pediatric[1] subjects have shown that tourniquet cuff pressures based on LOP measurements before cuff inflation significantly decrease mean tourniquet cuff pressures and are sufficient to maintain a satisfactory surgical field.

Wide contour cuffs with variable fasteners have been shown to occlude blood flow at significantly lower pressures than standard cylindrical cuffs.[11,14,16–20] When used in conjunction with LOP, wide contour cuffs can significantly reduce the necessary cuff pressures to maintain an adequate surgical field in adult populations.[11] This has not yet been demonstrated in the pediatric literature.

The primary objective of this study was to evaluate if a difference in tourniquet cuff pressure can be achieved in a pediatric population using a wide contour cuff in conjunction with an automated plethysmographic tourniquet device capable of measuring LOP when compared with a standard pressure. Secondary objectives were to assess the effect of the previously described technique on the quality of the bloodless surgical field and to evaluate whether there is a reduction in LOP when a wide contour cuff is used relative to a standard cylindrical cuff. We hypothesized that significantly lower tourniquet cuff pressures will be needed to maintain adequate hemostasis when LOP is used with a wide contour cuff to determine tourniquet cuff pressure.

METHODS

This study was approved by the university and hospital ethics review boards.

Inclusion/Exclusion Criteria

Subjects were invited to participate if they were aged between 10 and 17 years and were scheduled to undergo primary repair of the anterior cruciate ligament (ACL). The subjects were excluded if they had previous surgery to their ACL or were scheduled to undergo a repair of any concomitant injuries. All surgeries were performed by a single surgeon at a single tertiary pediatric institution. Baseline data were collected on all subjects including patient demographics, type of surgical reconstruction, and blood pressure.

Randomization

The subjects were randomized into either the control group or the experimental LOP group using variable block randomization. Sealed opaque envelopes were used for randomization; envelopes were grouped into the blocks of 4 and 6. Allocation was completed after enrollment in the study and blinded to the surgeon and participant.

In the control group, a standard cylindrical tourniquet cuff was selected according to the surgeon's usual practice; these cuffs had a width of 4 in and a length between 24 and 34 in (Zimmer ATS cylindrical cuffs; Zimmer Orthopaedic Surgical Products, Dover, Ohio). In the LOP group, the widest available cuff suitable for the limb location and shape was selected and applied according to a standardized guide provided by the supplier; these cuffs had a width of 6 in and 1 of 2 contour shapes (Delfi low pressure tourniquet thigh and arm cuffs; Delfi Medical Innovations Inc, Vancouver, British Columbia, Canada). The cuffs were connected to a Zimmer ATS 3000 tourniquet instrument (Zimmer Orthopaedic Surgical Products). The tourniquet instrument can be used to maintain a tourniquet pressure set by a surgical staff and includes a plethysmographic apparatus for automatically measuring LOP and for determining a recommended tourniquet pressure based on LOP (LOP plus a standard margin of safety varying from 50 mm Hg to 100 mm Hg, depending on the level of the measured LOP). The limb was then exsanguinated using a combination of elevation and an Esmarch bandage. After exsanguination, the tourniquet cuff was inflated to 300 mm Hg in the control group or to the recommended tourniquet pressure based on LOP measurement in the LOP group. Tourniquet inflation time was noted, as was blood pressure at the time of cuff inflation and deflation.

Data Collection

The surgeon was blinded to cuff selection, application, and pressure throughout the surgical procedure. Immediately after the surgical procedure, the surgeon rated the quality of the bloodless field by marking a small vertical line on a visual analog scale (VAS) ranging from 0 cm (surgical field obliterated by blood and unable to visualize procedure) to 10 cm (no blood in surgical field and perfect visualization). Comments about blood in the surgical field during the procedure were also noted at this time. A data analyst blinded to the randomization later converted the VAS scores into a distance measured to the nearest millimeter.

Sample Size

A priori sample size calculation determined that 21 subjects in each group were necessary to observe a clinically significant difference in tourniquet cuff pressure, with δ of 25 mm Hg, α of 0.05, and a power of 0.80 when compared with a standard pressure of 300 mm Hg.

Interim Analysis and Stopping Criteria

A planned interim analysis was completed midway through the study with stopping criteria including a significantly increased rate of complications (30% difference between the groups) or $P < 0.001$. Only one interim analysis will be performed by the biostatistician. This will be done after the Haybittle-Peto method, using $P < 0.001$ as the significance. The advantage of using this method is that $P < 0.05$ is used at the final analysis.

Data Analysis

Intention to treat analysis was used because this is an effectiveness trial. A 2-tailed z test was used to compare the mean tourniquet cuff pressure in the LOP group with the standard pressure of 300 mm Hg used in the control group. Unpaired Student t tests were used to compare mean VAS scores and differences in LOP between the control and the

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TABLE 1. Patient Characteristics and Results Summary

	n	Sex	Age, y	Cuff Pressure, mm Hg	LOP, mm Hg	VAS (0–10 cm)
Control group (standard cylindrical cuff and standard pressure)	11	5 females 6 males	14.2 (range, 10–16)	300	133 (CI 110, 155)	9.0 (CI 8.5, 9.5)
LOP group (wide contour cuff and LOP)	10	7 females 3 males	15.1 (range, 13–17)	151 (CI* 145,160)	100 (CI 92, 105)	9.5 (CI 9.2, 9.9)
P	—	—	—	<0.001	0.01	0.053

*95% CI.

LOP groups. $P < 0.05$ was considered significant. All statistical calculations were done using Microsoft Excel 2004 (Microsoft, Seattle, Wash) and the SPSS Inc version 12.0 (Chicago, Ill).

RESULTS

The second stopping criterion was satisfied at the time of the planned interim analysis. The study was terminated after this planned interim analysis. Twenty-three subjects were recruited for the study between January 2007 and February 2008. All subjects recruited agreed to participate. One subject was excluded because no ACL tear was found during arthroscopy, and another was excluded because the pulse signal from the plethysmographic sensor was too weak to make an LOP measurement.

Complete data were recorded for 21 patients: 11 and 10 patients in the control and the LOP groups, respectively (Table 1). Patient demographics and the mean tourniquet inflation time were not statistically significant between the groups. The cuff pressure was 300 mm Hg for all patients in the control group and the mean cuff pressure was 151 mm Hg (SD, 8.8 mm Hg; 95% confidence interval (CI), 145.6–156.4 mm Hg) in the LOP group ($P < 0.001$; Fig. 1). The average LOP in the control group, in which the standard cylindrical cuffs were used, was 133 mm Hg (SD, 33 mm Hg; CI, 152–114 mm Hg). The average LOP in the LOP group, in which the wide contour cuffs were used, was 100 mm Hg (SD, 8.4 mm Hg; CI, 105.2–94.8 mm Hg). The mean decrease in LOP associated with the use of a wide contour cuff was 33 mm Hg ($P = 0.01$; Fig. 2). The mean tourniquet time in the control group was 91 ± 18 minutes and in the experimental group was 89 ± 12 minutes.

The quality of the surgical field was acceptable in all cases. The VAS scores for the control and the LOP groups were 9.0 (CI, 8.6–9.4) and 9.5 (CI, 9.2–9.8), respectively ($P = 0.053$; Fig. 3). There were no incidents of breakthrough bleeding that required an increase in cuff pressure during the surgical procedure. Although visualization was not

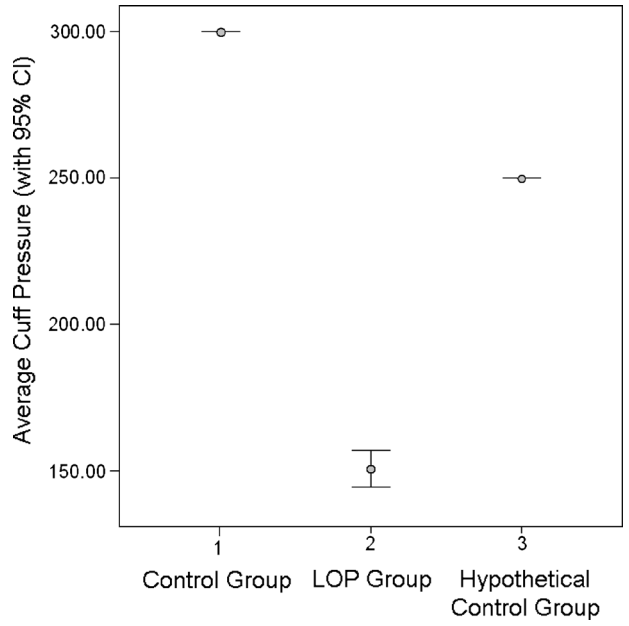

FIGURE 1. Average tourniquet cuff pressure was significantly lower in the group in which LOP was measured and wide contour cuffs were used (151 mm Hg), in comparison with the control group (300 mm Hg) and the hypothetical control group of 250 mm Hg ($P < 0.001$).

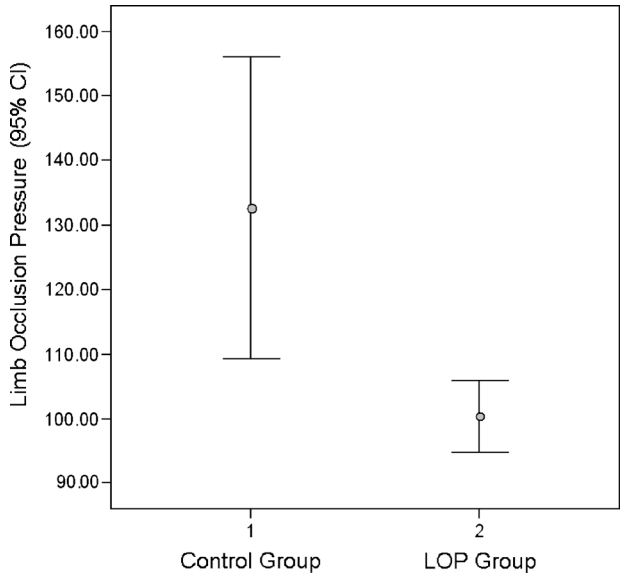

FIGURE 2. Limb occlusion pressure was significantly lower when wide contour cuffs were used, in comparison with narrower standard cylindrical tourniquet cuffs.

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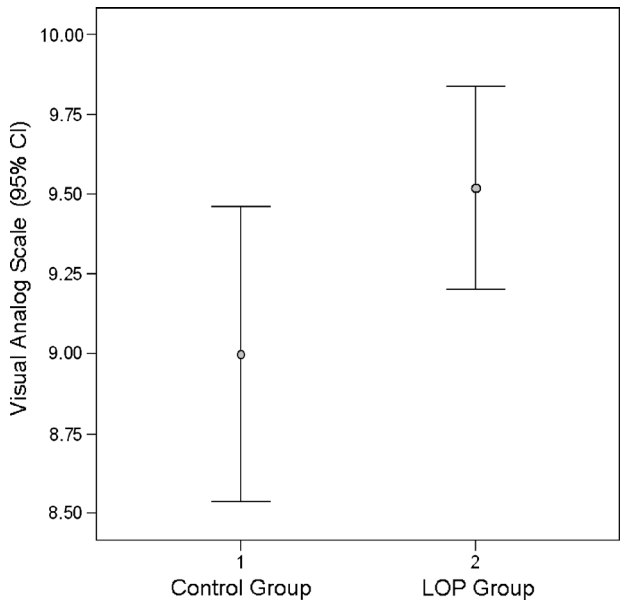

FIGURE 3. Average VAS scores were not significantly different in the group in which LOP was measured and wide contour cuffs were used, in comparison with the control group in which cylindrical cuffs were used at a tourniquet pressure setting of 300 mm Hg.

significantly affected, there was some bleeding in 5 cases (4 controls and 1 LOP patients). In the control group, blood in the surgical field was caused by temporary inadequate irrigation or was noted during the initial approach, reentry, or during manipulation of the knee. There was a small amount of breakthrough bleeding in 1 LOP case in a subject with a particularly large limb and a larger than average increase in blood pressure during the period of tourniquet cuff inflation.

DISCUSSION

In our study, our hypothesis was confirmed with a mean decrease in cuff pressure of 149 mm Hg ($P < 0.001$) in the LOP group (mean cuff pressure, 151 mm Hg) relative to the control group (cuff pressure, 300 mm Hg). Standard thigh tourniquet cuff pressure lower than that used in the control group of the study, such as 250 mm Hg, is commonly used by some surgeons. When we run an analysis comparing the LOP data with the hypothetical control data of 250 mm Hg, our results remain statistically significant ($P < 0.001$). The reduction in LOP with a wide contour cuff relative to a standard cylindrical cuff was 33 mm Hg ($P = 0.01$). There was a little effect demonstrated on the quality of the surgical field with similar mean VAS scores in the control and the LOP groups at 9.0 ± 0.4 and 9.5 ± 0.3, respectively ($P = 0.053$). These data suggest that significantly lower tourniquet cuff pressures based on LOP and the use of wide contour cuffs can be used effectively in the pediatric population without compromising the quality of the surgical field.

Previous studies in adult populations have shown that LOP can be used to optimize the tourniquet cuff pressure required to maintain a bloodless surgical field.[11–15] Measurement of LOP directly at the time of cuff application takes into account variables such as the type and the width of the cuff, the tightness of cuff application, the fit of the cuff to the limb, and the properties of the patient's soft tissues and vessels. Younger et al[11] compared a standard cylindrical cuff with a wide contour cuff using an automated plethysmographic technique for measuring LOP in adult subjects and reported results consistent with those of the current study. Lieberman et al[1] addressed the use of LOP in a pediatric population using Doppler ultrasound and set cuff pressures to 50 mm Hg more than the occlusion pressure. Of the 21 lower-extremity cases reported, the mean pressure necessary to provide an adequate bloodless surgical field was 177 mm Hg. Our mean pressure in the LOP group was 151 mm Hg, lower than the mean pressure found by Lieberman et al, perhaps because of the use of wide contour cuffs.

Although no pediatric studies have been reported, it has been shown in adult subjects that wide contour tourniquet cuffs occlude arterial blood flow at lower pressures than narrower cuffs.[10,11,14,16–20] In the study by Lieberman et al on pediatric subjects, an effort was made to use the widest tourniquet cuff available, but no specific width was reported. In the current study, wide contour cuffs (6 in) were used in the LOP group, and the standard cylindrical cuffs (4 in) were used in the control group. In addition, the contour cuffs used in the LOP group had pivoting fasteners, which allowed the contour cuff shape to be adjusted to closely match the shapes of the tapered thighs. The use of wide contour cuffs in the present study decreased the mean pressure by 33 mm Hg ($P = 0.01$). Although this result is a secondary outcome of the current study and only hypothesis generating, it suggests that wide contour cuffs decrease cuff pressure necessary to occlude arterial blood flow in pediatric patients, as has been previously demonstrated in adults.

A number of different tourniquet-related injuries and hazards have been reported in the literature including overpressurization, which may cause pain at the tourniquet cuff site[18,21,22]; muscle weakness[2,23]; compression injuries to blood vessels, nerve, muscle, or skin[3,4,6,7,24]; or extremity paralysis.[25–27] Minimizing tourniquet cuff pressure should decrease these tourniquet-related injuries and hazards.[5,7,14,18,28] However, underpressurization may result in blood in the surgical field and passive congestion of the limb[6,11] The incidence of blood in the surgical field in the current study is comparable to or better than that of the previous studies using LOP methods to determine cuff pressure.[1,11,12,14,15] The results of this study suggest that there is no associated decrease in the quality of surgical field when LOP is used as the basis for setting lower tourniquet cuff pressures. However, the quality of the surgical field was a secondary outcome, and the current study was not powered for a noninferiority trial, which would be necessary to confirm this result.

Erroneous LOP measurements can contribute to breakthrough bleeding and poor quality of surgical field. During LOP measurement, the limb should remain horizontal and motionless. Limb occlusion pressure measurement should be made before or after induction of anesthesia when blood pressure has stabilized to the level expected during surgery.[4,29] A misleading indication of LOP may occur if LOP is

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TABLE 2. Recommendations for Pneumatic Tourniquet Use in Pediatric Limb Surgery Based on Study Results and Relevant Clinical Literature

1 Cuff selection

Select the widest cuff suitable for the selected limb location,[11,14,18–20,29] and use a contoured cuff able to match the taper of the thigh.[14] Ensure that the cuff is clean and in a good working condition.[29]

2 Skin protection

Select a limb protection sleeve specifically designed for the selected cuff. If such a sleeve is not available, apply 2 layers of tubular stockinet or elastic bandage, sized such that it is stretched when applied to the limb at the cuff location and that the compression applied by the stockinet or elastic bandage is less than venous pressure (≈20 mm Hg) and less than the pressure of a snugly applied cuff.[4]

3 Cuff application

Apply the tourniquet cuff snugly over the limb protection sleeve, and prevent fluids such as limb preparation solutions, from collecting between the cuff or sleeve and the patient's skin.[29]

4 Limb occlusion pressure measurement and cuff pressure selection

Using the applied cuff, measure the patient's LOP and set the tourniquet pressure at LOP plus a safety margin: 50, 75, or 100 mm Hg, respectively, for LOP less than 130 mm Hg, LOP 131 to 190 mm Hg, or LOP between 190 and 300 mm Hg.[1,11,12,14–17,30] Limb occlusion pressure can be measured using an automated plethysmographic tourniquet system or manually using a Doppler stethoscope. To measure the LOP manually, locate an arterial pulse distal to the cuff, and then slowly increase the cuff pressure until the arterial pulse stops and remains stopped for several heartbeats.[29] Note the cuff pressure at this point, which is LOP, then deflate the cuff and confirm that the distal pulse resumes. During LOP measurement, the limb should remain horizontal and motionless. Limb occlusion pressure measurement should be made before or after induction of anesthesia once blood pressure has stabilized to the level expected during surgery.[29]

5 Exsanguination

Exsanguinate by elastic bandage or elevation, as appropriate for the patient and the procedure.[29]

6 Cuff inflation

Inflate the tourniquet cuff and monitor the tourniquet during use, as recommended by the manufacturer.[29]

7 Breakthrough bleeding

In the event that arterial blood flow is observed past the tourniquet cuff, increase the cuff pressure in 25 mm Hg increments until the blood flow stops.[11]

8 Tourniquet time

Minimize tourniquet time.[29]

9 Cuff deflation

Immediately on deflation of the tourniquet, remove the cuff and sleeve from the limb.[29]

measured shortly after the induction of anesthesia when blood pressure may fluctuate. In addition, it is recognized that excessive intraoperative fluctuation in blood pressure may result in breakthrough bleeding past the tourniquet cuff, regardless of how tourniquet cuff pressure is set. The recommended technique for pneumatic tourniquet use in pediatric limb surgery is summarized in Table 2.

A limitation of this study relates to the subjective rating of the quality of the bloodless surgical field. In an effort to increase accuracy and consistency, a surgeon, blinded to cuff type and pressure, performed all of the surgical procedures and ranked the quality of the visual field. Previous studies ranked the surgical fields in discrete groups, such as poor, fair, good, or excellent[11] or simply as adequate or inadequate.[1] A VAS was used in the current study in an effort to better detect more subtle or transient differences in arterial seepage. Visual analog scales are frequently used to measure subjective clinical phenomena such as pain; however, it has not previously been validated to assess the quality of bloodless surgical fields. In an effort to better control variability in the quality of visual field between different surgical procedures, only ACL reconstruction surgeries were included. Unfortunately, this skewed the study population to children older than 10 years because it is rare for younger children to rupture their ACLs (Table 3). A small sample size is an additional limitation of our study. Large pressure differences between the 2 groups at the time of the planned interim analysis resulted in $P < 0.001$ (using the Haybittle-Peto method) and satisfied the stopping criteria before the completion of full subject recruitment as planned in sample size calculations. We did not consider it ethically acceptable to continue the study because of the large pressure differences between groups.

The use of a tourniquet instrument capable of automatic LOP measurement and the use of wide contour cuffs can significantly reduce mean tourniquet cuff pressures in pediatric patients compared with the typical practice of 300 or 250 mm Hg. The plethysmographic technique of LOP measurement was effective and easily used on all but 1 patient recruited for the study, requiring significantly less time and user involvement compared with previously reported methods. In addition, the data suggest that wide contour cuffs result in additional decreases in tourniquet cuff pressures relative to the use of standard cylindrical cuffs in pediatric patients, as has previously been shown in adults. Finally, setting tourniquet cuff pressures to a level equal to LOP plus a predetermined margin of safety was shown to maintain a similar quality of bloodless surgical field; however, this study was not adequately powered to conclude noninferiority. Further studies are needed to confirm these results.

TABLE 3. Subject Ages

	Age, y
Control group (n = 11)	10, 11, 14, 14, 14, 15, 15, 15, 16, 16, 16
LOP group (n = 10)	13, 13, 15, 15, 15, 15, 16, 16, 16, 17

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