

American Academy of Orthopaedic Surgeons



Survey on Pediatric Device Development ♦ Final Report

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Executive Summary

- The Survey on Pediatric Device Development was distributed on February 3, 2005 to 524 POSNA members, 318 SRS members, and 185 individuals holding dual membership in POSNA and SRS. Responses were collected through February 25, 2005. A total of 321 responses were received for an overall response rate of 31%.
- A large proportion of respondents are full time academicians (55%) in practice for an average of 19 years. Differences in demographics were found between membership groups.
- One out of three respondents has used adult-sized devices on children in the past 36 months, reporting a median of 10% of patients receiving them. The most common problems they have encountered with using these devices are bulkiness/prominence and poor fit.
- One out of four respondents ordered custom devices for their patients in the past 36 months. Of this group, a median of 5% of the total pediatric devices they used were custom ordered. Few problems were cited, the most common being the high costs and time required to obtain customized devices.
- One out of three respondents has used devices 'off-label' in the past 36 months. Of the reported 'off-label' device users, the median percentage of devices used 'off-label' was 10%.
- On average, respondents indicated device manufacturers are 'somewhat' meeting the needs of their pediatric patients.
- According to respondents, children in age group 2 to 12 years were ranked as having the greatest need for pediatric-sized devices. Infants (aged 1 month to 2 years of age) were ranked second.
- Nearly half of respondents specified that seven devices (out of twelve listed on the survey) need development for pediatric patients. Variations are evident across membership groups.
- Just over one-third of respondents reported participating in pediatric device development at some time and have provided contact information. Dual members (POSNA and SRS) are more likely to have participated than exclusive SRS or exclusive POSNA members.
- Of those participating in pediatric device development, most have participated as device modification designers (53%) or device trial participants (43%).
- A total of 97 respondents (30%) indicated they would provide additional information on their experiences with pediatric device development if contacted.

Section 1: Background

In order to assess the economic, legislative, and regulatory barriers to pediatric device development, a task force was formed with representation from the NIH, FDA, industry, and pediatric specialists. To aid the task force in understanding these issues, the task force, in conjunction with the AAOS Department of Research and Scientific Affairs, contacted the US members of the Pediatric Orthopaedic Society of North America (POSNA) and Scoliosis Research Society (SRS). The Survey on Pediatric Device Development was distributed on February 3, 2005 to 524 POSNA members, 318 SRS members, and 185 individuals belonging to both POSNA and SRS. Four mailed copies were returned non deliverable. Responses were collected through February 25, 2005. A total of 321 responses were received for an overall response rate of 31%. At the time of distribution, individuals that were members in both societies were not flagged, and did receive duplicate copies of the survey (which may account for the increased response rate for this subgroup). However, few duplicate responses were received and were removed prior to analysis. Overall, members of SRS (and not of POSNA) were least likely to complete the survey.

Members of:	Total Distributed	Non-deliverable	Responded	Response rate
POSNA only	524	3	166	32%
SRS only	318	1	56	18%
Both POSNA and SRS	185		99	54%
Total	1027	4	321	31%

Data were collected, cleaned, and analyzed by the Survey & Information Analysis Team of the AAOS Research & Scientific Affairs Department. Where possible, data were examined to assess differences in survey responses across membership groups.

Demographics of Respondents

Several practice demographics were collected with survey data. Respondents were asked to provide their practice setting, their work status, and number of years in practice.

More than half (55%) of survey respondents report practicing in an Academic setting; 28% practice in a private setting. Nine percent indicate another type of practice setting and 8% did not respond to this demographic question. A considerably larger proportion of respondents who are dual members of SRS and POSNA reported practicing in an academic setting than exclusive SRS or exclusive POSNA members.

Crosstab

		member			Total	
		exclusive SRS member	exclusive POSNA member	member of both POSNA and SRS		
pracset	Private	Count	20	50	19	89
		% within member	37.0%	33.3%	20.9%	30.2%
	Academic	Count	32	80	65	177
		% within member	59.3%	53.3%	71.4%	60.0%
	Other	Count	2	20	7	29
		% within member	3.7%	13.3%	7.7%	9.8%
Total		Count	54	150	91	295
		% within member	100.0%	100.0%	100.0%	100.0%

Overall, three out of four respondents (78%) reported working full time. Only 3% indicated a part-time status, and 4% are retired. Fifteen percent did not provide this information. Insufficient cell data were available to analyze for group differences by work status.

On average, respondents have been in practice for 19 years, responses ranging from 1 year to more than 50 years in practice. On average, SRS members have been in practice fewer years than POSNA members and those in both societies.

Membership	Mean years in practice
Exclusive SRS	15.1
Exclusive POSNA	20.1
Both SRS and POSNA	19.0

POSNA and SRS population demographic data were not available to the AAOS Department of Research therefore comparisons between respondent and population demographics were not conducted.

Section 2: Responses

Alternatives to Pediatric-Sized Devices

Adult- sized devices for pediatric patients

More than one out of three respondents (38%) has used adult-sized devices on children in the past 36 months. These respondents reported a median of 10% of their pediatric patients received adult-sized devices. (A small number of respondents reported very high percentages of usage, skewing the mean positively. Therefore, median percentages are used to describe the central tendency of reported percentages).

Although no differences are evident between society membership groups in their report of adult-sized device usage, the percentage of patients who received adult-sized devices varied dramatically. As a group, SRS members reported much higher usage of adult-sized devices than POSNA members and those in both societies.

Membership	Mean % of patients receiving adult-sized devices in the past 36 months	Median % of patients receiving adult-sized devices in the past 36 months
Exclusive SRS	31.1	17.5
Exclusive POSNA	9.9	5.0
Both SRS and POSNA	19.5	10.0
All respondents	17.0	10.0

Respondents who used adult-sized devices in the past 36 months were then asked to indicate problems encountered. Approximately one in four respondents indicate problems such as the device being overly-bulky (27%) or having a poor fit (25%). Sixteen percent indicate the device does not accommodate pediatric patients with growth plates, and a very small percentage (3%) indicated other problems not listed. Only 6 individuals reported no problems.

Types of problems encountered: adult-sized device use

		Missing			Total
		No	Yes	data	
Device overly bulky and prominent	N	33	85	203	321
	%	10.3	26.5	63.2	100
Poor fit	N	38	80	203	321
	%	11.8	24.9	63.2	100
Design does not accommodate pediatric pts with growth plates	N	68	50	203	321
	%	21.2	15.6	63.2	100
Other problem	N	110	8	203	321
	%	34.3	2.5	63.2	100
None	N	112	6	203	321
	%	34.9	1.9	63.2	100

“Other” problems:

- TYPICALLY ONLY USE ADULT SIZE PRODUCTS ON ADULT SIZE PTS.
- SKIN BREAKDOWN
- RETIRED FROM PRACTICE
- 'PEDIATRIC' SIZE SPINE DEVICES NOT APPROVED FOR CHILDREN!
- NOT SMALL ENOUGH FOR THE ANATOMY
- NEED TO MODIFY DEVICE TO MAKE IT FIT
- LIABILITY - FDA HAS NOT APPROVED DEVICES FOR SKELETALLY IMMATURE
- LARGER HOLES TO BONE FOR HIP SCREWS
- IMPLANT (ESP. IM NAILS) HAVING TO BE CUT SHORTER
- HAVE NOT USED ADULT SIZES.
- CURRENTLY NOT DOING SURGERY
- CAN'T USE. ALL ADULT DEVICES ARE TOTAL HIPS AND TOTAL KNEES. ALL AAOS IS ON ADULT AT ANNUAL MEETING.
- CAN BE DANGEROUS FOR NECK COLLARS

Fewer than 5% of the 121 respondents who have used adult-sized devices in the past 36 months encountered problems with reimbursement.

Custom devices for pediatric patients

Just about one out of four respondents (23%) ordered custom devices for their pediatric patients within the past 36 months. Of the customized device users, it was reported that a median of 5% of the total pediatric devices they used were custom ordered (mean of 15%). No differences were found between membership groups.

Users of custom devices were asked if any problems were encountered with the devices. Sixteen percent (16%) of respondents indicated the time it takes to obtain custom devices was problematic; 13% cited the high cost a problem. Few respondents indicated reimbursement issues, or cited other problems not listed.

Types of problems encountered: Customized devices

		Missing			Total
		No	Yes	data	
Overall cost very high	N	28	43	250	321
	%	8.7	13.4	77.9	100
Time required to obtain	N	20	51	250	321
	%	6.2	15.9	77.9	100
Reimbursement issues	N	52	19	250	321
	%	16.2	5.9	77.9	100
Poor quality/instrumentation	N	63	8	250	321
	%	19.6	2.5	77.9	100
Other	N	66	5	250	321
	%	20.6	1.6	77.9	100
None	N	63	8	250	321
	%	19.6	2.5	77.9	100

Other problems with customized devices:

- ACL BRACE NOT AVAILABLE FOR PEDS
- DON'T KNOW ABOUT REIMBURSEMENT ISSUES
- NEED T CUSTOMIZE 'INTRAOPERATIVELY' WITH METAL CUTTING TOOLS.
- OFTEN WITHOUT APPROPRIATE SIZED INSTRUMENTATION
- WRONG IMPLANT SENT ON OCCASION

'Off-label' use of devices

Respondents were asked about "off-label" use of pediatric devices. One out of three respondents (33%) reported using a device "off-label" in the past 36 months. The median percentage of pediatric devices used in the past 36 months "off-label" was 10% (mean of 21%). POSNA members reported a considerably lower percentage of "off-label" usage in the past 36 months than SRS members or dual-members.

Membership	Mean % of pediatric devices considered 'off-label' use in the past 36 months	Median % of pediatric devices considered 'off-label' use in the past 36 months
Exclusive SRS	28.3	10.0
Exclusive POSNA	13.6	5.0
Both SRS and POSNA	26.9	10.0
All respondents	21.3	10.0

Meeting the Needs of Pediatric Patients

Survey recipients were asked to what extent device manufacturers are currently meeting the needs of their pediatric patients. On average, respondents rated device manufacturers as 'Somewhat' meeting their needs (3.5 on a scale of 1 ('Not at all') to 5 ('Completely')). Two out of five respondents indicated that device manufacturers are 'somewhat' meeting their needs, and another two out of five indicated their needs were currently being met (a rating of '4' or '5'). Less than 10% said their needs were not being met ('1' or '2' rating). This rating did not vary by membership groups.

Respondents were asked to rank four age groups of children (newborn, infant, child, and adolescent) in the order of the need for pediatric-sized devices. The percentages of respondents ranking each pediatric age category are shown in the chart below. Respondents rated the child group (ages 2 to 12) as having the greatest need for pediatric-sized devices (61% rated this group as '1'). Nearly one-third of respondents (31%) ranked infants as second in need. Rankings did not vary by society membership.

	Ranked 1st	Ranked 2nd	Ranked 3rd	Ranked 4th	Picked, but did not rank	missing (did not rank)	Total
Newborn (n=216)	5.3%	5.6%	19.6%	34.9%	1.9%	32.7%	100%
Infant (n=233)	17.8%	31.2%	21.2%	0.3%	2.2%	27.4%	100%
Child (n=285)	61.4%	15.6%	9.7%	0.6%	1.6%	11.2%	100%
Adolescent (n=219)	5.9%	16.8%	15.3%	29.6%	0.6%	31.8%	100%

Respondents were asked to identify devices needing development for pediatric orthopaedic patients. Twelve items were listed on the survey form, and write-in space was provided for devices not listed. Seven items were marked as needing development by at least 47% of respondents. Devices are listed below in order of percentage endorsed. Differences were found in the need for device development across society member groups.

Question 6: In your opinion, what types of devices need to be developed to meet the needs of pediatric orthopaedic patients?

	Total respondents					SRS only					POSNA only					Both SRS and POSNA								
	%	No	%	Yes	n	Total	%	No	%	Yes	n	Total	%	No	%	Yes	n	Total	%	No	%	Yes	n	Total
Implantable self-expanding devices for longitudinal limb lengthening**	42.1		57.9		318	100%	73.2		26.8		56	100%	37.8		62.2		164	100%	31.6		68.4		98	100%
Strong, non-reactive bioabsorbable screws*	44.7		55.3		318	100%	60.7		39.3		56	100%	44.5		55.5		164	100%	35.7		64.3		98	100%
Self-expanding spinal deformity control devices for the growing child**	46.2		53.8		318	100%	46.4		53.6		56	100%	55.5		44.5		164	100%	30.6		69.4		98	100%
Innovative spinal deformity devices**	49.4		50.6		318	100%	37.5		62.5		56	100%	62.2		37.8		164	100%	34.7		65.3		98	100%
Strong, non-reactive bioabsorbable plates	50.3		49.7		318	100%	57.1		42.9		56	100%	53		47.0		164	100%	41.8		58.2		98	100%
Minimally invasive growth modulation instrumentation for spine deformity**	52.2		47.8		318	100%	37.5		62.5		56	100%	65.2		34.8		164	100%	38.8		61.2		98	100%
Bioabsorbable IM rod fixation for trauma*	53.5		46.5		318	100%	67.9		32.1		56	100%	53		47.0		164	100%	45.9		54.1		98	100%
Implantable devices for self-expansion angular deformity correction*	62.6		37.4		318	100%	76.8		23.2		56	100%	57.3		42.7		164	100%	63.3		36.7		98	100%
Implantable, long-term mechanical physis*	76.7		23.3		318	100%	89.3		10.7		56	100%	74.4		25.6		164	100%	73.5		26.5		98	100%
Novel drug delivery systems	81.8		18.2		318	100%	87.5		12.5		56	100%	79.9		20.1		164	100%	81.6		18.4		98	100%
Total joint replacement for children**	85.5		14.5		318	100%	98.2		1.8		56	100%	84.8		15.2		164	100%	79.6		20.4		98	100%
Growing rod instrumentation for the cervical spine	88.7		11.3		318	100%	83.9		16.1		56	100%	90.2		9.8		164	100%	88.8		11.2		98	100%
Other	93.1		6.9		318	100%	98.2		1.8		56	100%	91.4		8.6		164	100%	92.9		7.1		98	100%

*significant group differences (p<.05)

**significant group differences (p<.01)

Space was provided to submit other devices needing development.

- ALL OF THE LISTED IMPLANTS WOULD HAVE SOME POTENTIAL BENEFIT
- ANATOMICAL PLATES THAT CONFORM BUT AVOID THE PHYSIS
- BASICALLY ALL, BUT THE ONES I MARKED ARE THE ONES I'M MOST IN NEED OF IN MY PRACTICE.
- BETTER ARTHROSCOPY INSTRUMENTATION FOR THE 6-12 YEAR OLDS
- BETTER FITTING INTRAMEDULLARY IMPLANTS (RODS) FOR DEFORMITY CORRECTIONS ESPECIALLY HUMERUS, FEMUR, TIBIA.
- BETTER HIP OSTEOTOMY FIXATION PLATE, BETTER LONG BONE HOLDING/REDUCTION CLAMPS
- BETTER PEDIATRIC SIZE ANGLED BLADE PLATES
- BLADE PLATES DESIGNED TO ACCOMMODATE PHYSIS? BETTER, EXPANDABLE RODS FOR OI
- CAN'T THINK OF ANY
- DYNAMIC HIP COMPR.. SCREW AND SIDE P... FOR HIP FRACTURES
- EXTERNAL FIXATOR FOR ANGULAR DEFORMITY CORRECTION OF HIP
- FIXED HIGHER ANGLE BLADE PLATES , BLOUNT STAPLES W/SHORT TINES
- GET APPROVAL FOR EXISTING PEDIATRIC DESIGN
- GROWTH MODULATION? DEVICES FOR SCOLIOSIS (INCLUDING RA.... FUSIONLESS DEVICES)THE FDA NEEDS TO BE MUCH FRIENDLIER TO THESE TYPES OF DEVICES AND DEVELOPMENT
- HIP SCREWS/PLATE MORE ADAPTABLE FOR VARYING SIZE
- I DO NOT USE ANY OF
- INTRAMEDULLARY RODS CAPABLE OF INTERLOGIC
- NON FUSED INSTRUMENTATION FOR ADOLESCENT SCOLIOSIS
- NONFUSION SPINE DEFORMITY CORRECTION DEVICES
- NOTE - SPINAL DEFORMITY DEVICES, NOT SO MUCH INNOVATIVE, RATHER SMALLER, LESS BULKY DEVICES.
- PEDIATRIC ANTEGRADE IM FEMUR NAIL.
- PEDIATRIC TRAUMA DEVICES - RODS, ETC.
- PROPERLY INSTRUMENTED BLADE PLATE SYSTEM FOR PROX. FEMUR INSTRUMENTATION
- SLIDING SCREWS FOR SCRE?
- SLING AND SWATHES/FRACTURE-WALKERS
- SMALL PEDICLE SCREWS FOR THORACIC SPINE IN CHILDREN
- THE NEEDS ARE MUCH MORE BASIC THAT THESE LISTED. NEED A LOCKED IM NAIL GREATER ENTRY FOR SUBT..., FEMUR FKS IN ADOLESCENTS (NOT WIDELY AVAILABLE, AND T... SYSTEM IS VERY STIFF, AN ADULT ... MODIFIED FOR CHILDREN)
- TRAUMA SYSTEM, PLATES SCREWS ETC SPECIFICALLY FOR CHILDREN.

Pediatric Device Development

Overall, 38% of respondents have participated in pediatric device development at some time. Dual-members, however, are much more likely to have participated in pediatric device development than other respondents. Half of dual-member respondents (55.3%) have participated in pediatric device development, whereas 32% of POSNA and 37% of SRS members have.

Of those that have participated in pediatric device development (n=123), SRS members are most likely to have participated as an inventor or co-inventor in pediatric device development. Dual-society members have the highest percentage of serving as device modification designer and device trial participation (64% and 52%, respectively).

Question 7a: How have you participated [in pediatric device development]?

	Total respondents				SRS only				POSNA only				Both SRS and POSNA			
	% No	% Yes	n	Total	% No	% Yes	n	Total	% No	% Yes	n	Total	% No	% Yes	n	Total
Device modification designer	46.7%	53.3%	122	100%	60.0%	40.0%	20	100%	52.0%	48.0%	50	100%	36.5%	63.5%	52	100%
Device trial participant	56.6%	43.4%	122	100%	65.0%	35.0%	20	100%	62.0%	38.0%	50	100%	48.1%	51.9%	52	100%
Inventor*	72.1%	27.9%	122	100%	40.0%	60.0%	20	100%	76.0%	24.0%	50	100%	80.8%	19.2%	52	100%
Co-inventor	75.4%	24.6%	122	100%	50.0%	50.0%	20	100%	90.0%	10.0%	50	100%	71.2%	28.8%	52	100%
Other	90.2%	9.8%	122	100%	90.0%	10.0%	20	100%	90.0%	10.0%	50	100%	90.4%	9.6%	52	100%

*significant group differences (p<.05)

Respondents were given the option of submitting other ways they had participated in pediatric device development. Several have served as consultants and advisors in the device development process.

- ADVISOR (2)
- CONSULTANT (4)
- DISCUSSED PROBLEMS WITH DESIGNERS
- EVALUATE PROTOTYPE DEVICE & INSTRUMENTS AND SUGGEST MODIFICATIONS PRIOR TO PRODUCTION.
- FAILED MISERABLY BECAUSE OF MINIMAL INTEREST FROM MANUFACTURERS BECAUSE OF LOW \$ POTENTIAL
- GAVE FEEDBACK
- GROWTH MODULATION? DEVICES FOR SCOLIOSIS (INCLUDING RA.... FUSIONLESS DEVICES)
- HIP DYSPLASIA
- I'VE TRIED, BUT COMPANIES NOT INTERESTED IN MY IDEAS.

Current contact information was solicited from device development participants. A total of 97 respondents (30%) indicated they would provide additional information on their experiences with pediatric device development if contacted.

Appendix A: Survey



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AAOS

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SURVEY ON PEDIATRIC DEVICE DEVELOPMENT

TO:

FAX:

The U.S. Congress is interested in economic, legislative, and regulatory barriers to pediatric device development. Subsequently, a task force has been formed with representation from the NIH, FDA, industry, and pediatric specialists. To aid the task force in understanding these issues, the POSNA, SRS, and AAOS are seeking input from its members. Please assist us by completing this survey and returning it to AAOS via fax at (847) 574-7550 by February 25, 2005.

1. In the past 36 months, have you used adult-sized devices on children because the pediatric-sized device was not available? Yes No (skip to question 2)

a. What % of your pediatric patients received adult-sized devices in the past 36 months? %
(if none, enter '0')

b. What types of problems have your patients encountered as a result of the adult-sized device?

- Poor fit
- Adult design does not accommodate pediatric patients with growth plates
- Device overly bulky and prominent
- Other
- None

c. Have you encountered any problems with reimbursement for using adult-sized devices in children? Yes No

2. Have you ordered custom devices for your pediatric patients within the past 36 months because pediatric-sized devices were not available? Yes No (skip to question 3)

a. What % of the total pediatric devices you used in the past 36 months were customized? %
(if none, enter '0')

b. What problems did you encounter with custom devices? (mark all that apply)

- Overall cost very high
- Time required to obtain
- Reimbursement issues
- Poor quality of device/poor device instrumentation
- Other
- None

3. What % of the pediatric devices you used in the past 36 months would be considered an 'off-label' use ('off-label' = any use not defined by the manufacturer)? %
(if none, enter '0')



SURVEY ON PEDIATRIC DEVICE DEVELOPMENT

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4. To what extent are device manufacturers currently meeting the needs of your pediatric patients? Not at all Somewhat Completely

5. Based on the pediatric population subgroups listed below, please indicate which age group you feel has the greatest need for pediatric device development. Rank the groups 1 through 4, where '1' indicates the greatest need and '4' the lowest. Although you may have difficulty prioritizing, please use each ranking only once.

Newborn (from birth to 1 month of age) Infant (greater than 1 month to 2 years of age) Child (greater than 2 years to 12 years of age) Adolescent (greater than 12 years to 21 years of age)

6. In your opinion, what types of devices need to be developed to meet the needs of pediatric orthopaedic patients? (Please mark all that apply.)

Strong, non-reactive bioabsorbable plates
 Strong, non-reactive bioabsorbable screws
 Novel drug delivery systems
 Innovative spinal deformity devices
 Total joint replacement for children
 Growing rod instrumentation for the cervical spine
 Bioabsorbable IM rod fixation for trauma
 Implantable, long-term mechanical physis
 Minimally invasive growth modulation instrumentation for spine deformity
 Self-expanding spinal deformity control devices for the growing child
 Implantable self-expanding devices for longitudinal limb lengthening
 Implantable devices for self-expansion angular deformity correction
 Other(s)

7. Have you ever participated in pediatric device development? Yes No

a. How have you participated? (Select all that apply)

Inventor Device modification designer
 Co-inventor Other
 Device trial participant

AAOS may wish to contact you personally to discuss your experiences with pediatric device development. If you grant us permission to do so, please provide us with current contact information. PLEASE PRINT.

Name:

Phone: - -

Email:

Please provide the following information about your practice:

Practice setting: Private Practice Academic Practice Other

Work Status: Full time Part time Retired Years in practice:

THANK YOU FOR YOUR PARTICIPATION.
 Please return both pages via fax (no cover sheet) to (847) 574-7550 by February 25, 2005 .

