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석 사 학 위 논 문

Comparison of the equivalence between
OPENCAST® and conventional polyester cast
in pediatric upper extremity fractures
— Prospective randomized control study —

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나 상 수
2020년
6월

나상수의 석사학위 논문을 인준함

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감사문

제가 계명대학교 동산의료원 정형외과에 입국하여 4 년 간의 수련 생활을 무사히 마치고 전문의로서의 새 발을 내딛게 많은 가르침을 주시고 격려하며 스승으로서의 은혜를 베풀어 주신 송광순 교수님, 이시욱 교수님께 진심 어린 감사를 드립니다. 국내에 몇 안되는 소아 정형외과 분야의 선구자이시며 권위자이신 송광순, 이시욱 교수님께 배우며 그 결과인 논문을 작성 할 수 있어 큰 영광으로 생각합니다.

2020년 6월

나 상 수

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1. Introduction

Adolescent upper extremity fractures, such as distal radius and humerus fractures, commonly occur in children. The characteristics of fractures are different between children and adults, with the former often requiring conservative treatment using casts. Although the plastic cast is used worldwide for about 170 yr, complications are still present, including cast-saw injuries, pressure sores, rashes, compartment syndrome, skin necrosis, and nerve injuries (1).

There is a reported 0.72% prevalence of burns or abrasions during cast removal, and conventional plastic casts can produce itchy skin lesions because of a lack of water exposure or ventilation holes, resulting in unpleasant odors (2). OPENCAST® easily adapts the shape of the body part it is applied to because its thermoplastic resin allows sweat to evaporate through its large ventilation holes quickly; this type of cast is free of problems like odor, itchiness, and ulcer-induced infection. However, there are no comparative studies on the clinical efficacy and usefulness of these types of casts.

The purpose of this study is to compare the equivalence and effectiveness between the newly developed heat-deformed mesh-type casts, OPENCAST®, and a conventional polyester cast, NEALCAST®. Comparisons between the two confirmed the advantages and disadvantages of OPENCAST® and evaluated the possibility of complementing the shortcomings of existing polyester casts.

2. Materials and Methods

2.1 Patients selection:

A prospective, randomized controlled study was conducted from July 5, 2017, to April 22, 2018, on pediatric patients (aged 3 - 17 yr old) who were diagnosed with upper extremity fractures and have undergone cast fixation. Patients who failed cast application or refused treatment were excluded. A total of 86 patients were recruited for the study, and a power test identified a 10% dropout rate; nine patients dropped out because they declined to participate. Among the remaining patients, 78 were selected for the study, and informed consent was obtained from their guardians. Patients with fractures above and below the elbows were randomly assigned their groups through a random number table, with 38 in OPENCAST® and 40 in the polyester NEALCAST® control group (Figure 1). This study was approved by the ethics committee (IRB No. 2017-04-026-010).

2.2 Radiologic evaluation:

Fracture union was evaluated in two-, four-, and eight-week intervals after casting using simple radiographs. For follow-up radiographs, the humerus lateral condylar fracture was evaluated from three different views (anteroposterior, lateral, and internal oblique), the articular fracture was evaluated from four views (anteroposterior, lateral, internal oblique, and external oblique), and the radius or ulnar shaft fracture was evaluated using anteroposterior and lateral views (Figure 2).

2.3 Functional evaluation:

Three questionnaires, the American Shoulder and Elbow Surgeons (ASES) assessment form (3), the Short Form Survey - 36v2 (SF-36v2) (4), and the Pediatric Outcomes Data Collection Instrument (PODCI) (5) were used to assess the degree of function in two-, four-, and eight-week intervals after casting. The questionnaires were evaluated statistically, and a T-test was used for the upper extremity function evaluation and the quality of life questionnaire survey.

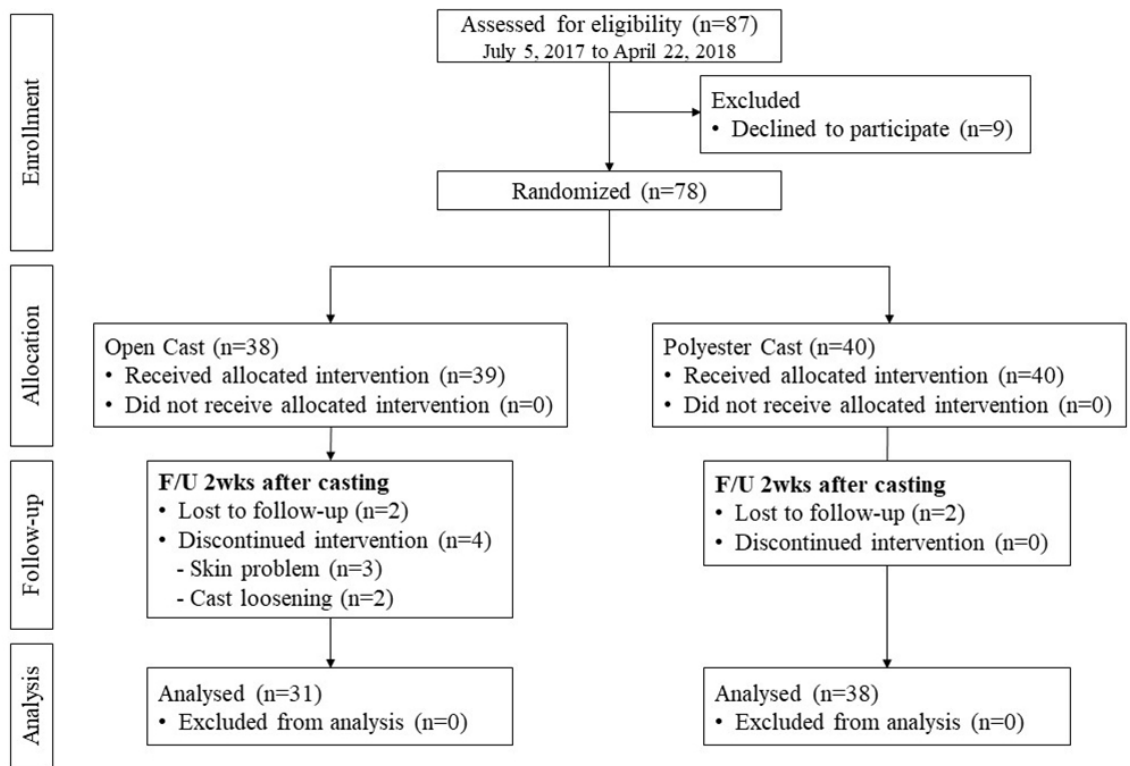


Figure 1. Flow chart of randomized control study for dividing patients into OPENCAST® and NEALCAST® groups.

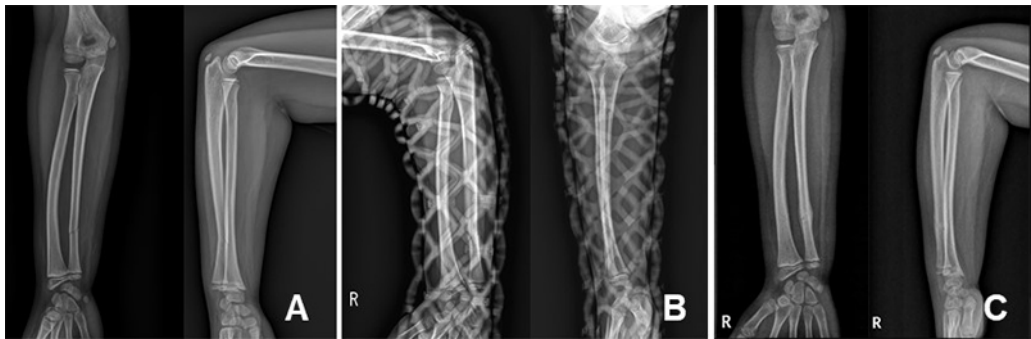


Figure 2. Initial X-ray for distal ulnar shaft fracture (a). Closed reduction with OPENCAST® (b). Last follow-up after eight weeks (c).

3. Results

Of the 78 patients, 38 were in OPENCAST® group and 40 were in the NEALCAST® group. Seven patients dropped out of the first group (two from follow-up loss, three from skin problems, two from mismatched cast sizes); two patients dropped out of the second group due to follow-up loss. Finally, a total of 69 patients were analyzed (31 were in OPENCAST® group and 38 were in the NEALCAST® group.). The subjects' mean age was 7 yr and 2 mo, their mean weight was 27.7 kg, and their average height was 124 cm (Table 1). For fracture locations, there were 38 cases on the right side and 31 cases on the left side; 35 were above the elbow and 34 were below the elbow. Among the fractures located above the elbow, there were 21 supracondylar fractures, 11 lateral condylar fractures, and 3 medial condylar fractures. Below the elbow, there were 16 distal radius fractures, 7 Monteggia fractures, 3 distal radioulnar fractures, 3 distal ulnar fractures, 2 forearm bone fractures, 2 radial neck fractures, 1 olecranon fracture, and 1 radial shaft fracture (Figure 3). Post-surgical casting occurred for 28 cases, and 41 cases received casting without surgery.

The bone union rate was the same in both OPENCAST® and NEALCAST® groups, and all cases showed proper callus formation in the follow-up radiographs. However, one NEALCAST® group patient showed a small internal gap during follow-up in the eighth week. This gap was considered a progress bone union because the patient did not experience pain and showed functional score improvements and a diminishing radiologic gap. As for the upper extremity function test with the ASES questionnaire, there was no statistically significant difference

between the two groups during the second week ($p=0.068$), fourth week ($p=0.376$), and eighth week ($p=0.401$) of casting (Table 2). The SF-36v2 subgroups showed significant differences in Role-Physical (RP; $p<0.05$), Bodily Pain (BP; $p<0.05$), Social Functioning (SF; $p<0.05$), and Physical Component Scores (PCS; $p<0.05$) after the second week of casting. Although there were no significant differences between the two groups in each parameter in the fourth week after casting, a significant difference in Vitality (VT; $p<0.05$) was found in the eighth week (Table 3). In the quality-of-life evaluation using the PODCI score, there was a significant difference in sports and physical function in the second week after casting ($p<0.05$) and in transfer and basic mobility scale in the eighth week after casting ($p<0.05$) (Table 4). On the happiness scale, both groups' results showed p -values less than 0.05 and average scores greater than 80 (NEALCAST® average = 92.37, OPENCAST® average = 83.23) in the fourth and eight weeks (Table 5). Both groups showed no significant difference in the happiness scale p -values between male and female patients during the fourth week (NEALCAST® $p<0.05$ / OPENCAST® $p<0.05$). However, the average value was much larger in OPENCAST® group (polyester cast average=63, OPENCAST® average=91.43) (Table 6). Four OPENCAST® patients experienced skin allergies or bullae due to the ventilation holes, but these instances improved after proper padding (Figure 4).

Table 1. Demographic Data

Variables	Sequence		Total (n=78)	p-value*
	A (n=40)	B (n=38)		
Age (months)	86	86.2	86.1	0.980
Height (cm)	123.9	124.1	124	0.965
Weight (kg)	26.6	28.7	27.6	0.464

* Student's t-test

Table 2. ASES form results

	Student's T test					
	Levene's equal dispersion test		T test for equality of means			
	F	p value	t	p value	Mean difference	Standard error difference
second week	0.329	0.568	1.855	0.068	6.164	3.323
Fourth week	2.149	0.147	0.892	0.376	3.972	4.454
Eighth week	0.172	0.680	0.845	0.401	3.109	3.680

Table 3. SF-36v2 results

Variables	Second week	Fourth week	Eighth week
	p value*		
RF	0.084	0.066	0.065
RP	0.025*	0.331	0.058
BP	0.028*	0.405	0.855
GH	0.195	0.434	0.106
VT	0.389	0.755	0.036*
SF	0.011*	0.424	0.495
RE	0.523	0.890	0.291
MH	0.589	0.972	0.604
PCS	0.006*	0.134	0.061
MCS	0.088	0.704	0.138

*p value < 0.05

Table 4. PODCI results

Variables	Second	Fourth	Eighth
	week	week	week
	p value*		
Upper Extremity Scale	0.474	0.388	0.069
Transfer & Basic Mobility Scale	0.296	0.567	0.023*
Sports and Physical Functioning	0.039*	0.306	0.410
Pain/Comfort Scale	0.154	0.307	0.304
Happiness Scale	0.092	0.884	0.313
Global functioning scale	0.415	0.215	0.108

*p value < 0.05

Table 5. Happiness scale comparing fourth- and eighth-week results of each cast group

Source		t	p value
Plastic cast	Second week / Fourth week	0.187	0.853
	Fourth week / Eighth week	-4.207	0.000*
Open cast	Second week / Fourth week	-1.650	0.109
	Fourth week / Eighth week	-2.065	0.048*

*p value < 0.05

Table 6. Happiness scale comparing males and females in each cast group

Independent sample test			
Source		t	p value
Plastic cast	Second week	-0.398	0.693
	Fourth week	2.123	0.041*
	Eighth week	0.11	0.991
Open cast	Second week	-0.498	0.622
	Fourth week	-2.169	0.038*
	Eighth week	-0.580	0.600

*p value < 0.05

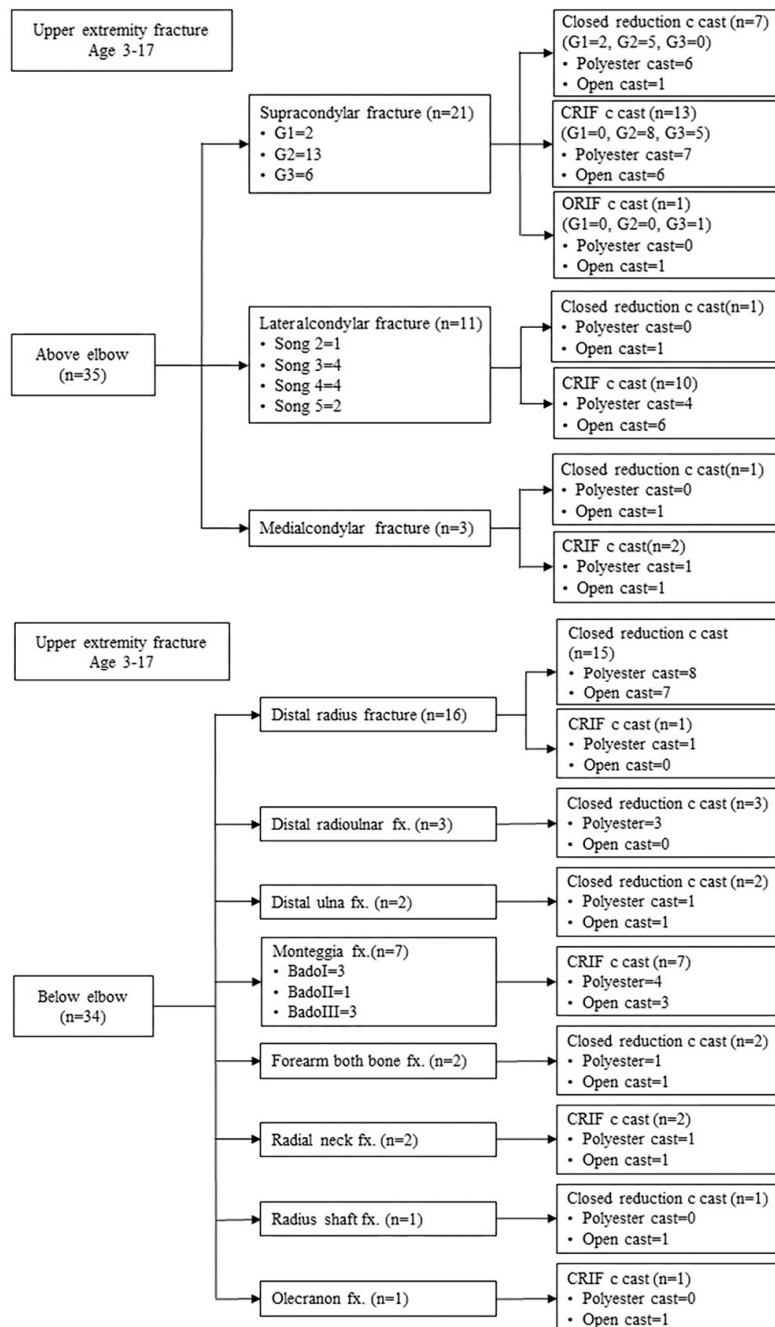


Figure 3. Type of fracture and cast performed in pediatric upper extremity fracture

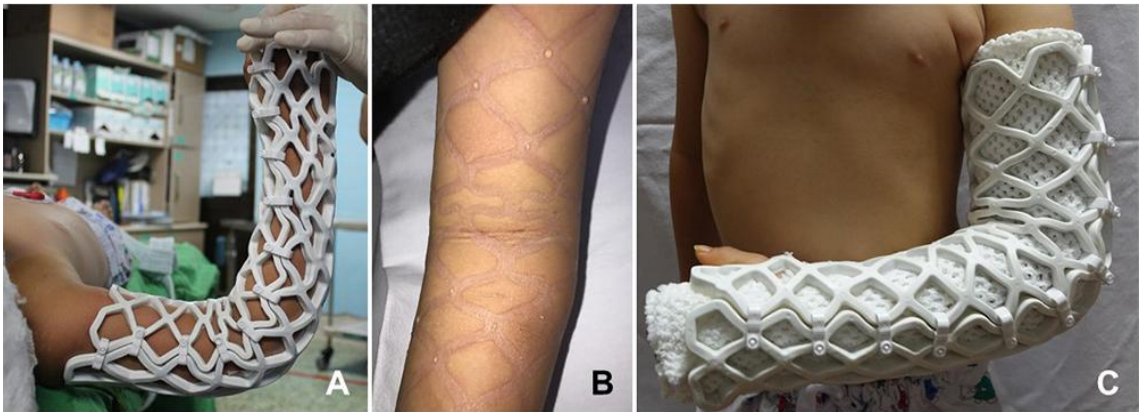


Figure 4. Bullae after OPENCAST® application (a,b) and padding added to OPENCAST® (c)

4. Discussion

Cast fixation is one of the most commonly performed procedures in orthopedic surgery and is currently used as a conservative treatment method for acute fractures, sprains, and postoperative immobilization (8,9). A gypsum or plaster cast was fragile and heavy, whereas fiberglass or polyester casts are comparably lighter. Additionally, both plaster and polyester share the disadvantage of poor air ventilation and sweat evaporation because of their closed structures (10,11).

A conventional polyester NEALCAST® cannot directly check bone alignment, rotation, and length after casting, but OPENCAST® can be easily inspected visually and immediately corrected if necessary. The thermoplastic resin's properties allow several modifications after applying heat, which makes anatomical casting along the skin outline easy. Moreover, it is possible to continuously observe the lesion site after casting. The patient can also continue wearing the cast while taking showers. Cast-saw injuries are prevalent 4.3% of the time, which can burn into a patient's skin and causes discomfort, but OPENCAST® is quickly removed by opening a clip (12), which burn to skin and induces massive social cost, but OPENCAST® simply open the clip when remove it, So it does not cause saw injury and has no social cost.

OPENCAST® showed no significant difference in bone union rate compared to conventional polyester casts ($p=1.0$), and it also demonstrated sufficient fixation strength to achieve the same union ratio as existing casts. Thus, OPENCAST® can be a viable alternative option for bone union, the original purpose of performing the cast. Secondary efficacy was assessed by the ASES, SF-36v2, and PODCI scores, and

there was no significant difference in ASES score during the second-, fourth-, and eighth-week intervals in the upper extremity functional index.

For SF-36, the RP, BP, SF, PCS indices of the second week were statistically significant, while the average value was higher than OPENCAST®. These results came about because the hexagonal structure of OPENCAST® caused psychological anxiety, and the adaptation period of the initial patient was rather long.

For PODCI, sports and physical function in the second week after casting ($p < 0.05$) and in transfer and basic mobility scale in the eighth week after casting ($p < 0.05$) were statistically significant, while the average value was higher in the polyester cast. Patients may experience anxiety while taking part in sports or other physical activities during the first two weeks after applying OPENCAST® due to its open structure. The thumb hole of the cast may also cause limitations in thumb movement during the eighth week, but this could be solved with molding after factoring in the thumb's full range of motion.

The happiness scales for males and females were statistically significant in the fourth week after casting in both the NEALCAST® and OPENCAST® groups (polyester cast $p < 0.05$, OPENCAST® $p < 0.05$). The average score was higher in the conventional polyester cast group's male patients (male: 80.61, female: 63.00), while in OPENCAST® groups, females showed higher scores (male: 67.25, females: 91.43). These results show greater visual satisfaction and stability for males and cosmetic and functional satisfaction for females. Based on the results, there is no difference according to the type of cast in upper limb functions. There was no statistically significant difference from the existing polyester cast, which shows the possibility that OPENCAST® could replace the current cast.

OPENCAST® can be clinically useful because of its excellent ventilation and convenience in addition to performing similarly with conventional polyester casts. Further studies can plan and implement research that reflects this point. Unlike conventional casts that have padding between the cast and the skin, OPENCAST® has direct contact with the skin and has the advantage of allowing doctors to directly check for skin lesions early and addressing them through the ventilation holes compared to conventional casts.

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Comparison of the Equivalence between OPENCAST[®] and Conventional Polyester Cast in Pediatric Upper Extremity Fractures

- Prospective Randomized Control Study -

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(Abstract)

Adolescent upper extremity fractures commonly occur in children, often requiring conservative treatment using casts. During cast removal, cast burns or abrasions can occur and conventional plastic casts can produce itchy skin lesions because of a lack of water exposure or ventilation holes, resulting in unpleasant odors. OPENCAST[®] easily adapts the shape of the body part it is applied to because its thermoplastic resin allows sweat to evaporate through its large ventilation holes quickly. The purpose of this study is to compare the equivalence and effectiveness between the newly developed heat-deformed mesh-type casts, OPENCAST[®], and a conventional polyester cast. A prospective, randomized controlled

study was conducted from July 5, 2017, to April 22, 2018, on pediatric patients (aged 3–17 yr old) who were diagnosed with upper extremity fractures and have undergone cast fixation. A total of 86 patients were recruited for the study, nine patients dropped out because they declined to participate. 78 were selected for the study. Among them, nine patients dropped out of the group(Four from follow-up loss, three from skin problems, two from mismatched cast sizes). Finally, a total of 69 patients were analyzed (31 were in OPENCAST® group and 38 were in the NEALCAST® group). Radiographic evaluation and clinical scores including ASES, SF-36v2, and PODCI were measured up second, fourth, eighth week intervals. Equivalence validation was evaluated using bone healing of fracture site and comparing the clinical scores. There was no significant difference in bone healing rate according to the type of cast was found for both groups. Similarly, no significant difference between clinical scores. OPENCAST® can be used as alternative option for the treatment of pediatric upper extremity fractures.

소아 상지 골절에서 OPENCAST®와 기존 폴리에스테르 캐스트와 의 동등성 비교

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(초록)

소아 상지 골절은 어린이에게서 흔히 발생하며, 보존적 치료나 수술 후에 캐스트를 사용한 고정이 필요한 경우가 잦다. 기존의 캐스트는 제거 중에 환자에게 화상이나 열상이 발생할 수 있으며 물에 젖을 시 환기 구멍이 부족하여 가려운 피부 병변을 유발하며 불쾌한 냄새를 유발할 수 있다. OPENCAST®는 열가소성 수지 소재로 인해 인체의 개개인의 구조에 쉽고 알맞게 적용될 수 있고 큰 통풍구를 통해 수분을 빠르게 증발시킬 수 있다. 또한 제거 시 캐스트 톱을 이용하지 않아 화상이나 열상이 발생할 일이 없다. 이 연구의 목적은 새로 개발 된 열 변형 메쉬 유형 캐스트 (OPENCAST®)와 기존 폴리에스테르 캐스트 (NEALCAST®)의 동등성과 효과를 비교하는 것이다. 2017 년 7 월 5 일부터 2018 년 4 월 22 일까지 상지 골절로 진단을 받고 캐스트 고정을 받은 소아 환자 (3 세에서 17

세 사이)에 대한 전향적 무작위 대조 연구가 수행되었다. 총 86 명의 환자가 선택되었고, 9 명의 환자는 참여를 거부하여 탈락했다. 78명의 환자 중 9명(4명은 연락 두절, 3명은 피부 병변 이상, 2명은 캐스트 사이즈의 헐거워짐)이 탈락하여 69명의 환자가 분석되었다(OPENCAST® 31명, 폴리에스테르캐스트 38명). 캐스트 이주 차, 사주 차, 팔주 차에 각각 방사선학적 검사와 ASES, SF-36vs, PODCI를 통한 임상점수로 각 캐스트군의 동등성을 평가하였다. 두 개의 그룹에서 골 유합 정도와 임상 점수 결과에서 유의한 차이는 보이지 않았다. 따라서 소아 상지 골절 환자에서 기존의 폴리에스테르 캐스트를 대체하여 OPENCAST®가 대안이 될 수 있다.