The Long Term Follow Up of Helmet Therapy Following Endoscopic Suturectomy For Infants with Sagittal Craniosynostosis

Sagital Kraniosinostoz Tanılı Bebeklerde Endoskopik Süturektomi Sonrası Kask Tedavisinin Uzun Süreli Takibi

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ABSTRACT

Objective: Infants with sagittal craniosynostosis are treated with endoscopic suturectomy and remodeling helmets. The long term effects and the effects that occur after the completion of remodeling helmet treatment have not been investigated. The purpose of this study is to investigate the long term effects of remodeling helmet and effects that occur after the completion of remodeling helmet treatment.

Material and Methods: 14 infants were included in the study. The children were assessed post-op, after the completion of remodeling helmet and at 6 months' follow-up using a 3D laser acquisition system. The anterior-posterior(AP), medio-lateral(ML) cranial measurements, cranial circumference(CC), diagonal measurements, cephalic ratio(CR) and cranial vault asymmetry index(CVAI) were assessed.

Results: The infants used the remodeling helmet for 35±3.4 weeks. When the post-op and completion results are examined, it can be seen that during remodeling helmet usage duration, AP, ML, CC measurements, the CR and CVAI have statistically improved, resulting in normalization of cranial shape ($p<0.05$). When the follow up results are examined, it can be seen that there was no deterioration in the symmetry of the cranial shape and the AP, ML, CC measurements and the CR and CVAI were preserved ($p>0.05$) whilst the infants' craniums continued to grow at a normal rate.

Conclusion: The present study shows that when remodeling helmet therapy is completed, cranial development continues at normal rates. There is no deterioration in cranial symmetry in the long term, and the effectiveness of the treatment continues after the remodeling helmet therapy is completed.

Key Words: Child development, Craniosynostoses, Endoscopy, Infant, Orthotic Devices

ÖZ

Amaç: Sagital kraniosinostozlu bebekler endoskopik süturektomi ve kranial kasklar ile tedavi edilir. Kullanılan bu kaskların uzun vadeli etkileri ve kask tedavisinin tamamlanmasından sonra ortaya çıkan etkiler henüz araştırılmamıştır. Bu çalışmanın amacı, kranial kaskın uzun vadeli etkilerini ve kask tedavisinin tamamlanmasından sonra ortaya çıkan etkileri araştırmaktır.

Gereç ve Yöntemler: Çalışmaya 14 bebek dahil edildi. Bebekler ameliyat sonrası, kaskın yeniden şekillendirilmesinin tamamlanmasından sonra ve 6 aylık takipte bir 3D lazer sistemi kullanılarak değerlendirildi. Anterior-posterior(AP), medio-lateral (ML) kranial ölçümler, kranial çevre(KÇ), diyagonal ölçümler, sefalik oran(SO) ve kranial kubbe asimetri indeksi(KKAI) değerlendirildi.

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Bulgular: Bebekler 35±3.4 hafta boyunca yeniden şekillendirme kaskı kullandılar. Ameliyat sonrası ve tamamlama sonuçları incelendiğinde, kranial kask kullanımı sırasında, AP, ML, KÇ ölçümlerinin, SO ve KKAI'nin istatistiksel olarak iyileştiği ve bunun sonucunda kafa şeklinin normalleştiği görülmektedir ($p<0.05$). Takip sonuçları incelendiğinde kranial şekil simetrisinde bozulma olmadığı ve bebeklerin kraniumlarında simetrinin büyüme devam ederken AP, ML, KÇ ölçümleri ile SO ve KKAI'nin korunduğu ($p>0.05$) görülmektedir.

Sonuç: Bu çalışma, kranial kask tedavisi tamamlandığında, kranial gelişimin normal oranlarda devam ettiğini göstermektedir. Uzun vadede kranial simetride herhangi bir bozulma olmadığı ve kranial kask tedavisi tamamlandıktan sonra tedavinin etkinliğinin devam ettiğini ortaya koymaktadır.

Anahtar Sözcükler: Bebek, Çocuk gelişimi, Endoskopi, Kraniosinostoz, Ortez Cihazları

INTRODUCTION

The neurocranium which surrounds and protects the brain forms the cranial vault of the skull. The cranial vault consists mainly of flat bones; the frontal and parietal bones; the squamous parts of the temporal bone; and interparietal part of the occipital bone. The development of these bones begins at early embryogenesis and continues until adulthood where the neurocranium eventually increases about 50% in size (1). Most of the growth of the skull occurs at sutures which are found between the cranial bones and it occurs perpendicular to the direction of the suture (2).

Craniosynostosis is defined as a congenital deformity that causes premature fusion of one or multiple cranial sutures (3). The premature and pathological closure of sutures prevents further bone formation at this site and an abnormal compensatory growth occurs in unaffected sutures. This compensatory growth results in abnormalities in the cranial and facial structures (4). Craniosynostosis occurs in approximately 1 in 2000 live births and is classified according to the fused suture (5). The prevalence of coronal synostosis (unicoronal or bicoronal) is 20–25% and metopic synostosis is 5–15%. The rarest form is lambdoid at 0–5% The most commonly encountered type is sagittal craniosynostosis which comprises 40–55% of craniosynostoses (6). Sagittal craniosynostosis, also called scaphocephaly, occurs due to the premature fusion of the sagittal suture and results in increased growth of the anteroposterior (AP) direction of the skull (7).

Until the mid-1900's simple suturectomies and cranial vault remodeling were widely used for the surgical treatment of craniosynostosis however, due to prolonged operative time, need for blood transfusion, significant scalp mobilization, and need for subsequent reconstructive procedures, nowadays, a novel procedure; endoscopic suturectomy is used (8). Endoscopic suturectomy adopts 3 basic principles. Firstly, endoscopic suturectomy is recommended early in life. Secondly, when endoscopic suturectomy is performed at the correct time, the growing brain causes expansion of the skull into a normal shape. Third, to prevent the tendency of the cranial vault to revert to a defective shape, an adjunct vault remodeling helmet which was introduced by Persing et al. (9) in 1986 is used (10). To fabricate a customized cranial orthosis (a remodeling helmet) the infants' skull is precisely measured after endoscopic suturectomy (11). Remodeling helmets promote the correction of head shape by alleviating the pressure on the flattened area of the cranium and allowing cranial expansion in the desired directions. This remodeling helmet which is worn 23 hours a day, is well tolerated, leads to significant correction of craniofacial abnormalities, is safe, effective, and associated with excellent results in the short term (12-14). However, the long term effects of remodeling helmet and the effects that occur after the completion of remodeling helmet treatment have not yet been investigated. Therefore, the aim of this study is to investigate the long term effects of remodeling helmet and effects that occur after the completion of remodeling helmet treatment.

MATERIALS and METHODS

Participants included in this study were infants with a diagnosis of sagittal craniosynostosis who were younger than 6 months of age and had been treated with endoscopic suturectomy. Infants who had syndromic craniosynostosis and those who had an accompanying disease were excluded from this study. Also if the obligatory remodeling helmet usage time was not adhered to, patients were excluded from the study. All parents provided their written informed consent. The study was approved by the Gazi University ethics review board, numbered 01.02.2021-E18936, and the authors complied with the ethical designs of the 1975 Declaration of Helsinki.

The patients were placed on the surgical table in the prone position using soft gel support. Two incision lines of 4 cm, which perpendicularly cut the sagittal suture, were determined 2-3 cm behind the anterior fontanel and 2 cm in front of the lambda. The periosteum between the incision lines was dissected. A 0 degree 4 mm thick endoscopic camera was used (Karl Storz Germany). The bone strip was removed using a Kerrison rounger, bone scissors and ultrasonic bone cutters. Barrel osteotomies were performed behind the coronal suture and in front of the lambdoid suture, parallel to the sutures. Following the bone strip excision, irrigation with Ringer's lactated solution and bleeding control was achieved in all patients. The skin was closed subcuticularly.

Following surgery, all patients were fitted with a custom made remodeling helmet within 1 week following the procedure. All patients were instructed to use the remodeling helmets 23 hours a day in order to achieve the desired head shape.

Remodeling helmets are made from thermoplastic material and this allows the ability for adjustments to be made. As the infants' skulls grew, the helmets were re-adjusted to enable a perfect fit. According to the literature, the usual duration of remodeling helmet usage is 1-1.5 years or until normocephaly is reached (13).

Prior to endoscopic suturectomy, following endoscopic suturectomy, and every 2 weeks until completion, the infants' heads were measured using the STARscanner imaging system. Also, this device was used to manufacture the remodeling helmet. The STARscanner imaging system has previously been used in infants with craniosynostosis to fabricate the remodeling helmet and follow-up cranial development (15). This device uses multiple surface lasers to generate a three dimensional (3-D) reconstruction of the patients' head. The infant is placed in supine position and the images are acquired with four safe, low-energy lasers in approximately 2 seconds. The sellion, left tragus, and right tragus are marked on the 3D image and from these measurements, an axial reference plane and 10 parallel levels are generated. Level 3 has previously been determined as the most useful plane for analysis (15).

Using the STARscanner software, measurements such as; oblique diagonal measurement, cranial length and breadth can be generated. Also specific measurements such as the cephalic ratio (CR) and the cranial vault asymmetry index (CVAI) can be measured. The CR is determined by dividing the cranial length by the cranial breadth. The CVAI is determined by taking the difference between the two oblique diagonal measurements and dividing by the larger of the two oblique–diagonal measurements. A CVAI of 0 represents ideal symmetry (15).

The infants were assessed periodically and three of these assessments were used in our analysis. The first assessment was performed within 1 week after endoscopic suturectomy. Using measurements obtained in this assessment, the infants were fitted with remodeling helmet and were assessed every two weeks. The second assessment included in the analysis was performed when the peak CR was achieved for 3 consecutive measurements and indicates the completion of the remodeling helmet treatment. The third assessment included in analysis was the 6 months' follow-up after the completion of remodeling helmet.

Statistical analyses

Statistical analyses of the study were carried out with "Statistical Package for Social Sciences" (SPSS) version 21.0 (SPSS Inc., Chicago, IL, USA) software. The normal distribution of the data was analyzed with visual (histogram and probability graphs) and analytical (Shapiro-Wilk test) methods. The Wilcoxon test was used to compare the change between post-op values and after the treatment values and also to investigate the change between after the treatment values and 6 months' follow-up after the completion of remodeling helmet. The level of significance was set at p<0.05.

RESULTS

14 infants, (6 female and 8 male) with sagittal craniosynostosis were included in the study. The average remodeling helmet usage in our study was 35±3.4 weeks. When the analysis results of the post-op and end-of-treatment measurements are examined, it can be seen that during remodeling helmet usage duration, the CR has statistically improved (Table I, p=0.028), indicating that the cranial shape has changed from a scaphocephaly to a normocephalic shape. The analysis of the circumference, ML, AP and diagonal measurements show that the infants' heads have grown larger in a symmetric ratio and that the asymmetry in the cranial vault (CVAI) has statistically decreased (Tablel - II, p<0.050).

When the analysis results of the end-of-treatment and 6 months' follow-up measurements are examined, it can be

Table I: Comparison of Post-Op and End of Treatment Measurements.

	Post-Op Median IQR	End of the Treatment Median IQR	p*
Cranial breadth (M–L) (mm)	115.6 (107.3/119.1)	128.9 (122.3/133.9)	0.028
Cranial length (A–P) (mm)	151.9 (145.8/159.4)	159.9 (156.7/167.8)	0.018
Cephalic ratio (CR) (M–L/A–P)	0.74 (0.72/0.77)	0.78 (0.76/0.81)	0.028
Circumference (mm)	429.1 (415/446.3)	471.2 (449/487.2)	0.018
Oblique–diagonal 1, at 30.0 degrees (mm)	145.9 (138.7/153.8)	158.3 (152.5/165.7)	0.018
Oblique–diagonal 2, at 30.0 degrees (mm)	144.4 (138.4/149.3)	159.1 (152.2/165.8)	0.028
Oblique diagonal difference (mm)	2.7 (1.6/4.6)	0.3 (0.1/1.7)	0.063
Cranial vault asymmetry index (CVAI)	1.71 (1.07/3.19)	0.2 (0.1/1.07)	0.043

p < 0.05** *within the groups after helmet treatment (Wilcoxon Signed Ranks Test),* ***post-op: *postoperative,* ***IQR:*** *Interquartile Range,* ***mm:*** *millimeters,* ***M-L:*** *medial to lateral,* ***A-P:*** *anterior to posterior,* ***Circumference (mm):*** *Linear distance around the skull at the specified level,* ***Cranial breadth (M–L) (mm):*** *Maximum medial to lateral distance at the specified level,* ***Cranial length (A–P) (mm):*** *Maximum anterior to posterior distance at the specified level,* ***Cephalic ratio (M–L/A–P):*** *Ratio of maximum cranial breadth to maximum cranial length,* ***Oblique–diagonal 1, at 30.0 degrees (mm):*** *Maximum anterior to posterior diameter at 30 degrees from the sagittal plane (left),* ***Oblique–diagonal 2, at 30.0 degrees (mm):*** *Maximum anterior to posterior diameter at 30 degrees from the sagittal plane (right),* ***Oblique diagonal difference (mm):*** *Difference of the left and right oblique diagonal diameters,* ***Cranial vault asymmetry index (CVAI):*** *Difference between the two oblique diagonal diameters divided by the larger of the two oblique-diagonal diameters.*

Table II: Comparison of End of Treatment and 6 Months Follow-up Measurements.

	End of the Treatment Median IQR	6 Months Later Median IQR	p*
Cranial breadth (M–L) (mm)	128.9 (122.3/133.9)	130.1 (125.8/136.1)	0.018
Cranial length (A–P) (mm)	159.9 (156.7/167.8)	167.9 (164.8/175.5)	0.018
Cephalic ratio (CR) (M–L/A–P)	0.78 (0.76/0.81)	0.78 (0.75/0.79)	0.176
Circumference (mm)	471.2 (449/487.2)	485.8 (472.3/493.6)	0.018
Oblique–diagonal 1, at 30.0 degrees (mm)	158.3 (152.5/165.7)	161.8 (158.4/167.3)	0.018
Oblique–diagonal 2, at 30.0 degrees (mm)	159.1 (152.2/165.8)	163.8 (160.8/166.7)	0.018
Oblique diagonal difference (mm)	0.3 (0.1/1.7)	1.22 (0.61/2.73)	0.128
Cranial vault asymmetry index (CVAI)	0.2 (0.1/1.07)	0.75 (0.36/1.56)	0.128

p** *< 0.05 within the groups after helmet treatment (Wilcoxon Signed Ranks Test),* ***post-op: *postoperative,* ***IQR:*** *Interquartile Range,* ***mm:*** *millimeters,* ***M-L, medial to lateral:*** *A-P, anterior to posterior,* ***Circumference (mm):*** *Linear distance around the skull at the specified level,* ***Cranial breadth (M–L) (mm):*** *Maximum medial to lateral distance at the specified level,* ***Cranial length (A–P) (mm):*** *Maximum anterior to posterior distance at the specified level,* ***Cephalic ratio (M–L/A–P):*** *Ratio of maximum cranial breadth to maximum cranial length,* ***Oblique–diagonal 1, at 30.0 degrees (mm):*** *Maximum anterior to posterior diameter at 30 degrees from the sagittal plane (left),* ***Oblique–diagonal 2, at 30.0 degrees (mm):*** *Maximum anterior to posterior diameter at 30 degrees from the sagittal plane (right),* ***Oblique diagonal difference (mm):*** *Difference of the left and right oblique diagonal diameters,* ***Cranial vault asymmetry index (CVAI):*** *Difference between the two oblique diagonal diameters divided by the larger of the two oblique-diagonal diameters.*

seen that 6 months after completion of remodeling helmet treatment, the improvements obtained in CR were preserved and no statistically significant change has occurred in the CR (Table II, p=0.176). This Indicates that the cranial shape did not deteriorate after discontinuing the remodeling helmet. Furthermore, the analysis of the circumference, ML, AP and diagonal measurements show that 6 months after discontinuing the remodeling helmet, the infants' heads continued growing larger in a symmetric ratio and normocephaly was preserved (Table II, p<0.050). The correction obtained in the CVAI was also statistically maintained (Table II, p>0.050.

DISCUSSIONS

As it can be seen from the results of the present study, endoscopic suturectomy and remodeling helmet used in conjunction lead to positive results in the early term correction of cranial measurements in infants with sagittal craniosynostosis. Additionally, the present study shows that when treatment is concluded and remodeling helmet therapy is completed, cranial development continues at normal rates. Furthermore, there was no deterioration in cranial symmetry in the long term, and the effectiveness of the treatment continued after the remodeling helmet therapy was completed.

In their study, Iyer et al. (11) investigated optimal duration of postoperative remodeling helmet use following endoscopic suturectomy for sagittal craniosynostosis. They concluded that continuing helmeting after peak CR was reached did not improve final outcomes. Additionally, patients who discontinued using remodeling helmet after reaching their peak CR were found to have significantly worse anthropometrics at last follow-up (11). These results imply that helmet removal when maximum CR is achieved may be appropriate for craniosynostosis patients, while helmeting beyond the peak does not change final outcome. In our study, we also concluded remodeling helmet when peak CR was reached and it can be seen that continuing remodeling helmet therapy until peak CR leads to positive results in the correction of head shape both in the short and long term in infants with sagittal craniosynostosis.

The study conducted by Pickersgill et al. (16), showed that there was a regression of CR following endoscopic suturectomy and remodeling helmet in craniosynostosis. In the mentioned study, remodeling helmet usage was around 28 weeks; however, the average remodeling helmet usage in our study was 35±3.4 weeks. Cranial growth rate is extremely rapid during the first few years of life but slows down as the child grows older. We believe the difference may have occurred due to the difference in remodeling helmet duration. The children in our study used the helmet until peak CR was achieved. Therefore, using the helmet for a longer period of time may have had a beneficial effect on the preservation of the achieved correction (14).

In the study performed by Berry-Candelario et al. (17), children who were treated with endoscopic suturectomy were followed until 6 years of age, however the cranial measurements were not taken, children were only monitored for complications. In a different study, Jimenez et al. investigated the management of craniosynostosis using endoscopic suturectomy and remodeling helmet for up to 50 months and concluded that treatment of craniosynostosis with endoscopic suturectomy was safe and efficacious. Even though the study states that subjectively normocephaly was reached, only information regarding the surgical procedures were provided and the long-term effects of remodeling helmet on cranial measurements were not assessed (18).

Riordan et. al conducted a retrospective cohort study where they examined the outcomes of endoscopic suturectomy in infants with craniosynostosis (19). Prior to and following endoscopic suturectomy and remodeling helmet, the children's head circumference was measured in centimeters and compared to the World Health Organization's recommendation guideline, additionally the CR was calculated (20). Median follow-up was 5.9 years. When the results of the mentioned study were examined, it can be seen that there was a normalization in CR and head circumference in 95.4% of children. The patients showed normalization of head circumference postoperatively by 12 months of age relative to WHO normal head growth data and thereafter. These findings are similar to our study. However, our study presents further data on cranial measurements indicating that endoscopic suturectomy is effective in the correction of cranial shape. Furthermore, the effects after the completion of remodeling helmet are more detailed in our study.

Fearon et al. conducted two studies where surgical outcomes and long-term growth of infants with craniosynostosis was evaluated. The first study, published in 2006 and the second study published in 2009, both demonstrated abnormal skull growth in children in the long term following the surgical correction of scaphocephaly (21, 22). It was stated that subsequent calvarial growth was abnormal, with a tendency toward recapitulation of the primary deformity. These studies differ from ours and we believe the differences may have occurred due to surgical differences. The surgical procedure used in the mentioned studies was cranial vault remodeling. In our study, endoscopic suturectomy was used and since the procedure was minimally invasive may have affected the healing and shaping of the skull. Additionally, in the two studies by Fearon et al, remodeling helmet was not used following cranial vault remodeling. Nowadays, studies state that the success of endoscopic suturectomy depends greatly on the remodeling helmet. The helmet has the ability to modify the calvarial growth pattern, and hence, the direction of growth in three dimensions. Without this guidance, cranial expansion occurs equally in all directions and the obtained correction after suturectomy remains incomplete (13). Therefore, when these results are compared, endoscopic suturectomy used together with remodeling helmet leads to promising results in the long term and also when the helmet therapy is completed.

The study by Persad et al. (23) investigated long-term 3 Dimensional CT follow-up after endoscopic sagittal craniosynostosis. The infants were fitted with helmets following endoscopic suturectomy, they were followed monthly until they were 8 months old and then yearly until they were 5 years old. The results indicate that the pre-post CR improved significantly with endoscopic suturectomy and remodeling helmet and the correction established in CR was maintained at the 5 year follow-up (23). Even though the infants were followed-up for a longer term in the present study, our findings correlate with this study. This can indicate that endoscopic suturectomy and remodeling helmet lead to correction in head shape and a preservation of correction in the long term. Our study differs from this study with the assessment method used and duration of follow-up. The STARscanner which was used in our study is harmless when compared to CT and this is an advantage. However, the infants were followed-up for a shorter duration in our study and this is our limitation.

Our study has some limitations. Fırstly our sample size was limited. Even though the effects of endoscopic suturectomy and remodeling helmet after the completion of the remodeling helmet treatment were investigated in this study, a study which investigates the effects in an even longer period would lead to great importance in understanding the long term effects that occur after the completion of remodeling helmet. There was no control group because all infants were treated with the same protocol which has been proven to be efficient, safe and bears great results.

CONCLUSION

In conclusion, the results of this study support the consensus of the literature that endoscopic suturectomy and helmet therapy improve cranial shape. Additionally, it shows that after the completion of remodeling helmet, cranial growth continues and the correction effect is maintained. The cranial development of subjects with sagittal craniosynostosis who used cranial orthosis after endoscopic suturectomy continued at normal rates, the infants did not have any deterioration in their cranial symmetry in the long term, and the effectiveness of the treatment continued after the completion of remodeling helmet treatment.

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