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Original Article

Serum nickel level in patients with facial bone fractures treated with 0.5mm stainless steel wire

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ABSTRACT

Background: Various treatment modalities have been employed in the management of facial fractures, including transosseous wiring using stainless steel wire. Transosseous wires used in fixing maxillofacial fractures gradually undergo disintegration leading to the release of nickel into the blood. **Aim:** To investigate the serum level of nickel in patients treated with stainless steel transosseous wires. **Methods:** This was a prospective study carried out over a period of nine months in the Department of Oral and Maxillofacial Surgery, University of Benin Teaching Hospital, Nigeria. The study involved 101 subjects, 77 males and 24 females (male: female ratio of 3:1) who had maxillofacial fractures. The age of the subjects ranged between 10 and 70 years. Blood samples were collected at four different periods from each patient before the insertion of 0.5mm transosseous wires, at one, three and six months. **Results:** The results showed differences in the amounts of nickel released from transosseous wire during different periods of treatment. There was increase in nickel level in the first month (0.46 ± 0.09µg/l), reaching its highest levels in the sixth month (0.68 ± 0.06 µg/l). **Conclusion:** Transosseous wiring using 0.5mm stainless steel wire release measurable amount of nickel into patients' serum. The serum level of nickel in the patients in this study was comparable to the values found in healthy individuals, showing that the patients did not attain toxic serum levels for nickel within the period of study. It is however recommended that transosseous wires should not be removed within six months.

Key words: Serum nickel, facial bone, fracture, stainless steel wire, transosseous, maxillofacial surgery.

INTRODUCTION

The face is the most exposed and vulnerable part of the body to injuries. It has been documented that 20–60% of injured passengers in automobile accidents have some degree of facial fractures.[1] Managing skeletal and soft tissue injuries of the face constitute quite a significant proportion of the workload of the oral and maxillofacial surgeons in Nigeria.[2] Some studies in Nigeria have shown that aetiologies of fractures of the facial skeleton are mainly due to road traffic accident,[3] interpersonal violence,[4] industrial accident[5] and gunshot injuries.[6]

Over the years, various treatment modalities have been employed in the management of facial fractures. These include the use of plates and screws,[7] extra oral pin fixations[8] and transosseous wiring using stainless steel wire.[9,10] In spite of the recent popular use of plates and screws in the treatment of facial bone fractures, the use of stainless steel wires is still very popular amongst maxillofacial surgeons in our environment.

However, the stainless steel wires that are regularly used as transosseous wires in fixing maxillofacial fractures gradually undergo disintegration leading to the release of nickel into the blood. Previous investigators[11,12] have reported an increase in nickel concentration in the blood weeks and months after exposure to various sources of nickel.

Studies conducted to establish the reference levels of nickel in serum of the general population revealed the acceptable normal level of nickel in serum for healthy individuals as 0.46± 0.26 µg/L[13] and hypernickelaemia as > 1.1µg/L.[14] Due to the widespread use of nickel and nickel alloys in some treatment procedures in medical practice, patients undergoing such treatments are constantly and inadvertently exposed to nickel. Studies have shown that the consequences of such exposure, which are associated with the slow release of nickel into the blood stream, include carcinogenicity, nausea, weakness, headache, myocardial infarction, angina pectoris and kidney dysfunction.[15,18]

There is a demonstrable increase in nickel level due to retention of stainless steel prostheses in non maxillofacial region has been documented.[19] Increase level of nickel in blood and saliva were also demonstrated in patients with orthodontic appliances by some researchers,[20] but this has not been demonstrated with transosseous wires used in the treatment of maxillofacial fractures. It is theoretically possible that nickel may dissolve from stainless steel wires due to corrosion and cause unfavourable effects. This study was therefore aimed at investigating the serum level of nickel in patients treated with 0.5mm transosseous wires in our hospital.

METHODOLOGY

The research was a prospective study carried out over a 9-month period, from April to December 2010. It was a self-controlled study where baseline values (pre-test value) were used as control values. The study was approved by the Research and Ethics Committee of the Hospital. Written informed consent was also obtained from the patients. A questionnaire was used to assess the 132 patients' suitability and willingness to participate in the study. One hundred and one (101) of the patients comprising 77 males and 24 females fulfilled the inclusion criteria and were recruited into the study.

The inclusion criteria for the study included all consecutive patients treated for maxillofacial fractures using stainless steel 0.5mm wire (transosseous wires) at the Department of Oral and Maxillofacial Surgery of the UBTH, Benin City, who were aged 10 to 70 years and required transosseous wiring in oral and maxillofacial region. Patients without stainless steel wire in other parts of the body, and who were willing to participate in the study. Exclusion criteria were patients not willing to participate in the study, pregnant women, fractures not involving both mandible and maxilla at the same time and industrial workers with nickel exposure.

All patients involved in any form of maxillofacial trauma resulting in maxillofacial fractures were selected by careful clinical examination. The patients were treated at the same department for facial bone fractures using transosseous wires. Injuries sustained involving bone tissues were noted and recorded. Conventional plain radiographs relevant to the fracture under investigation were obtained. Each patient was given appropriate definitive management, closely monitored and followed up for a period of six months after treatment.

Definitive treatments for all the selected patients were done under general anaesthesia. Open Reduction and Internal Fixation (ORIF) were done for all the subjects. On the first day, 5 ml of blood was collected to estimate the baseline level of nickel in serum of the individual patients before the placement of 3 cm of 0.5mm transosseous stainless steel wire. Five millilitres of blood was subsequently collected at 1, 3, and 6-months intervals after the insertion of transosseous wire respectively. All the blood samples were collected before the patients had their meals for the day to rule out any dietary sources of nickel. Patients were discharged after 10 days post surgery .They were recalled at 1 , 3, and 6 months intervals and 5 ml of venous blood was again taken from each patient for analysis.

The venous blood was allowed to clot and thereafter spun at 450, 000 rev/min for 10 minutes. Serum was collected and transferred to screw capped plastic test tubes. The sera were stored at -20^{O}C until required for analysis which was done at the Biochemistry Department of Nigeria Institute for Oil Palm Research, (NIFOR), Benin City using Atomic Absorption Spectrometer.

Statistical analysis

All data were recorded in the format designed for the study. The results of the level of blood nickel measured at different times were compared with the level of blood nickel before treatment using student t-test and analysis of variance (ANOVA) where necessary to determine the significance in the differences of values. The normal level of nickel in serum for healthy individuals is 0.46$^{\pm}$ 0.26μ/L[13] while serum value of >1.1μg/L was considered hypernickelaemia[14]. Significance level was set at 0.05 and adopted power of 95%. Data was evaluated using a statistical Software Package for Social Science (SPSS Version 15; SPSS Chicago).

RESULTS

One hundred and one patients made up of 77 males and 24 females (male: female ratio of 3:1) were treated. Table 1 shows the age distribution of the patients. The age range of 21-30 years (41.5%) was mostly affected.

Table 2 shows that Road traffic accident accounted for the majority of the injuries (63.4%) followed by assault (12.9%). Sport was recorded as the least cause of facial fracture.

Table 1: Age distribution of 101 patients with fractures

Age (years)	Frequency	Percentage (%)
10-20	16	15.8
21-30	42	41.5
31-40	25	24.8
41-50	9	8.9
51-60	5	5.0
61-70	4	4.0
Total	101	100.0

Table 2: Aetiological distribution of fractures

Source of fracture	Frequency	Percentage (%)
Domestic accident	7	6.9
Assault	13	12.8
Fall	12	11.9
RTA	64	63.4
Sport	5	5.0
Total	101	100.0

Table 3 shows the mean serum level of nickel increase which is significant with the number of stainless steel wires inserted.

Table 4 shows that the mean serum level of nickel increased significantly with the duration of insertion with a gradient increase from first to sixth month.

Table 5 shows mean serum nickel in relation to gender.There is no significant differences of serum nickel level in male and female

Figure 1 shows a gradient increase in nickel serum level when compared with the standard value. Figure 2 shows mean serum nickel level in relation to age. In the pre insertion values, there is a slight significant difference in serum level among the age groups (*P* = 0.042). After one month, the difference in mean serum nickel levels among the age groups was not statistically significant (*P*=0.498) however, after the sixth month, there is significant increase in the serum level (*P* = 0.047) across all the age groups.

Table 3: Mean serum level of nickel in relation to number of stainless steel wires inserted

Number of stainless steel wires inserted	One month after treatment(µg/l ± SD)	Three months after treatment(µg/l ± SD)	Six months after treatment(µg/l ± SD)
1	0.3066 ± 0.09	0.4641 ± 0.08	0.4641 ± 0.07
2	0.2965 ±0.05	0.4546 ± 0.09	0.4546 ± 0.09
3	0.3062 ±0.08	0.4814 ± 0.10	0.4814 ± 0.06
4	0.3740 ± 0.04	0.4620 ± 0.09	0.4620 ±0.04
P- value	0.05	0.03	0.03

Table 4: Mean serum nickel level in relation to duration of insertion

Duration (months)	Mean Serum Nickel Level µg/l ±SD
Pre-treatment	0.3106 ± 0.008
1 month post – treatment	0.4623 ± 0.093
3 months post – treatment	0.6511 ± 0.079
6 months post – treatment	0.6821 ± 0.068
P – value	0.001

Table 5: Mean serum nickel in relation to gender.

Sex	Before treatment µg/l ±SD	One Month after treatment µg/l ± SD	Three months after treatment µg/l ± SD	Six months after treatment µg / l± SD
Male	0.3143 ± 0.0774	0.4592 ± 0.0931	0.6576 ± 0.0807	0.6941 ± 0.0816
Female	0.3177 ± 0.0839	0.4712 ± 0.0899	0.6323 ± 0.0740	0.6944 ± 0.0821
P - value	0.500	0.532	0.661	0.662

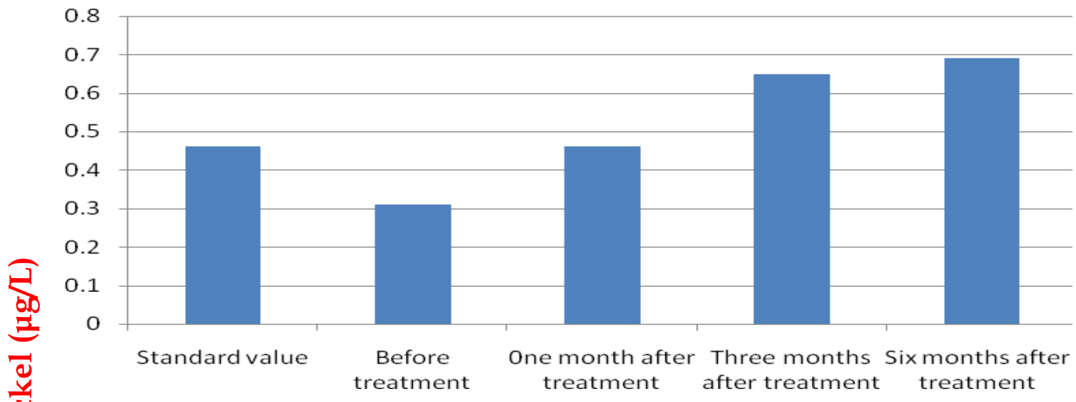

Figure 1: Comparison of mean serum nickel (µg/L) in subjects with standard value

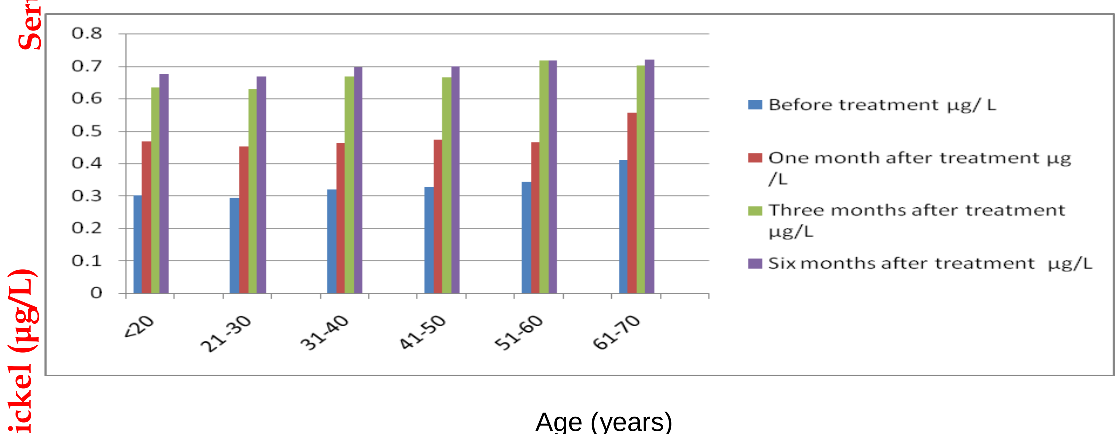

Figure 2: Mean serum nickel level in relation to age

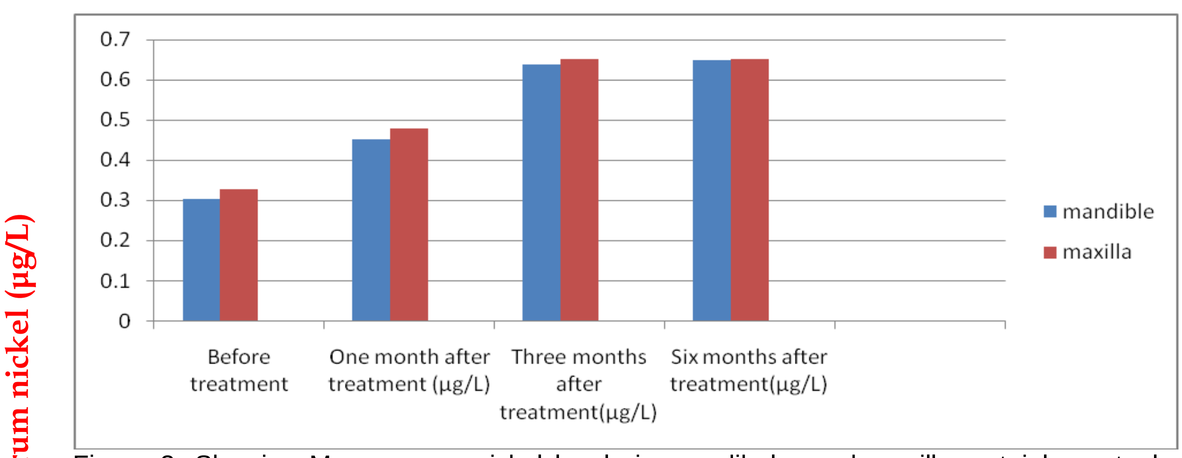

Figure 3: Showing Mean serum nickel levels in mandibular and maxillary stainless steel wire insertion

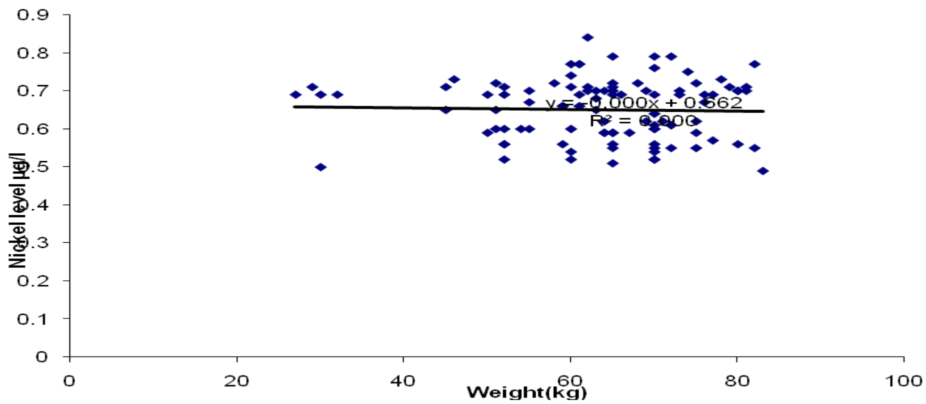

Figure 4: Relationship between weight and serum nickel level one month after treatment (r = 0.028, *P* = 0.58 There was no correlation in serum level of nickel with weight after one month of wire insertion)

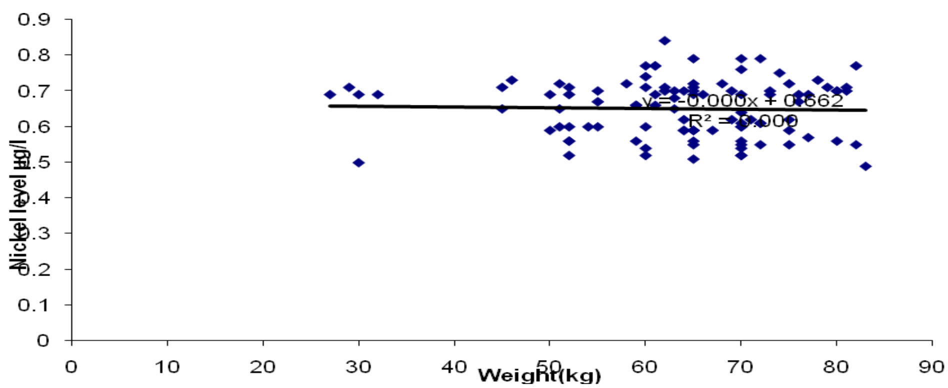

Figure 5: Relationship between weight and serum nickel level three months post treatment (r = 0.28, *P* = 0.67 There was no correlation in serum level of nickel with weight after three months of wire insertion)

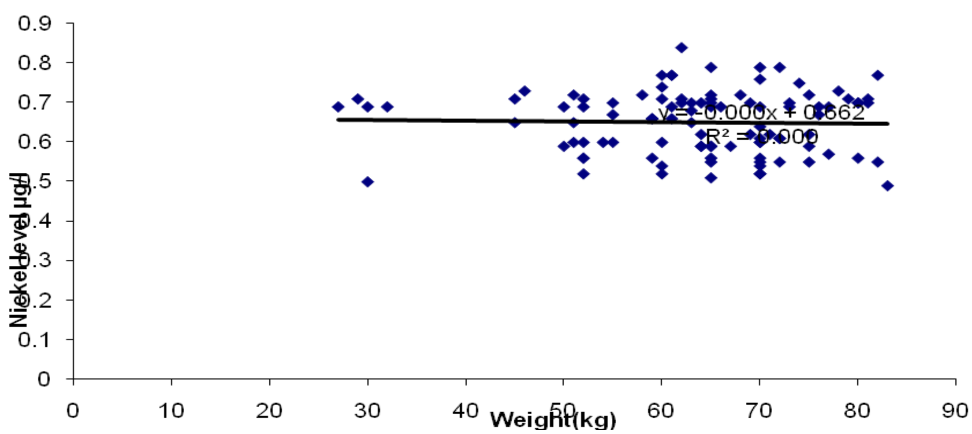

Figure 6: Relationship between weight and serum nickel level six months after treatment
(r = 0.029, *P* = 0.58 There was no correlation in serum level of nickel with weight after six months of wire insertion)

Figure 3 shows mean serum nickel levels in mandibular and maxillary stainless steel wire insertion. Separate blood samples were collected from isolated mandibular and maxillary fractures. There was shows no statistical significant differences of serum nickel level in mandible and maxilla before insertion of wire (*P*= 0.155). Similarly, after first and sixth month of insertion, the difference between serum levels of nickel in mandible and maxilla remained statistically not significant (*P*=0.149 and 0.849) respectively, but there was a slightly higher level in the maxilla.

Figures 4, 5 and 6 show relationships between weight and serum nickel level one month, three months and six months respectively after insertion**.** There was no correlation in serum level of nickel with weight.

DISCUSSION

To the best of our knowledge, this appears to be the first study that assesses the level of serum nickel in patients treated with 0.5mm stainless steel transosseous wires in Nigeria.

Corrosion is a generally slow but progressive phenomenon and it is undesirable because it can lead to mechanical failure of treatment, release and disseminate corrosion particles, which can produce adverse biological reactions in the host.[21] Several previous studies have reported the corrosive behaviour of orthodontic wires in the oral cavity,[22] implants used in fixing fractures and stainless steel wires used in spine arthrodesis.[23] There is no known similar study on the corrosive process of transosseous wires used in the management of facial fractures.

When we compared our findings with the standard normal value of serum nickel, we found the mean serum level of nickel to be 0.31 ± 0.08µg/L for the baseline value, 0.46 ± 0.09µg /L after one month, 0.65± 0.08 µg/L after three months and 0.68 ± 0.06 µg/L after six months of insertion of wires indicating an increase in serum nickel level. However, the observed increase in serum nickel was within the normal range in healthy individuals. This is in agreement with Sunderman *et al.*[13] who reported the standard mean serum nickel in healthy individuals to be 0.46 ± 0.26µg/L. The values from this study showed that although serum nickel increased after six months it remained within normal range. This finding agrees with an earlier study[24] that found an increase in serum nickel level which remained within standard value after 4-5 months. The reason for the increase in serum nickel was the leaching of stainless steel wire inserted in the body.

This study demonstrate a gradient increase in serum nickel with the duration of insertion of the transosseous wires and also showed that serum nickel levels increased statistically in the treated patients with time. The level of serum nickel in the patients before treatment was within the normal range in healthy individuals, which is 0.46 ± 0.26 µg/l.[13] Although the level increased statistically above baseline value with time at six months, it remained within normal value. The clinical significance of this study is that the level of nickel was found to increase although clinical features suggestive of nickel toxicity was not found among the study subjects. Serum value of >1.1µg/L is considered hypernickelaemia.[14]

In this study, there was a higher level of serum nickel in those with transosseous wire in the maxilla than mandible, although this was not statistically significant. There is currently no previous study to compare this finding. The vascularity and reduced density of maxilla may be the reason for the slight difference. Also, the study showed significant increase in serum nickel level with increase in number inserted wires. It is our opinion that the increase may be due to cumulative release of serum nickel from the various transosseous wires.

The study showed no significant differences in serum nickel for patients less than 40 years of age. This is in agreement with Leach *et al.*[18] who reported that there was no statistical differences in nickel serum found among groups less than 40 years of age. However in the sixth month, there appeared to be significant difference in the level of serum nickel at the age of 60 years. This finding agrees with Linden *et al.*[14]who reported hypernickelaemia with serum nickel concentrations as high as 3.1µg/L in the elderly. Also, previous study by Kim *et al.*[23]

reported an increase in serum level above age of 60 years. The reason for the increase at such age may be attributed to impaired renal clearance which is said to be found in the elderly leading to accumulation of nickel in the body.

The study showed no significant differences of serum nickel level in male and female. Sex differences in serum nickel from the use of stainless steel transosseous wires have not previously been demonstrated and so no statistical record to compare this finding. However, this finding may suggest that serum nickel level is the same in both male and female.

In this study, there was no correlation between serum nickel level and weight of the subjects. No data are available in the literature to compare with this finding. This may invariably mean that metabolism of nickel is the same irrespective of the weight of the patient.

The findings from this study indicate that measurable amounts of nickel can be found in serum of patients with transosseous wires. It can be said that there could be a release from transosseous wires but the values in any period of the treatment do not reach toxic levels and are similar to those found in healthy individuals. The long term implication of nickel ion exposure is unknown.

Some authors recommend stainless steel wire removal to all patients once fracture union is achieved,[25] but this surgical procedure has some potential complications like progressive loss of correction.[26] The economic cost of removing wires is also quite considerable. Determination of the levels of serum nickel will useful in determining patients who require wire removal. However removal of transosseous wires cannot be recommended because serum nickel level was found to be within reported normal range.

CONCLUSION

This study showed that the mean serum level of nickel was within normal range during the period of study. There was gradient increase in mean serum nickel level with duration of insertion of stainless steel wire .There was no significant difference in level of serum nickel in stainless steel wires insertion in maxilla wiring and mandible wiring although the level was slightly higher in the maxilla .The mean serum nickel level was independent of age, gender and weight of subjects. Also, elevated levels of nickel can be measured after insertion of transosseous wires.

Levels of nickel ions in the body fluids probably do not reach a level that can cause side effects at six months hence routine removal of the stainless steel wires is not to be recommended within the period. As demonstrated by this study, serum nickel levels increased after insertion of stainless steel wires.

It is recommended that baseline nickel levels be establish in patients with specific kinds of stainless steel instrumentations and to monitor nickel level at interval as a part of the periodical clinical evaluation. This may allow an early diagnosis and prevention of local and systemic complications. Prostheses with minimal susceptibility to metal corrosion should be selected by the maxillofacial surgeons and, if feasible, remove wires when there is evidence of corrosion or mechanical failure. Since the level of serum nickel was within normal standard value after six months, the use of stainless steel wires for treatment of fractures can only be recommended for six months which is the duration of this study. However, it is recommended that further studies be conducted beyond 6months.

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