

## Main Article

Alison Conybeare takes responsibility for the integrity of the content of the paper

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## Abstract

**Objective.** Bone conduction hearing implants are a well-established method of hearing rehabilitation in children and adults. This study aimed to review any changes in provision in England.

**Methods.** The total number of bone conduction hearing implantations performed was analysed from 2012 to 2021 utilising Hospital Episode Statistics data for England.

**Results.** The total number of procedures has increased by 58 per cent. One-stage bone conduction hearing implantations in adults accounts for the largest proportion of this increase (93 per cent of the total). The number performed in children has remained stable and accounts for 73 per cent ( $n = 433$ ) of all two-stage procedures.

**Conclusion.** The data show that bone conduction hearing implant surgery is becoming increasingly popular, particularly in adults. This has correlated with the increase in availability, national recommendations and choice of devices.

## Introduction

Bone conduction hearing implants transmit sound to the inner ear by the vibration of a processor in contact with the skull, thus bypassing the normal auditory canal. It is used in those individuals with congenital or acquired absence of the ear canal, or those with pathology preventing effective sound conduction.<sup>1–18</sup>

Bone conduction hearing implants consist of two parts: a processor device that converts sound to a digital signal, and a mount or attachment connecting this device to the overlying skin or directly to the temporal bone. The processor comprises a microphone, amplifier, digital processor and transducer. Here, sound is converted into a digital signal that drives a vibrating mass transducer. This vibration energy is then transmitted to the skull by the proximity of the vibrating processor to bone. The processor can be mounted on the mastoid bone by either non-surgical or surgical options, and can be provided either unilaterally or bilaterally in the treatment of conductive hearing loss, mixed hearing loss or a single-sided sensorineural deafness.<sup>1–22</sup>

In surgically placed bone conduction hearing implants, mechanical vibration of the processor is transmitted directly to the skull through a titanium screw 'fixture' secured to the mastoid bone. Classically, these types of devices are divided into percutaneous (skin-penetrating) and transcutaneous (skin-preserving), depending on the surgical approach and the specific design of the implanted device. Successful implantation is dependent on osseointegration of the implanted fixture with the surrounding bone, which occurs during wound healing and increases over time.<sup>1,4,8,19</sup>

Bone conduction hearing implantation can be performed as a one-stage procedure, whereby a titanium fixture is implanted into the temporal bone to which an abutment and/or transcutaneous device is simultaneously attached. After a short soft tissue healing period, the sound processor can then be attached and used.<sup>1,2,4,11,13,14,16</sup>

Alternatively, in two-stage procedures, the fixture can be placed and the overlying skin closed. After a period of healing time (normally 12 weeks), a second procedure is then undertaken to secure the abutment or transcutaneous device to the fixture through or under the skin. This two-stage approach allows for osseointegration prior to applying the mechanical load of the abutment and processor. Two-stage procedures are often utilised in paediatric patient groups, or in adults with significant co-morbidities or abnormal temporal bones which may reduce the overall security of the fixture leading to the implant falling out, termed a fixture failure.<sup>1,2,4,11,13,14,16</sup>

Bone conduction has been known of since at least the Renaissance period, when Girolamo Cardano demonstrated its existence through teeth. However, it was not until Goteborg's design in 1977 that the first bone conduction hearing device was implanted. In the lead up to 2009, the majority of bone conduction hearing implants were supplied by one company (Cochlear®),<sup>6,8,9,16,17</sup> although other companies (e.g. Entific® and Nobel Biocare®) did precede Cochlear. Then, Oticon introduced its first bone conduction device on a background of hearing aid technology.<sup>3</sup> In 2012, Med-El used its background in

cochlear and middle-ear implants to develop the first active bone conduction implant (the Bonebridge), then the non-surgical adhesive Adhear system in 2017.<sup>21</sup> With the introduction of this competition, the speed in which bone conduction hearing implant technology has developed over the last 14 years has increased considerably (Figure 1).

Newer devices, such as the Cochlear Osia<sup>®</sup> (first introduced into the UK in December 2018, but not widely available until much more recently), sit the processor entirely under the skin, directly on the bone.<sup>23</sup> This negates the need for a percutaneous abutment, reducing the risk of skin complications and loosening, but was initially criticised for reduced sound quality. However, the active processor sitting directly on the bone has reduced this problem, and, as no osseointegration is required, it only requires one surgical stage.<sup>4,5,7,10,12,18,19,21,23</sup>

Although there are many examples in the literature of patient-related outcomes with regard to bone conduction hearing implants,<sup>1,2,4-10,13,16,18</sup> overall, the findings are from individual institutions; there have been no previously published data on the total number of bone conduction hearing implantations performed in England as a whole.

The Department of Health provides Hospital Episodes Statistics, which is a dataset containing records of all patients admitted to National Health Service (NHS) hospitals in England and which describes what procedures have been performed.<sup>24</sup> This is published on an annual basis. Private hospitals are not included, although private patients treated in NHS hospitals are. The database does not give specific individual information on patient admissions, the bone conduction hearing implant system employed, or the type of fixture or abutment used, but it does give an overview of current surgical rates in England. Data are available on ‘main procedures and interventions’, which can be subdivided into four-character Office of Population Censuses and Surveys (‘OPCS’) Classification of Interventions and Procedures version 4 codes and the statistics related to them. The Hospital Episodes Statistics data are limited by data entry errors, as they rely on the correct coding of all operative procedures. The Payment by Results Assurance Framework audited 50

trusts across the UK in 2014 and found an average error rate of 7 per cent (range, 1.1–45.8 per cent).<sup>25</sup>

This study aimed to review the number of bone conduction hearing implantations performed in adults and children, and determine any changes in provision from 2012 to 2021.

**Materials and methods**

‘Main procedures and interventions’ data for the available years (2012–2021) were downloaded in Microsoft Excel format. The period 2012–2021 is when the data can be best compared, as, prior to 2012, the data do not distinguish between different age groups. However, this is a particularly fortuitous timeframe in that it also covers the explosion of bone conduction hearing implant technology as we described earlier. The operative ‘OPCS-4’ codes relating to bone conduction hearing implants were considered in order to examine any changes in patterns of provision. These included: first-stage insertion of fixtures for a bone conduction hearing prosthesis (code D13.1), second-stage insertion of fixtures for a bone conduction hearing prosthesis (D13.2) and one-stage insertion of fixtures for a bone conduction hearing prosthesis (D13.5).

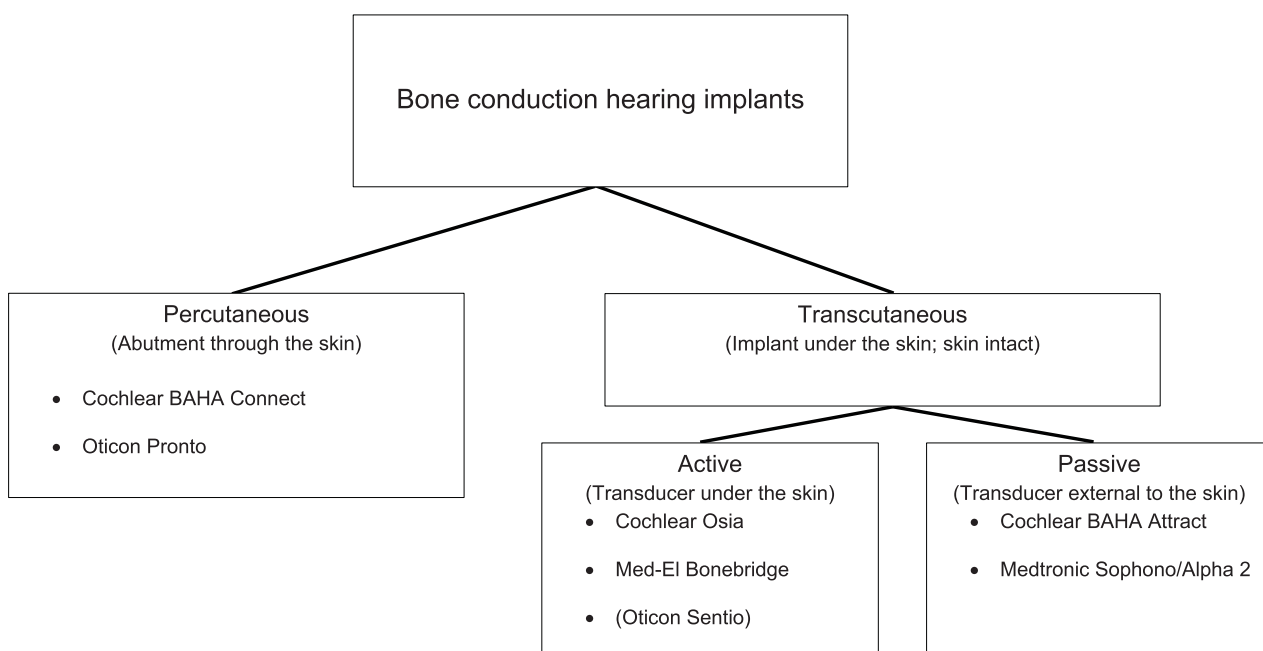
Unspecified codes were excluded from the study (including: code D13.6, fitting of an external hearing prosthesis to bone conduction fixtures; D13.8, other specified attachment of a bone conduction hearing prosthesis; and D13.9, unspecified attachment of a bone conduction hearing prosthesis).

Data for children (aged 0–16 years) and adults (aged 17–90 years or older) were compared over time. Hospital Episodes Statistics data are presented in 24 age categories. These, where appropriate, have been amalgamated to allow for useful comparison.

**Results**

*One-stage fixture insertion*

This section concerns one-stage insertion of fixtures for a bone conduction hearing implants (code D13.5). Over the study



**Figure 1.** Bone conduction hearing implant types. BAHA = bone-anchored hearing aid

period, 9171 one-stage implantations were performed. Of these, 673 (7.9 per cent) were in children under the age of 16 years and 8498 were in adults. In the adult population, the most common age group for implantation was 50–69 years (1895 implantations for those aged in their fifties and 1850 for those aged in their sixties) over the total study period. Devices were implanted in 45.5 per cent ( $n = 4077$ ) male patients and 55.5 per cent ( $n = 5094$ ) female patients. A mean of 1102 (range, 741–1370) implantations occurred each year until 2020, when a significant reduction in implantations took place. Only 352 surgical procedures were performed in 2020–2021, of which 25 were in children and 327 were in adults (Table 1). A further reduction is noted in 2020–2021, when only 352 procedures were performed. The fall in the provision of single-stage procedures likely reflects the impact of the coronavirus disease 2019 (Covid-19) pandemic and the subsequent reduction in all surgical procedures performed across NHS England.

The total number of one-stage implants has increased by 58 per cent, from 741 (2012–2013) to 1370 (2018–2019), with the largest single increase, from 948 to 1145, occurring in 2015–2016 ( $p = 0.06$ ). The adult population accounts for the largest proportion of this total increase, accounting for an average of 1021 one-stage procedures each year.

The number of one-stage procedures performed in children has not significantly fluctuated over the study period, with a mean of 81 procedures performed annually. However, there is a similar trend in increased provision from 2012 to 2020 (from 51 to 80 procedures, respectively).

### Two-stage fixture insertion

When examining the data recorded for first-stage insertion of fixtures for a bone conduction hearing implants (code D13.1) and second-stage insertion of fixtures for a bone conduction hearing implants (D13.2), it would be expected that the total numbers of each should be roughly equivalent over each year, as the procedures are affiliated with each other. However, these data suggest that far more first-stage procedures are being performed than second-stage procedures, with particular apparent discrepancy in the adult population (Table 2).

Over the study period, a total of 1102 first-stage procedures have been performed, 409 of these in children and 693 in

**Table 2.** First- and second-stage fixture insertion for bone-conduction hearing implants for children and adults

Fixture insertion stage	Year	Total (n)	Children (aged 0–16 years) (n)	Adults (aged 16+ years) (n)
1st-stage insertion*	2012–13	130	66	64
	2013–14	132	51	81
	2014–15	121	48	73
	2015–16	144	52	92
	2016–17	147	57	90
	2017–18	138	47	91
	2018–19	129	47	82
	2019–20	117	33	84
	2020–21	44	8	36
	Total	1102	409	693
2nd-stage insertion†	2012–13	83	60	23
	2013–14	83	61	22
	2014–15	63	52	11
	2015–16	71	56	15
	2016–17	69	53	16
	2017–18	72	54	18
	2018–19	73	47	26
	2019–20	59	33	26
	2020–21	24	17	7
	Total	597	433	164

\*D13.1 and †D13.2 Office of Population Censuses and Surveys ('OPCS') Classification of Interventions and Procedures version 4 codes

adults. The number of second-stage procedures over this same time is recorded as 433 in children and 164 in adults. In this case, 529 first-stage procedures in adults did not progress to the second stage. However, it is much more likely that this discrepancy is a result of coding errors. As demonstrated above, adults are far more likely to undergo a one-stage procedure, and such a large difference between first- and second-stage total numbers in adults, as presented here, may be attributed to the confusion in coding between a one-stage procedure (code D13.5) and a first-stage procedure (D13.1).

Within the paediatric population, this discrepancy does not occur, with approximate equal numbers of first-stage ( $n = 409$ ) and second-stage ( $n = 433$ ) procedures being performed each year and over the total study period, as expected.

Overall, the total numbers of procedures coded D13.1 and D13.2 have not fluctuated significantly from year to year, with the exception of 2020–2021, when there was a 38 per cent reduction in first-stage insertion and a 40 per cent reduction in second-stage procedures, as compared to the previous year. This likely reflects the impact of the Covid-19 pandemic, as previously suggested.

### Paediatric implantation

A total of 673 children aged under 16 years were provided with bone conduction hearing implants via a one-stage procedure between 2012 and 2021. The peak provision between 2016 and 2018 showed an average of 104 cases per year. The

**Table 1.** One-stage fixture insertion for bone-conduction hearing implants for children and adults\*

Year	Total (n)	Children (aged 0–16 years) (n)	Adults (aged 16+ years) (n)
2012–13	741	51	690
2013–14	869	62	807
2014–15	948	66	882
2015–16	1145	92	1053
2016–17	1239	102	1137
2017–18	1337	106	1231
2018–19	1370	89	1281
2019–20	1170	80	1090
2020–21	352	25	327
Total	9171	673	8498

\*Office of Population Censuses and Surveys ('OPCS') Classification of Interventions and Procedures version 4 code D13.5

mean number of cases recorded is 81 per year over the total study period. Children were most commonly implanted between the ages of 10 and 14 years (279 procedures), accounting for 41 per cent of all one-stage implantations in children. Thirty-six children (5 per cent) aged under four years were implanted using a one-stage procedure over the same time.

A similar pattern is also demonstrated in first- and second-stage procedures, with totals of 409 and 433 procedures respectively. There was a mean of 51 first-stage procedures and 52 second-stage performed annually. There was no significant fluctuation in implant provision year to year, except for the impact of the Covid-19 pandemic in 2020–2021 (Figure 2). Two-stage procedures are more commonly performed in children aged five to nine years ( $n = 214$ ), accounting for 52 per cent of these patients.

Procedure codes in each age group are demonstrated in Table 3. A total of 1515 procedures have been performed in children aged under 16 years in the 9-year study period. Of these, 127 procedures (8.4 per cent) have been performed on patients aged under four years.

## Discussion

Analysis of Hospital Episodes Statistics data from 2012 to 2020 shows an overall increase in all bone conduction hearing implant procedures included in the study. The year 2020–2021 shows a significant decrease in the numbers of all procedures, as a direct result of the Covid-19 pandemic; therefore, these data should be considered with caution when drawing conclusions. Further analysis of Hospital Episodes Statistics data in the future will be necessary to assess the ongoing impact of the pandemic on bone conduction hearing implant provision in England. Throughout the remaining discussion, the data collected from the year 2020–2021 will be excluded.

## Funding

There was an increase in single-stage bone conduction hearing implantations in 2015–2016. This is interesting as it was when an updated version of the consensus guidelines for bone conduction hearing implants in the UK was published.<sup>22</sup> This document recommended that clinical commissioning groups support the use of bone conduction hearing implants as per the manufacture guidelines, providing a clear pathway and negating the need for multidisciplinary team input on every patient (as was required previously).<sup>11,22</sup> This change in policy is likely to have eased the process and therefore made bone conduction hearing implants more accessible. The provision

of this service has also become more widely available across England, increasing access for patients and the awareness of this type of hearing aid. Procedures can be performed under local anaesthetic as day-case surgery, which is attractive to both the surgeon and patient.

The overall increase in the provision of bone conduction hearing implants could also be due to a combination of improved surgical approach (which have moved towards skin-sparing techniques) and improvements in fixture and abutment design.<sup>2,4,6,8,9,11,13,14</sup> These two factors have led to a decrease in complication rates, with regard to both soft tissue complications and fixture failure rates, in adults and children.<sup>13,26,27</sup>

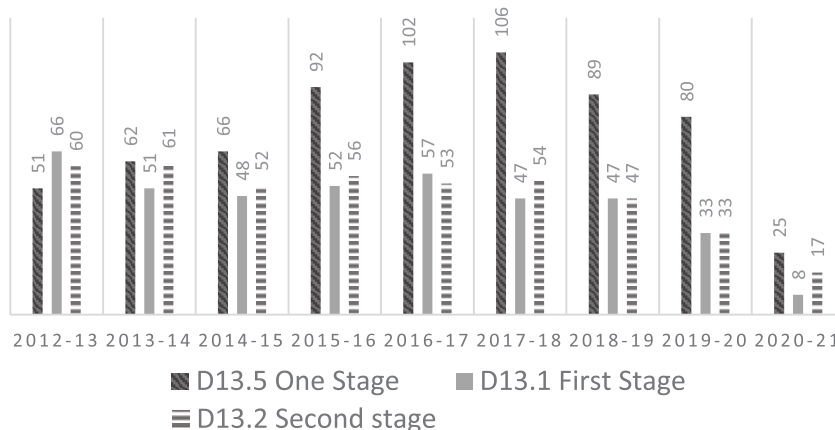
## Paediatric considerations

Children are equally likely to undergo either a one-stage or a two-stage procedure. Two-stage procedures are more common in younger children aged under 5 years, and one-stage procedures are more common in children aged over 10 years.<sup>10,11,15,17</sup> These data are expected, as the clinical commissioning policy of NHS England 2013 recommends that implant surgery be performed in two stages in children aged up to 10 years.<sup>11</sup> However, patient age at implantation is highly debated in the literature.<sup>10,11,13,15,17</sup> Kruyt and colleagues' systematic review, published in 2020, suggests there is no higher rate of implant loss in children undergoing single-stage surgery.<sup>13</sup> In fact, it went on to suggest that the complication rate is lower in single-stage surgery compared to two-stage surgery, although specific age groups were not reviewed and the groups were too heterogeneous for formal conclusions to be made.

Interestingly, there was a small decrease in the number of children having both one-stage and two-stage bone conduction hearing implantations in 2018–2019 even before the pandemic. The cause for this is not known; however, it may be related to the introduction of newer, less invasive, non-surgical alternatives (such as the adhesive retained Adhear system) or alterations in coding with different newer devices. Only future studies will be able to tell if this is a true downward trend.

## Limitations

It is important to note that Hospital Episodes Statistics data are based upon the correct clinical coding of procedures and interventions. A major limitation of this study was the lack of clarity provided by the coding parameters, leading to variability and data identification bias. A disproportionate number of first-stage procedures were recorded when comparing to second-stage data; this is likely to reflect coding where



**Figure 2.** Total number of bone conduction hearing implantations performed in children aged 0–16 years during 2012–2021.

**Table 3.** Fixture insertion for bone-conduction hearing implants in children

Fixture insertion	Year	Age 0 years	Aged 1–4 years	Aged 5–9 years	Aged 10–14 years	Aged 15 years	Aged 16 years	Total
1-stage insertion*	2012–13	0	5	15	24	2	5	51
	2013–14	0	9	18	19	9	7	62
	2014–15	0	4	19	29	7	7	66
	2015–16	0	5	37	38	5	7	92
	2016–17	1	2	49	42	4	4	102
	2017–18	0	4	43	41	8	10	106
	2018–19	0	4	38	40	3	4	89
	2019–20	0	2	31	32	6	9	80
	2020–21	0	0	7	14	2	2	25
	Total	1	35	257	279	46	55	673
1st-stage insertion†	2012–13	0	11	29	21	3	2	66
	2013–14	0	8	24	15	3	1	51
	2014–15	0	8	22	14	3	1	48
	2015–16	0	5	30	15	1	1	52
	2016–17	0	8	31	16	0	2	57
	2017–18	0	3	30	13	1	0	47
	2018–19	0	6	27	11	2	1	47
	2019–20	0	2	18	11	0	2	33
	2020–21	0	1	3	3	0	1	8
	Total	0	52	214	119	13	11	409
2nd-stage insertion‡	2012–13	0	7	26	25	1	1	60
	2013–14	0	7	33	18	2	1	61
	2014–15	0	5	33	9	3	2	52
	2015–16	0	8	27	19	1	1	56
	2016–17	0	3	33	14	2	1	53
	2017–18	0	3	35	14	1	1	54
	2018–19	0	3	28	11	3	2	47
	2019–20	0	1	18	10	2	2	33
	2020–21	0	2	7	8	0	0	17
	Total	0	39	240	128	15	11	433

Data represent numbers of cases. \*D13.5, †D13.1 and ‡D13.2 Office of Population Censuses and Surveys ('OPCS') Classification of Interventions and Procedures version 4 codes

one-stage procedures were incorrectly coded as first-stage procedures. The accuracy of clinical coded data has been addressed nationally, and a checklist for hospital managers has been suggested as a way to improve coding and hence appropriate payment.<sup>25</sup> As a result, it is hoped that the quality of coding will continue to improve and these current inaccuracies will become a thing of the past. Future Hospital Episodes Statistics data interrogation can confirm or refute this suggestion.

Furthermore, the operation codes do not include information of surgical approach, or design of fixture or abutment, nor do they distinguish between transcutaneous and percutaneous devices. Over the study period, there have been several new devices introduced to the market, as well as modifications in design and connectivity options. These include alterations of width and texture of implants and abutments, and the introduction of new passive and active technology. There have also been some devices withdrawn from the market. As the Hospital Episodes Statistics dataset does not include implant specifics, no comment can be made regarding the overall

changes in demands of each implant design, although this would be an excellent area for future study.

- Hospital Episodes Statistics data can be utilised to depict national trends in healthcare provision
- Bone conduction hearing implants are well established for hearing rehabilitation in both adults and children
- Rapid technological advances have been made in bone conduction hearing implants over the last 40 years
- The usage of bone conduction hearing implants has increased dramatically over the last decade in adults, but remained static in children

More recently, middle-ear implants have been introduced. However, given the increased surgical time and the requirement to enter the middle ear, these procedures should be coded separately to other bone conduction hearing devices, although this cannot be assured in this dataset.

Hospital Episodes Statistics data also do not state the laterality of the implantation; some individuals may receive

bilateral implantation. Therefore, when interpreting these results, we must consider this to be the total number of procedures rather than the total number of patients. Nevertheless, the data are useful in presenting emerging trends in bone conduction hearing implant provision in England.

## Conclusion

Both one-stage and two-stage procedures are utilised in adult and paediatric populations in England. Adults are more likely to undergo a one-stage implantation, accounting for 93 per cent of procedures, the provision of which has increased over time by 58 per cent. Children are equally likely to have either a one-stage or a two-stage procedure. However, two-stage procedures are more common in younger children aged under 5 years, and one-stage procedures are more common in children aged over 10 years. The total number of implantations in children has not significantly increased over time. Overall, the data show that bone conduction hearing implant surgery is becoming increasingly popular, particularly in adults. This correlates with the increase in availability, national recommendations and choice of devices.<sup>1,3,5,7,8,10,11,15–18,19–21,24</sup>

**Competing interests.** None declared

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