NICE National Institute for Health and Care Excellence

NICE advice

StoneChecker for kidney stone evaluation

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is StoneChecker. It is a medical imaging software tool, based on texture analysis. Its intended use is for evaluating the physical and texture characteristics of kidney stones on non-contrast enhanced CT scan images.
- The **innovative aspects** are an algorithm designed to provide measurements including size and volume of kidney stones, and to identify heterogeneity in the stone structure by enhancing features of the CT image not visible to the naked eye.
- The intended **place in therapy** would be to use it with conventional CT scans in secondary care for people with kidney stones larger than 4 mm.
- The **main points from the evidence** summarised in this briefing are from 3 observational studies in the UK and China. The results of these studies suggest that CT texture analysis using StoneChecker can differentiate uric acid from non-uric stones on unenhanced CT. This may make it possible to predict the number of shocks needed to treat kidney stones.
- **Key uncertainties** around the evidence or technology are that the evidence is limited in quality and quantity. All studies had small sample sizes. One study was experimental, and the analysis was based on passed stones that were provided by patients. A further study was published only as a conference abstract.
- The **cost** of StoneChecker is £5,000 (excluding VAT) as an annual subscription fee. The **resource impact** is currently unclear because of a lack of evidence in clinical practice.

The technology

StoneChecker is medical imaging software used to measure key kidney stone parameters to generate a set of textual metrics. It uses an application (TexRAD, licensed by Feedback Medical Ltd) that analyses the texture in an existing radiological scan. The aim is to help clinicians assess a stone's heterogeneity and any characteristics not visible to the naked eye. It creates a visual 'map' of a kidney stone.

The technology is designed to be used with conventional CT scans to help clinical decision making about diagnosing and treating people with kidney stones. It imports imaging data and calculates metrics based on individual pixel data points within a given region of interest. These metrics assess stone heterogeneity, including texture irregularity, not provided by conventional CT scans. The technology can also use filters to extract and enhance existing CT images to help assess stone composition. This can potentially be used to predict treatment failure on pre-treatment CT, and to identify and select patients who are most likely to benefit from the treatment.

StoneChecker software runs on existing Windows-based machines or workstations, and can be integrated with a hospital picture archiving and communication system to import files containing CT images.

Innovations

StoneChecker uses an algorithm aimed at measuring the size and volume of kidney stones. It can also assess stone heterogeneity using filtration-histogram-based texture analysis, which enhances the details seen with conventional CT. Currently, there is no standardised method of measuring the physical and texture parameters that enable clinicians to predict treatment outcomes.

Current care pathway

The NICE guideline on renal and ureteric stones: assessment and management recommends that low-dose non-contrast CT should be offered to adults (except if pregnant) with suspected renal colic within 24 hours of symptoms presenting.

StoneChecker would be used with standard CT scans in people with kidney stones to measure stone parameters and to inform clinical decision making about treatment choice.

Population, setting and intended user

StoneChecker is intended to be used with non-contrast CT scans in a secondary care setting in people with kidney stones to measure and evaluate the stones. The device would most likely be used by urological surgeons or radiologists. The company estimates the technology could be used to evaluate at least 100,000 cases of kidney stones each year in the UK.

Costs

Technology costs

StoneChecker costs at £5,000 (excluding VAT) as an annual subscription fee. The company stated that this is potentially only an early-adopter price. It explained that a future subscription model may take into consideration such factors as the volume of cases analysed per site or per workstation, or the number of users.

Costs of standard care

No estimate for the complete cost of existing care for CT in people with kidney stones could be identified. In the NHS, the cost of non-contrast CT of 1 area of the body ranges from £71 to £81, depending on the person's age.

Resource consequences

There is no evidence on the resource and cost consequences of StoneChecker. It is imaging software and is intended to be used with conventional CT scans. Use of the technology is not expected to have any significant impact on resource use. However, extra staff time may be needed for training on how to use the technology and for interpreting the metrics. This might be offset by improving workflow for urologists and radiologists.

Regulatory information

StoneChecker is CE marked as a class I medical device. It is intended to work as an aid when assessing kidney stones detected with conventional CT scan. No medical device alerts for this technology have been identified.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Kidney stones are most common in people between 30 years and 60 years. Also, people can have an underlying condition that may result in kidney stones, for example, kidney disease or cancer. This may mean that someone is disabled if such a condition has had a substantial and long-term effect on their ability to do daily activities. Age and disability are protected characteristic under the Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Three studies are summarised in this briefing, including a total of 57 kidney stones from 50 patients plus additional 607 cases of shockwave lithotripsy.

The evidence for StoneChecker includes 3 observational studies (2 full publications and 1 conference abstract).

Table 1 summarises the clinical evidence, and its strengths and limitations.

Overall assessment of the evidence

The studies included in table 1 examine the accuracy of CT texture analysis (CTTA) software for distinguishing uric acid (UA) and non-UA stones and predicting shockwave lithotripsy outcomes. Studies report that CTTA in vivo and ex vivo using unenhanced CT images can accurately differentiate UA stones from non-UA stones, and can also help to predict number of shocks needed when using shock wave lithotripsy to treat kidney stones. Two studies were funded by the company.

Table 1 Summary of selected studies

Cui et al. (2017)	
Study size, design and location	A cross-sectional study of 5 patients with 7 kidney stones varying in size from 3 mm to 6 mmm done in the UK.
Intervention and comparator	CTTA on CT scan images using CTTA software. No comparator.
Key outcomes	CTTA metrics showed a mean HU density was statistically significantly positively corrected to number of shocks needed to fragment the stone (correlation co-efficient: 0.806, p=0.028). CTTA metrics of entropy and kurtosis predicted 92% of the outcome of number of shocks to fragment the stone. This was better than using stone volume or density.
Strengths and limitations	This was an experimental study, and CTTA was based on passed kidney stones that were provided by 5 volunteers. It examined imaging-related factors that were associated with number of shocks needed to fragment the stone. But other clinical-related factors, such renal morphology, congenital anomalies and stone nature (de novo or recurrent), were not included in the analysis when predicting the outcome. Funding of the study was not reported, and 1 study author is a director and shareholder of Feedback Plc. This is the company that developed and markets the TexRAD texture analysis algorithm used in the study.
Zhang et al. (2018)	
Study size, design and location	A cross-sectional study of 14 patients with 18 UA stones and 31 patients with 32 non-UA stones, done in the UK.
Intervention and comparator(s)	CTTA on CT scan images using CTTA software. No comparator (fourier transform infrared spectroscopy as reference standard).
Key outcomes	CTTA showed that the accuracy of texture features for differentiating UA from non-UA stones ranged from 88% to 92%. CTTA incorporated metrics including skewness and kurtosis had a sensitivity of 94.4% and specificity of 93.7% for differentiating UA stones from non-UA stones.

Strengths and limitations	Small sample size. The retrospective design may have introduced selection bias and overestimated diagnostic accuracy.
Cui et al. 2017 (abstract)	
Study size, design and location	A cross-sectional study of 607 cases of SWL done in the UK and China.
Intervention and comparator(s)	CTTA on CT scan images using CTTA software. No comparator.
Key outcomes	UK data showed a 46% of success rate (completely stone free) with SWL. Variables associated with a significantly lower SWL success rates were: increasing age, female, larger stone sizes, higher mean and standard deviation of the HU, 2 or more stones in the same location, vesico-urteric junction location and higher CTTA calculated entropy and total. The predicted probability of success rates was 84% using CTTA. The data from China produced a model of similar predictive ability.
Strengths and limitations	A cross-sectional study. The study was funded by StoneChecker Software Limited.
Abbreviations: CTTA, CT texture analysis; HU, Hounsfield unit; SWL, shockwave lithotripsy; UA, uric acid.	

Recent and ongoing studies

No ongoing or in-development trials were identified. The company noted that an unpublished paper on the technology is currently under review, which is investigating potential factors that affect outcome of extracorporeal shockwave for renal stones.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Five specialists were familiar with or had used this technology before.

Level of innovation

Experts said the concept of StoneChecker was novel compared with standard picture archiving and communication systems. Currently, standard CT only measures stone size and identifies the location of the stone in urinary tract. It does not measure or calculate stone characteristics before treatment. This software could provide parameters such as stone volume, cumulative stone volume and statistical measures of the distribution of Hounsfield units within the stone.

Experts noted that there were similar technologies available, but StoneChecker was more flexible for data analysis by comparison and was compatible with existing Windows operating systems. One expert said that StoneChecker was a minor variation of the standard of care, and that dual energy CT scans currently used in some NHS trusts could provide stone characterisation.

Potential patient impact

Experts considered that the technology provided useful data about kidney stones that could inform the discussion between the doctor and the patient about treatment options. Two experts noted that StoneChecker produced an accurate calculation of the volume of a kidney stone and a more accurate representation of total stone burden, which could help clinical decision making about treatment choice. Both experts stated that treatment based only on stone size measurement could be inappropriate for some people because of misclassification of their kidney stones. One expert said that the potential benefit of using StoneChecker was to identify patients at high risk of shockwave lithotripsy failure, who would be referred for other treatments, so reducing their number of hospital visits. Experts considered that people with no symptoms but with multiple stones or with large stone burdens needing treatment such as shockwave lithotripsy were most likely to benefit from the technology.

Potential system impact

One expert noted that the technology has been used only in kidney stone disease research, and that there was no adequate evidence on using the technology in clinical practice. Therefore, the immediate impact of the technology is unknown. Experts considered that, with further research, StoneChecker could potentially improve the efficiency and effectiveness of stone disease treatment and would reduce the overall cost of care for people with stone diseases.

General comments

One expert considered that StoneChecker was easy to use and could provide kidney stone characteristics that would be essential to improving the effectiveness of stone treatments. Experts noted that current data on the technology are very limited in routine clinical practice. They also noted that the usability and practical aspects of the technology should be carefully considered, including:

- Who would use the software, for example, urologists or radiologists?
- What is the reliability of the software between different readers who use the technology? What level of training that is needed?
- Whether the technology can be accessed via hospital picture archiving and communication systems or other computer applications?
- Whether CT scan images need to manually download to StoneChecker?
- How StoneChecker reported data would be displayed or stored, and would these data be in a separate file or be linked to existing electronic patient records?

One expert stated that dual energy CT scans were available in some NHS trusts, and could provide stone characterisation for people with kidney stones. The use of StoneChecker would be an additional cost for these trusts.

Specialist commentators

The following clinicians contributed to this briefing:

- Helen Cui, urology registrar, Oxford University Hospital NHS Foundation Trust, was involved in developing technology.
- Michael Kimuli, urology consultant, Leeds Teaching Hospital, did not declare any interests.
- Hrishi Joshi, urological surgeon, University Hospital of Wales, consultancy in the commercial healthcare sector.
- Robin Cleveland, professor of engineering science, University of Oxford, consultancy in the commercial healthcare section, and co-author of Cui et al. 2017.
- Ese Adiotomre, consultant radiologist, Leeds Teaching Hospital NHS trust, did not declare any interests.
- Julian Keanie, consultant uroradiologist, Western General Hospital, Edinburgh, did not declare any interests.

Development of this briefing

The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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