

## Research Assessment Exercise 2020 Impact Case Study

**University:** [The Hong Kong Polytechnic University ]  
**Unit of Assessment (UoA):** [15 chemical engineering, biomedical engineering, other technologies (incl. environmental engineering & nautical studies) and marine engineering ]

**Title of case study:** [Scolioscan: A Novel Radiation-free Assessment for Scoliosis Using 3D Ultrasound Imaging ]

### (1) Summary of the impact

[The unit developed a novel radiation-free imaging technique for scoliosis, which is the most common spinal disease among adolescents with prevalence of around 5% in Hong Kong and China. During 2013-2019, it has been registered as a medical device in the EU and Australia. Through a start-up company named Telefield Medical Imaging Ltd (<http://www.scolioscan.com>), 18 sets have been installed in hospitals or clinics in Netherlands, Italy, Bosnia, Poland, Romania, Australia, and China (Beijing, Guangzhou, Shenzhen, Hong Kong, Macau). As a result, over 5000 scoliosis patients have benefited by reducing the potential harm of radiation in scoliosis detection. That led to a total revenue of over HKD5.1M, and 10 new jobs provided for bachelor or master degree graduates (still have at least 5 posts under recruitment), and a patent licensing and royalty fee of HKD1.3M to the university. In addition, this technology has led to a shareholder investment of over HKD32M, with a recent external investment of HKD4.7M for 5% share, making the company valued at least HKD94M. ]

### (2) Underpinning research

[Scoliosis is defined as the lateral deformity of spine and commonly coupled with spinal rotation and is mostly developed during adolescent stage (adolescent idiopathic scoliosis, AIS). About 20% of kids with scoliosis will progress if not promptly treated, thus, continuous monitoring is needed. The current clinical gold standard for scoliosis assessment is X-ray imaging, which has radiation hazard. During the monitoring and treatment, scoliosis patients need to receive continuous X-ray exposure. A recent study in Denmark has demonstrated that the X-ray exposure to scoliosis patients can induce 5 times more cancer 25 years later in comparison with control group<sup>1</sup>. Another limitation of X-ray image is that it uses 2D information to depict 3D spine deformity. That affects significantly the timely evaluation of the outcome of nonsurgical treatment, such as spinal bracing and scoliosis-specific exercise, which targets 3D correction of spinal deformity, not to say to provide real-time feedback information during exercise treatment or brace fitting, which is critical to achieve optimized treatment.

Scolioscan® was developed based on research works of Prof YP Zheng's team on 3D ultrasound image system [1], image reconstruction method [2], scanning methods [3,9], measurement method [6], validation [4], and research on different applications [6-8] during the period of 2005-2019. The basic principle of this technique is to use an ultrasound probe to scan over the spine to capture a sequential of images together with the corresponding probe location and orientation. Using patented scanning and image reconstruction methods, coronal and sagittal images as well as 3D model of spinal are obtained. The related research has been funded by the Research Grant Council (RGC) General Research Fund (PolyU5332/07E, HKD0.45M, 2008-2010), Innovation and Technology Fund (UIM/213, HKD6.3M, 2012-2014), etc. Based on these earlier works, RGC supported Prof Zheng as the Project Coordinator a total fund of HKD12M with its first Research Impact Fund in Jan 2019 to further investigate the prediction of scoliosis progression using 3D ultrasound imaging, which has been commented by proposal reviewer as a “ground-breaking method” in the field of scoliosis management. The first-of-its-kind palm-sized 3D ultrasound imaging system for radiation-free scoliosis assessment, named “Scolioscan Air” has won



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<sup>1</sup> Simony A, et al. Incidence of cancer in adolescent idiopathic scoliosis patients treated 25 years previously. *Eur Spine J* 25(10): 3366-3370, 2016.

the Grand Award, Gold Medal with the Congratulations of Jury, and Special Merit Award at the 47th International Exhibition of Inventions of Geneva in April 2019. |

### (3) References to the research

1. Development of a portable 3D ultrasound imaging system for musculoskeletal tissues. *Ultrasonics*. 43: 153-163, 2005. (DOI: [10.1016/j.ultras.2004.05.003](https://doi.org/10.1016/j.ultras.2004.05.003))
2. A three-dimensional (3D) ultrasound imaging system for assessing scoliosis. *US 8,900,146 B2; China 201080040696.0; Japan 5849048; Canada 2,769,150; Australia 2010278526; and EP 2459073B1* (Entered into 12 EU Countries). Jul 27 2019. (<https://patents.google.com/patent/US8900146B2>)
3. Freehand 3D ultrasound system for assessment of scoliosis. *Journal of Orthopaedics Translation*. 3(3): 123-133, 2015. (DOI: [10.1016/j.jot.2015.06.001](https://doi.org/10.1016/j.jot.2015.06.001))
4. Ultrasound volume projection imaging for assessment of scoliosis. *IEEE Transactions on Medical Imaging*. 34(8): 1760-1768, 2015. (DOI: [10.1109/TMI.2015.2390233](https://doi.org/10.1109/TMI.2015.2390233))
5. A reliability and validity study for Scolioscan: a radiation-free scoliosis assessment system using 3D ultrasound imaging. *Scoliosis and Spinal Disorders*. 11:13, 2016. (DOI: [10.1186/s13013-016-0074-y](https://doi.org/10.1186/s13013-016-0074-y))
6. Automatic measurement of spine curvature on 3-D ultrasound volume project image with phase features. *IEEE Trans on Medical Imaging*. 36(6): 1250-1262, 2017. (DOI: [10.1109/TMI.2017.2674681](https://doi.org/10.1109/TMI.2017.2674681))
7. An effective assessment method of spinal flexibility to predict the initial in-orthosis correction on the patients with adolescent idiopathic scoliosis (AIS). *PLOS ONE*. 12(12): e0190141, 2017. (DOI: [10.1371/journal.pone.0190141](https://doi.org/10.1371/journal.pone.0190141))
8. Pattern of coronal curve changes in forward bending posture: a 3D ultrasound study of AIS patients. *European Spine Journal*. 27(9):2139-217, 2018. (DOI: [10.1007/s00586-018-5646-5](https://doi.org/10.1007/s00586-018-5646-5))
9. Analysis of sagittal profile of spine using 3D ultrasound imaging: A phantom study and preliminary subject test. *Computer Methods in Biomechanics and Biomedical Engineering: Imaging & Visualization*. 1-13. [10.1080/21681163.2019.1566025](https://doi.org/10.1080/21681163.2019.1566025), 2019. (DOI: [10.1080/21681163.2019.1566025](https://doi.org/10.1080/21681163.2019.1566025))
10. A fast 3-D ultrasound projection imaging method for scoliosis assessment. *Mathematical Biosciences and Engineering*. 16: 1067-1081, 2019. (DOI: [10.3934/mbe.2019051](https://doi.org/10.3934/mbe.2019051)) |

### (4) Details of the impact

- [In 2012 the technique developed by the Unit was licensed to Telefield Medical Imaging Limited (with a total licensing income of HKD1.3M up to Sep 2019) (see company webpage *Corroboration Sources 1, 2*), which resulted in the register of Scolioscan® as a trademark for the technique in 2013, up to over 10 countries up to now. As a result, this technique has attracted Telefield Limited to invested over HKD32M to develop Scolioscan into a business during 2012-2019 (*Corroboration Source 3*). Thus, the technique allowed to develop the first and only 3D ultrasound spine imaging device in the market, significantly reducing the risk of radiation in assessment and optimizing conservative treatment of scoliosis, by providing timely treatment outcome assessment and real-time feedback during treatment.
- In 2016, Scolioscan was registered in the EU as a Class-IIa medical device (CE mark) (*Corroboration Sources 4 5*), and in 2017, Scolioscan was also registered in Australia as a medical device (TGA, Class-IIa) (*Corroboration Source 6*). Scolioscan was classified as Innovative Medical Device by CFDA Guangdong Bureau for its CFDA registration in China (*Corroboration Source 7*)
- The registration is a critical step for an innovative medical device (involving manufacturing site and process audit, safety test, device functionality test, clinical trials, etc.), and as a result, Scolioscan has become a medical device that can be used in hospitals and clinics to serve patients in all EU countries and Australia, as well as many other countries recognizing EU registrations. During the period of 2013-2019, 18 sets of Scolioscan have been installed in following hospitals and clinics in Utrecht, the Netherlands (*Corroboration Source 8*); Milan, Italy; Banja Luka, Bosnia and Herzegovina; Radom, Poland; Constana, Romania; Sydney & Melbourne, Australia (*Corroboration Sources 9, 10*); Beijing, Guangzhou, Shenzhen, Macau, and Hong Kong, China. (*Corroboration Source 3*)

- Due to the presence of Scolioscan in the clinics above mentioned, during the period 2013-2019, over 5000 scoliosis cases have been scanned with the technique developed by the Unit. As a result, the risks associated with scoliosis' traditional X-ray detection have been significantly reduced in the patients treated with Scolioscan sets for these kids. A clinical study (involving 442 schoolchildren, 2017-2019) conducted in a local hospital has verified at least 50% of X-ray can be avoided by using Scolioscan to confirm whether a subject should be referred for further treatment, with a threshold of Cobb angle 20 degrees (Dr. TP Lam, Department of Orthopaedics and Traumatology, Prince Wales Hospital, Hong Kong). Also, as a result of using Scolioscan to give visual feedback for the progress, scoliosis subjects and their patients have been better motivated for conservative treatment, such as exercise treatment, as demonstrated in a clinical study in a hospital in Shenzhen, China (Dr. Michael To, Department of Orthopaedics and Traumatology, HKU Shenzhen Hospital) (See also *Corroboration Source 11*)
- Because of convenient and accurate mass screening capability provided by Scolioscan, the unit has been supported in 2019 by Hong Kong Jockey Club with a donation of HKD18M to establish a comprehensive 5-year school scoliosis screening program and community support services for scoliosis patients with Scolioscan assisted brace design and progression monitoring. The program has already ordered 2 sets of Scolioscan Air and 1 set of Scolioscan SCN801. The program supports a team of staff for scoliosis screening and treatment and will benefit at least 6000 kids. The Scolioscan Air is brought to schools to conduct screening so that suspected cases can be confirmed on site accurately, without X-ray and without any delay (*Corroboration Source 12*). Scolioscan has also stimulated or facilitated many other scoliosis awareness and assessment activities in Hong Kong and elsewhere, with one recent example with China-Hong Kong-Macau Chiropractic Society (*Corroboration Source 13*).
- Furthermore, Scolioscan has generated 10 jobs for Bachelor and Master's degree graduates in HK via Telefield Medical Imaging Limited, with another 5 openings by Sep 30 2019, and has already generated a revenue of HKD5.1M (2013-2019) (see *Corroboration Sources 3, 13*). Besides this, in Jun 2019 the company has been selected by Hong Kong Science and Technology Park Limited for its accelerating program to support start-ups (LEAP program <https://www.hkstp.org/>), with a total funding support of HKD4.7M for 5% share, making the Telefield Medical Imaging Limited an estimated value of at least HKD94M. (See details in *Corroboration Source 3*)
- Finally, we would like to elaborate how Scolioscan has been helping kids all over the world by sharing a story about how Scolioscan helps a 2 years old girl in Beijing to avoid having X-ray exposure and relieving her family. (See details in *Corroboration Source 14*)  
 She was found to have a tilting posture and suspected to have early onset scoliosis. Her mother was so concerned about the factor that the girl was suggested to take X-ray every 6 months by her doctor to understand the cause of the tilting posture and its progressing. Our collaborating company Telefield Medical Imaging Limited was installing a set of Scolioscan in a rehabilitation hospital in Beijing at that time. The girl's mother learned this news, and waited for the arriving of the machine, and the girl was scanned by Scolioscan first in Dec 2018, and then around every 3 months. The imaging results first confirmed that she just had a mild scoliosis, instead the tilting posture was caused by some deformity in the sacrum (which was later confirmed by X-ray, also the only X-ray taken so far). The mother was greatly relieved with the results, and she felt so happy that she and the clinicians can know her girl's spine condition and monitor potential progression without further X-ray exposure. This is one of the happiest moments for the whole team that our research results can lead to Scolioscan to help these kids like this baby girl. The following two sets of images showing the examination results for coronal, sagittal and 3D view of this girl's spine scanned on Mar 18 2019, and Jun 4 2019, as examples. The scanning and analysis for this girl will continue, and she can avoid all the X-ray, originally needed every 6 months, which means a lot for her family, and her long-term health, quality of life.

- Scolioscan has raised global interests in applying it for various clinical applications in different places by different organization. For example, Children’s Scoliosis Foundation would like to acquire it for helping kids with scoliosis in Tanzania and Ghana in Africa (*Corroboration Source 15*); A group from Imperial College London, UK, plans to use it to help scoliosis patients in Sri Lanka (*16*); A Paediatric Endocrinologist from Birmingham Women’s and Children’s Hospital, UK, plans to use it for assessing spine for patients with metabolic bone disease, which makes spinal easy to be curved (*17*); A German Clinic commented it an excellent device for supporting exercise treatment of scoliosis (*18*) DPM Sleep Solution Limited plans to use Scolioscan for evaluating pillow design (*19*); United Imaging Healthcare (the biggest medical imaging company in China) intends to use Scolioscan for spinal brace 3D printing for scoliosis (*20*). The Scolioscan Air has been widely reported, one example cannot be found at *Corroboration Source 21* |

**(5) Sources to corroborate the impact**

1. Webpage of start-up company Telefield Medical Imaging Limited based on Scolioscan technology: <http://www.telefield-imaging.com.hk/>
2. Scolioscan Review by Medgadget: <https://www.medgadget.com/2015/06/scolioscan-enabling-radiation-free-diagnosis-scoliosis.html>
3. Letter from Telefield Medical Imaging Limited about Scolioscan business: PDF file
4. EU CE mark certification for Scolioscan registered as Class-IIa medical device: PDF file
5. Scolioscan product brochure: PDF file
6. Australia TGA certification for Scolioscan registered as Class-IIa medical device: PDF file
7. China CFDA registration for Scolioscan, classified as Innovative Medical Device by CFDA Guangdong Bureau: PDF file
8. Prof Rene Castelein, Chair of Department of Orthopaedic Surgery, University Medical Center Utrecht, Utrecht, The Netherlands presenting their clinical results of using Scolioscan for kids with idiopathic scoliosis in the annual conference of Scoliosis Research Society IMAST, Cape Town, 2017: <https://www.youtube.com/watch?v=XAU-yYDdfVc&t=15s>
9. Dr. Jeb McAviney, a chiropractor and CEO of Scoliocare Limited, Australia giving training about Scolioscan to physiotherapists from Indonesia: <https://instantpm.net/p/B2idzVXAM-d>
10. Staff in Scoliocare Limited, Australia, announcing the installation of Scolioscan in their clinics and introducing the operation of Scolioscan: <https://twitter.com/hashtag/scoliocare>
11. Clinical application of Scolioscan in HKU Shenzhen Hospital verified that Scolioscan can help to increase the compliance of kids for useful home exercise treatment: PDF file
12. Due to Scolioscan, in 2019 by Hong Kong Jockey Club donated HKD18M to the unit to establish a school scoliosis screening program and community support services for scoliosis patients with Scolioscan assisted brace design and progression monitoring: PDF file
13. An example of Scolioscan quotation provided by Telefield Medical Imaging Limited, with unit price of USD60K: PDF file
14. A clinical case of how Scolioscan helps a 2 years old girl to avoid using X-ray and to relieve her mother’s psychological burden on X-ray exposure, with the images of developing spine and email communication with the mother: PDF file
15. Children’s Scoliosis Foundation would like to acquire it for helping kids with scoliosis in Tanzania and Ghana in Africa, email communication: PDF file
16. A group from Imperial College London, UK, plans to use it to help scoliosis patients in Sri Lanka, email communication: PhD file
17. Birmingham Women’s and Children’s Hospital, UK, plans to use Scolioscan for assessing spine for patients with metabolic bone disease, with email communication: PDF file
18. A German clinic commented Scolioscan can facilitate exercise treatment: PDF file
19. DPM Sleep Solution Limited plans to use Scolioscan for evaluating pillow design: PDF file
20. United Imaging Healthcare (the biggest medical imaging company in China) intends to use Scolioscan for spinal brace 3D printing for scoliosis, with email communication: PDF file
21. Media report about Scolioscan Air: <https://www.nsmmedicaldevices.com/news/polyu-introduces-scolioscan-air/>