

# move! 88

*a new way of thinking about everyday life  
in medicine and in the clinic*

STIMULI FROM ORTHOPAEDICS AND THE PROFESSIONAL FIELD – FOR PHYSICIANS, SPECIALISTS AND EXECUTIVES

*Focus on science*

## Affinis Short – quality control from the registry



*Product in focus*

## balanSys UNI Fix unicondylar knee prosthesis



*From the professional field*

## Learning from brain research: how language works in patients' minds





# Affinis Short – quality control from the registry

By Peter Münger, Head of Clinical Affairs, Mathys Ltd Bettlach

Registry data creates a reliable basis for evaluating the quality of the procedure and implant.

A closer look at two major registries reveals how the Affinis Short,

one of the most commonly implanted stemless shoulder prostheses, is performing.

The stemless Affinis Short humeral head prosthesis has been used successfully since 2009, and its usage figures are growing rapidly. The reason for its high popularity is the exceptionally straightforward surgical technique, the result and optimised anatomical reproduction and state of the art, wear resistant materials incorporated. Alongside various short stem implants, there are now a number of prostheses on the market that are based on a similar, stemless anchoring concept.

Shoulder endoprosthesis do not yet enjoy the long and global tradition of registry data that knee and hip prostheses do. Data collection on the latter began in 1970 in Sweden, being the only hip registry of its kind at the time. Fortunately, however, there are now also registries that document the performance of shoulder

joint replacements. The most informative registries are currently the «National Joint Registry for England, Wales, Northern Ireland and the Isle of Man» (NJR) and the «Australian Orthopaedic Association National Joint Replacement Registry» (AOANJRR).

### Analysis of current NJR registry data for the Affinis Short

In the NJR, the Affinis Short is listed as the most frequently implanted stemless prosthesis in the «stemless prosthesis» category with 1 088 documented cases as of the end of 2016.<sup>1</sup> In an extract from the registry of February 2018, which Mathys receives twice a year by virtue of its status as partner to the NJR, there were 1 489 cases documented in 1 392 patients by beginning of December 2017.<sup>2</sup>

The NJR also provides detailed information on the causes of revision for the Affinis Short (see Table 1). An analysis of the data first and foremost reveals that, out of 20 revision procedures carried out, not one of them was performed for aseptic loosening.

The results for total replacement of the shoulder joint with the Affinis Short, which is by far the most commonly performed procedure, are equally impressive:

By December 2017, the procedure had been documented as having been carried out 1 123 times on 1 049 patients.<sup>2</sup> The maximum follow-up period at this time was just over five years. In total, 96 different clinicians carried out this procedure. The patients treated with the Affinis Short were on average 69.4 years old and around 70 % of them were female. At

## Revisions

Reasons for revision of primary procedures in which the implant was used.

Reason for Revision	Number of procedures <sup>†</sup>	Expected Revisions <sup>*</sup>	p value
Infection	2	2.60	1
Instability	6	8.86	0.392
Cuff Insufficiency	9	13.92	0.21
Aseptic Loosening	0	2.93	0.124
Periprosthetic Fracture	0	0.90	1
Conversion Hemi To Total	7	6.31	0.684
Conversion Total To Hemi	0	0.23	1
Other/Not recorded	2	3.81	0.596
<b>Total Revisions</b>	<b>20</b>	<b>34.13</b>	<b>&lt; 0.011</b>

<sup>†</sup> Multiple reasons may be listed for one revision procedure

<sup>\*</sup> Based on all other Primary Shoulder Replacement, adjusted for agegroup, gender, and indications

Tab. 1 Causes of revision for the Affinis Short (NJR)

## Cumulative Revision Rate

Endpoint: All reasons for revision

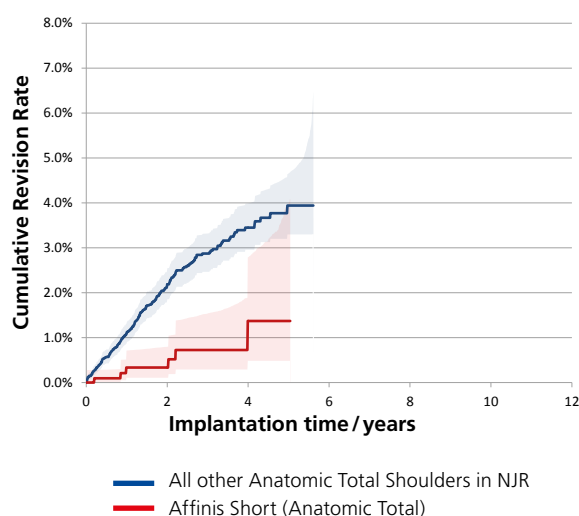


Fig. 1 Cumulative revision rates for the Affinis Short compared to all other anatomical total shoulder endoprosthesis (NJR)



the time of publication, a component of the prosthesis had had to be revised in six patients. After five years, the cumulative revision rate for the Affinis Short is 1.4 per cent, which is half the rate of all anatomical total prosthesis groups documented in the NJR (see Table 2). Due to the somewhat lower number of patients at risk, the confidence intervals of the five-year results overlap, thereby losing some of their statistical significance. As late as three years post-procedure, however, the revision rate for the Affinis Short is significantly better when compared to the documented anatomical prostheses (Fig. 1).

**Evaluation of the current AOANJRR registry data**

In the Australian registry, the Affinis Short is listed in the «mid-head shoulder prosthesis» category. The Affinis is by far the most frequently used prosthesis in this category.<sup>3</sup> As of the end of 2016, the registry documents a total of 733 mid-head procedures and 438

Affinis Short prostheses. In 2015 and 2016, the Affinis Short was the most frequently used product in this class in Australia. When compared to 2015 figures the number of documented cases has doubled.<sup>3</sup> More than 50 per cent of the documented mid-head prostheses come from Mathys. With a revision rate of 2.1 per cent, the category of mid-head prostheses has a significantly lower revision rate at a follow-up period of three years compared to a conventional total shoulder endoprosthesis (6.2 per cent). On the basis of this data, it can be assumed that the Affinis Short is contributing significantly to these excellent results.

**Pleasing prospects**

The data on the Affinis Short from the two major registries (NJR and AOANJRR) points in the same direction, which we believe to be a very pleasing sign and which we interpret as an indicator of the excellent behaviour of our implant. This also reflects the considerable positive feedback that Mathys receives from its

users. Future, and most importantly long-term follow-up of registry data, will confirm whether our high expectations will be met. We are, however, already convinced that we are on the right path!

**Sources**

- <sup>1</sup> 14<sup>th</sup> Annual Report 2017. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man
- <sup>2</sup> Data on file
- <sup>3</sup> Australian Orthopaedic Association National Joint Replacement Registry. Hip, Knee & Shoulder Arthroplasty Annual Report 2017

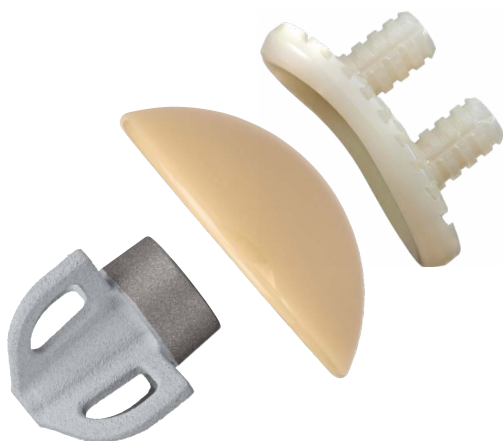
**Cumulative Revision Rate**

Endpoint: All revisions

Period/years	At Risk	Affinis Short (Anatomic Total)	All NJR Anatomic Total Shoulders
0	1 123	–	–
1	810	0.3% (0.1% – 0.7%)	1.0% (0.8% – 1.2%)
2	545	0.3% (0.1% – 0.8%)	2.0% (1.7% – 2.3%)
3	315	0.7% (0.3% – 1.5%)	2.6% (2.3% – 3.0%)
4	150	1.4% (0.5% – 2.8%)	3.2% (2.8% – 3.7%)
5	43	1.4% (0.5% – 4.0%)	3.7% (3.1% – 4.3%)
6		(–)	(–)
7		(–)	(–)
8		(–)	(–)
9		(–)	(–)
10		(–)	(–)

Cumulative revision rate with 95% confidence intervals  
Rate only reported for times where >40 remain at risk

**Tab. 2** Cumulative revision rates for the Affinis Short (NJR)



# balanSys UNI Fix unicondylar knee prosthesis

*The implant type and prosthesis design are important influencing factors of revision rates. The AOANJRR registry data is able to confirm whether the UKA balanSys UNI Fix has better revision rates than other UKA systems.*

The implantation of a unicondylar knee arthroplasty (UKA) is now classed as a standard procedure in cases of isolated, unicondylar knee arthritis when the knee ligaments are intact. The aim of a partial joint replacement is to alleviate pain and restore function.



Compared to a total knee replacement, unicondylar replacement is less invasive, the operating time is often shorter, and the patient's mobility is restored sooner after the operation with improved proprioception. The growing importance of mobility across all demographic groups represents a significant challenge to unicondylar knee joint prostheses.

The balanSys UNI Fix prosthesis tackles this challenge head-on with the primary goal of achieving a long prosthesis service life.

## Clinical results

Excellent clinical results have been demonstrated by the registry data from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR):<sup>1</sup>

The balanSys UNI system (fixed bearing) boasts the lowest cumulative revision rate of all unicompartmental knee replacement systems\*. With a cumulative revision rate of 8.1 per cent after 10 years, balanSys UNI Fix has a significantly lower revision rate compared to all of the other documented unicompartmental knee replacement systems. The average cumulative revision rate for unicondylar knee joint replacement is 14.6 per cent after 10 years.

vitamys – the vitamin E enhanced, highly cross-linked polyethylene is highly resistant against oxidation and exhibits superior wear resistance.<sup>2</sup> This material retains its excellent mechanical and tribological properties even after prolonged phases of accelerated ageing.<sup>2</sup>

These low associated wear rates<sup>3</sup> contribute to the long-term stability of implant fixation without any compromise in terms of inlay fixation. vitamys is therefore a tribological solution for «round-on-flat» articulations of the type generally used with balanSys UNI Fix and unicondylar «fixed-bearing» prostheses.

## Sources

<sup>1</sup> <https://aoanjrr.sahmri.com>

<sup>2</sup> Masterfile vitamys (V01\_2016, data on file)

<sup>3</sup> balanSys UNI in vitro testing (V05\_2016, data on file)

\* Annual Report 2017

## Keeping a close eye on post-op knees

An innovative medical product is enabling more effective monitoring of the post-operative recovery period, improving compliance and reducing rehabilitation costs.



Claris Healthcare has developed a monitoring system designed especially for home-based rehabilitation and the monitoring of older patients following TKR. Claris Reflex consists of a sensor which is placed on the knee that has undergone surgery, with the necessary software. With exercise instructions and feedback on how these exercises are being performed, patients are helped to carry out their rehabilitation at home. Doctors are able to track the progress of their patients in real time and are notified if there are any problems during the recovery process.

Claris Reflex registers every flexion and extension of the knee, the position of the patient's body, the temperature and the patient's compliance with training. The data is transferred automatically to a tablet or smartphone when the patient is within range of it. Hospitals can save time and money since better compliance means shorter hospital stays, less physiotherapy and fewer emergency admissions.

You can find out more about this medical product, which is currently approved in the USA, at <http://clarisreflex.com>



## Learning from brain research: how language works in patients' minds

*For patients, forthcoming surgery can be extremely stressful. In this state, patients are especially sensitive to how clinical personnel formulate their words. Used with purpose, positive words can calm patients and promote their recovery.*

«We are getting you ready right now!», «It will all soon be over!», «I'll look in on you again tomorrow if you're still here.» When it comes to communicating with patients, misunderstandings are very common. For you, it's perfectly clear what you're talking about. Yes, you might dispense with medical jargon but your patient doesn't know exactly what's about to happen to him or her. What you see as a routine procedure, for example the implantation of a total hip replacement, is something that your patient sees as potentially life-threatening. Fear and stress can put patients into a sort of trance – and their brains assume a different state of consciousness with highly focused attention and increased suggestibility.<sup>1</sup>

### Patient reinterpretation

Be aware that your patient will hungrily absorb everything he sees and hears while in this state and will relate it all to himself. A seemingly innocuous prompt to your assistant, «Give him all of it!», relating to the contents of the syringe, can be reinterpreted and make the situation worse for your patient than it actually is. Their increased suggestibility means that you can trigger pronounced mental and physical changes in your patient more easily than normal.<sup>1</sup> Rational explanations tend to be understood less by patients at this stage than figurative language. Psychology talks of «suggestions». These are statements that influence the way we feel, think and act in a language that our subconscious can understand. However, communication with patients is often – unintentionally – peppered with negative suggestions.<sup>2</sup>

### Negative suggestions as pain amplifiers

Even with the best intentions, if you prepare your patient for the pain they can expect by using the words «This is going to sting a bit», then this will produce even more pain. In a controlled, randomised study involving 159 patients who had to undergo a radiological

intervention, their anxiety and pain increased if the procedure was clearly prefaced with terms such as «stinging», «burning», «hot» or «sharp».<sup>3</sup> The brain also cannot distinguish between true pain and pain caused by expectation. In both cases, the same areas of the brain are active.<sup>4</sup>

or «duping», however. Instead, it is much more about offering an idea or possibility. Positive suggestions can calm heightened attention, especially in an anxious and stressed state, relieve pain and actively support the recovery process. This has already been confirmed in various reviews.<sup>5,6,7</sup>



### Positive suggestions as a soother

French pharmacist Émile Coué (1857–1926) was the pioneer of suggestion and founder of auto-suggestion. Coué discovered that medicines worked better if he suggested their effectiveness to patients. The idea of «suggestion» should not be equated with «pretending»

### Helpful phrases for endoprosthesis procedures

The University Orthopaedic Hospital in the Hungarian city of Debrecen has published a number of suggestions that may be of help in the context of joint replacement procedures:<sup>8</sup>

Even during their initial consultations, doctors used positive suggestions: «*Your body will recognise the implanted materials as if they are its own and will completely accept them. After the operation, your only task will be to help your body do its work and heal quickly and in the right way.*»

To prepare patients for the noises associated with implantation procedures, the doctors used re-framing by way of suggestion: «*If you hear noises during the operation, think of them like the noises from a house renovation: imagine that this renovation is the replacement of your hip / knee, and think how happy you will be to be able to use your joint again.*»

With the following positive suggestions, patients were prepared for the intensive care unit and post-operative recovery: «*You will recover easily and quickly after the operation. All of the drips, catheters and drains that you see for the first few days are there to help you heal perfectly...*»

The use of positive suggestion brings benefits for both the patient and the hospital: suggestions promote patients' ability to heal themselves and accelerate their recovery. They cost nothing and do not take up any additional time. In an ideal scenario, suggestions can even reduce surgery costs since drip and medication requirements are fewer, and complications occur less frequently.

<sup>1</sup> Hansen E, Bejenke C. Negative und positive Suggestionen in der Anästhesie – Ein Beitrag zu einer verbesserten Kommunikation mit ängstlichen Patienten bei Operationen. *Der Anaesthesist*. 2010;59:199–209.

<sup>2</sup> Häuser W, Hansen E, Enck P. Nocebo phenomena in medicine: their relevance in everyday clinical practice. *Dtsch Arztebl Int*. 2012; 109(26):459–65.

<sup>3</sup> Lang EV, Hatsiopoulou O, Koch T, et al. Can words hurt? Patient–provider interactions during invasive procedures. *Pain*. 2005; 114:303–9.

<sup>4</sup> Benedetti F, Lanotte M, Lopiano L, et al. When words are painful: Unraveling the mechanisms of the Nocebo effect. *Neuroscience* 2007; 147:260–71.

<sup>5</sup> Mistiaen P, van Osch M, van Vliet L, et al. The effect of patient–practitioner communication on pain: a systematic review. *Eur J Pain*. 2016;20(5):675–88.

<sup>6</sup> Ha JF, Longnecker N. Doctor-Patient Communication: A Review. *Ochsner J*. 2010; 10(1):38–43.

<sup>7</sup> Stewart M. Effective physician–patient communication and health outcomes: A review. *CMAJ* 1995; 152:1423–33.

<sup>8</sup> Szeverényi C, Csernátóy Z, Balogh A, Varga K. Examples of positive suggestions given to patients undergoing orthopaedic surgeries. *Interv Med Appl Sci*. 2013; 5(3):112–5.

## Download

*How to communicate in a brain-centric and positive manner*

**The 7 most important principles of brain-centric communication can be found here for you to [download](#).**



## Further reading



Calvin L. Chou, Lauro Cooley  
*Communication Rx: Transforming Healthcare Through Relationship-Centered Communication*  
McGraw-Hill Education; 2017

Eric Vance  
*Suggestible You: The Curious Science of Your Brain's Ability to Deceive, Transform, and Heal*  
National Geographic; 2016

Katalin Varga  
*Communication Strategies in Medical Settings: Challenging Situations and Practical Solutions (Consciousness and Human Systems)*  
Peter Lang GmbH; 2015

Jon Christianson, u.a.  
*Physician Communication with Patients: Research Findings and Challenges*  
University of Michigan Press; 2012

## Masthead

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