Smith+Nephew

Modular dual mobility (MDM) hip systems: Is there a risk of fretting corrosion?

Discussion points

- Metal ions released as a result of fretting corrosion may cause adverse local tissue reactions (ALTR) that can lead to implant revision[1]
- Implant retrieval has confirmed occurrence of fretting corrosion of the cobalt-chromium (CoCr) liner of MDM implants[2–8]
- Elevations in serum metal ions compared to reference levels from healthy volunteers have been detected in patients who received an MDM implant that utilises a CoCr liner[1,9–11]
- Malseated liners may be at risk for fretting corrosion[12]

The need for MDM systems

Dual mobility (DM) acetabular components have been designed to deliver increased range of motion with good stability, whilst reducing wear, in primary and revision total hip arthroplasty (THA) compared to standard implant designs.[1,13] However, use of monoblock DM systems can be limited by the absence of holes for supplemental screw fixation and the inability to attach an implant insertion handle to the acetabular shell.[1]

To address this need, current MDM systems include a CoCr liner between the titanium shell and the polyethylene (PE) articulating insert (Figure 1). This allows for screw fixation while providing an optimal surface for movement of the PE insert.[1]

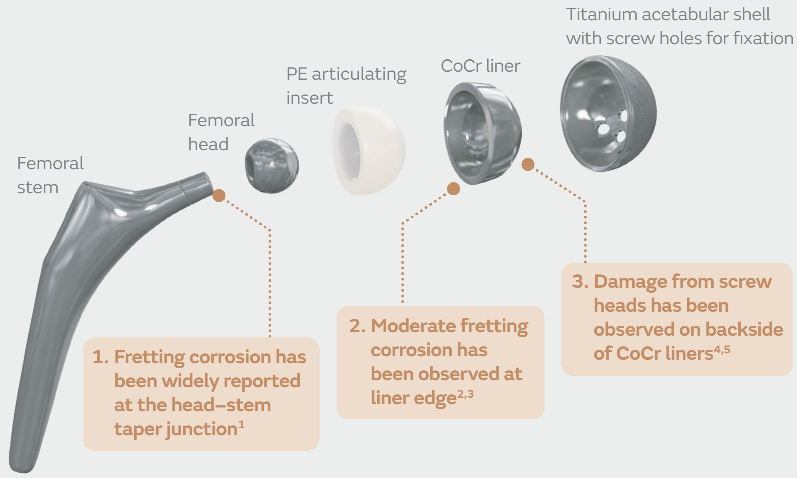


Figure 1. MDM system and sites of fretting corrosion (1–3) in MDM THAs

Is the liner-shell interface of MDM a risk for fretting corrosion?

Fretting corrosion is the damage caused by micromotion between two surfaces that results in the release of metal ions following exposure of non-oxidised metal to body fluids.[14] This normally occurs at the modular junctions (trunnion) of the THAs (eg, femoral head-stem), with the release of metal ions, specifically cobalt (Co), potentially leading to ALTR and subsequent revision.[1] In MDM implants, the CoCr liner interfacing with the titanium shell creates an additional modular junction at which fretting corrosion could occur (Figure 1).[1–5]

To help quantify this risk, a systematic literature review was performed to establish the current evidence base for fretting corrosion of the CoCr liner of MDM hip implants.*[15]

The literature review identified 16 publications that examined fretting corrosion in MDM implants; 15 clinical studies and one *in vitro* study. Of these, 14 publications investigated MDM® systems manufactured by Stryker Orthopedic (Mahwah, NJ, USA), one used MDM implants from Lima Corporate Spa (Villanova di San Daniele del Friuli, Italy) and one did not specify the type of implant considered. Key findings from these studies are summarised in this report. An overview of the characteristics of the 15 clinical studies are presented in Table 2.

Throughout this review, 'MDM' refers to the generic design of the modular hip system. Where a reference is made specifically to the MDM model manufactured by Stryker, this has been referred to as 'MDM (Stryker)'.

*Performed using Embase and PubMed to identify all relevant studies that detailed the use of MDM hip systems and the incidence of fretting corrosion as of 13 May 2021. There was no restriction on publication date and no other search filters were applied. Further relevant articles were identified by pragmatic searching of Google Scholar (screening through the first 10 pages of hits) and review of internal Smith+Nephew evidence library. Exclusion criteria were the absence of relevant data on fretting corrosion, off-label usage, duplicate publications and publications with only the abstract available, including conference abstracts.[15]

✚ Evidence in focus

How is fretting corrosion of the CoCr liner assessed?

1. MDM implant retrieval

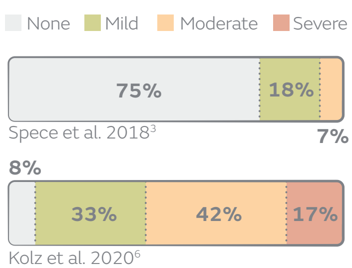
Analysis of retrieved implant components provides the most reliable evidence of fretting corrosion of the CoCr liner (Figure 2).

Retrieval studies are able to provide clear evidence of fretting corrosion, however, as implants are collected during revision surgeries, they may not describe the behaviour of well-functioning implants. The mean length of implantation with MDM implants across these studies is short- or mid-term. Fretting corrosion is a time-dependent phenomenon; therefore, longer implantation times may correlate to higher fretting corrosion scores. More data, however, are required to confirm this.

Of the identified studies...

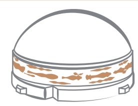
5 reported fretting corrosion in **retrieved MDM implants**[2–6]

Two studies demonstrated fretting corrosion of varying severity in retrieved MDM (Stryker) implants from primary and revision THA.[3,6]

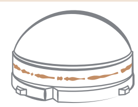


Three corrosion patterns were identified:[6]

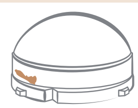
Generalised



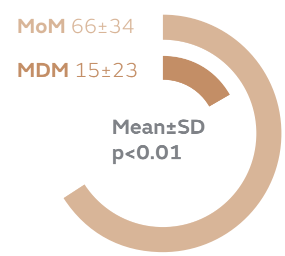
A stripe about the middle of the taper region



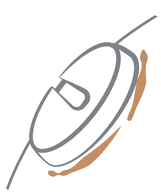
Focal areas of the taper closest to the joint surface



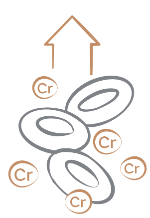
In one study, fretting corrosion was shown to be more severe with MoM implants versus MDM (Stryker) implants, however, the former group had a higher LOI[2]



Two studies noted fretting corrosion damage to the CoCr liner of MDM (Stryker) implants[4,5]

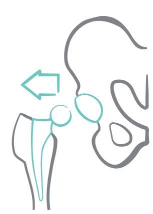


In a study specifically investigating fretting corrosion at the taper junction, Lombardo et al. identified fretting corrosion at the screw–liner interface[5]



In a study investigating rTHA survivorship and dislocation rate, in one patient with elevated serum Cr, Sutter et al. found scuffing thought to be from screws[4]

2 case studies reported fretting corrosion in **CoCr liners**[7,8]



Abdelaal et al. identified one patient requiring revision surgery due to IPD with moderate to/or severe corrosion of the liner eight years post surgery[7]

Sonn et al. identified three patients with fretting corrosion at the shell-liner interface, which in two cases was found to be canted[8]

Figure 2. Evidence of fretting corrosion of the CoCr liner from MDM implant retrieval studies

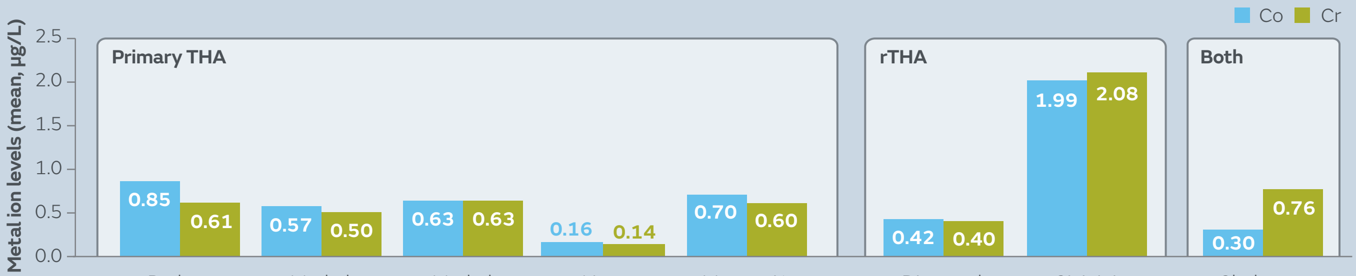
CoCr = cobalt-chromium, Cr = chromium, IPD = intraprosthetic dislocation, LOI = length of implantation, MDM= modular dual mobility, MoM = metal-on-metal, rTHA = revision total hip arthroplasty, THA = total hip arthroplasty

✚ Evidence in focus

2. Serum metal ions

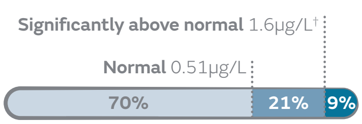
The literature review included ten publications that detailed metal ion levels in patients who received MDM implants (Figure 3).

Elevated serum metal ion levels, compared to reference levels from healthy volunteers, have been observed in patients following THA and investigated as a marker of fretting corrosion

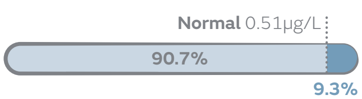


	Barlow et al. 2017[16]	Markel et al. 2019[17]	Markel et al. 2019[18]	Nam et al. 2019[11]	Matsen Ko et al. 2016[1]	Diamond et al. 2018§[10]	Civinini et al. 2020[9]	Chalmers et al. 2019[19]
Number of patients with metal ion levels >1µg/L*	NR	2 (7.1%)	5 (22.7%)	0 (0%)	9 (9.0%)	1 (6.3%)	5 (13.5%)	0 (0%)
Follow up (years)	1**	2	2	2	2	2***	5**	4**

Primary THA



Matsen Ko et al. reported 21/100 patients implanted with MDM (Stryker) to have elevated serum Co at 2.3 years follow up, however, the source of metal release could not confidently be determined[1]

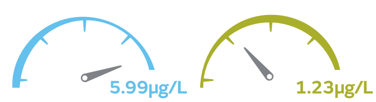


Nam et al. reported 4/43 patients implanted with MDM (Stryker) to maintain elevated serum Co at two years, three of whom received a ceramic femoral head, suggesting that this was related to the modular liner[11]

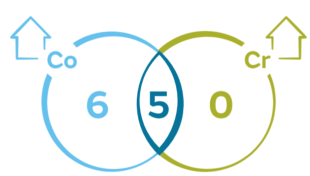
Abdelaal et al. and Sonn et al. also found patients implanted with MDM (Stryker) with CoCr levels above the normal range,[7,8] including one patient with tissue Cr levels of 8.3µg/L[7]

rTHA

In an evaluation of metal ions in 16 patients after MDM (Stryker) rTHA, the upper range for Co and Cr levels was 5.99µg/L and 1.23µg/L, respectively, once four patients with pseudotumours were excluded[10]



Civinini et al. reported 5/37 patients who received unilateral revision MDM THA (Delta TT, Lima Corporation) to have elevated Co and Cr, and 6/37 to have elevated Co only; all were asymptomatic[9]



Elevated Co and Cr ion levels were observed by Sonn et al. in an rTHA patient with a canted liner[8]

Ceramic-only femoral components

There is conflicting data regarding metal ion levels in patients receiving ceramic femoral heads[11,19]

3/4 patients with elevated Co levels in the study by Nam et al. received MDM (Stryker) implants with a ceramic femoral head, indicating increased Co was related to the CoCr liner[11]

2 years

In a study by Chalmers et al., of 24 patients receiving MDM (Stryker) for either complex primary or revision THA, mean CoCr levels at four years were below that deemed to be a clinically relevant elevation (≥1µg/L)[19]

5 years

One patient with 12µg/L Cr after five years (113 µg/L Cr pre-operatively) received revision due to an ALTR with Cr elevation that had reduced from 113µg/L pre-operatively[19]

Figure 3. Evidence of elevated serum metal ion levels in patients who received MDM implants

*The clinical significance of serum metal ion levels >1µg/L is unclear.[20] **Mean follow up reported. ***Follow up not specified; minimum 2 years. §Median values reported. †Symptomatic patients with Co levels >1.6µg/L have previously been reported as requiring revision due to ALTR secondary to fretting corrosion.[21] ALTR = adverse local tissue reaction, Co = cobalt, CoCr = cobalt-chromium, Cr = chromium, MDM = modular dual mobility, NR = not reported, rTHA = revision total hip arthroplasty, THA: total hip arthroplasty

✚ Evidence in focus

Are metal ion elevations normal after THA?

The literature review identified one study that considered whether metal ion elevations are 'normal' after THA.[16] The study investigated serum Co and Cr levels in 80 non-consecutive patients with well-functioning unilateral THA using a variety of bearing surfaces. No significant difference was found for serum Co and Cr levels between the four bearing surface groups (ceramic-on-ceramic [CoC], ceramic-on-polyethylene [CoP], metal-on-polyethylene [MoP] and MDM). However, a secondary analysis found patients with metal femoral heads (MoP, MDM [metal]) had significantly higher serum Co levels compared with those with ceramic heads (CoC, CoP, MDM [ceramic]): 1.05±1.25µg/L vs 0.59±0.24µg/L; p=0.0411.

Whole blood analysis

Whole blood analysis has been used in studies of patients with MDM implants to investigate markers of inflammation and their association with elevated serum metal ions. Two studies from Markel et al. reported serum metal ion levels for patients with MDM implants with ceramic femoral heads at 2 years of follow up (Table 1).[17,18]

Table 1. Pre- and postoperative serum metal ion levels for patients with mDM implants

	Metal ions	Preoperative	3 months	1 year	2 years	p-value
Study 1*[17] N=49	Co, µg/L (±SD)	-	-	0.63 (0.32)	0.57 (0.20)	0.358
	Cr, µg/L (±SD)	-	-	0.53 (0.16)	0.50 (0.00)	0.338
Study 2†[18] N=39‡	Co, µg/L (±SD)	0.51 (0.08)	0.85 (0.87)	0.64 (0.28)	0.63 (0.36)	0.045
	Cr, µg/L (±SD)	0.53 (0.14)	0.58 (0.26)	0.56 (0.17)	0.63 (0.38)	0.496

*Statistical testing conducted between 1 and 2 years follow up; †One-way analysis of variance (ANOVA) used to determine statistically significant differences among mean values at the four time points. Paired Student's t-test showed the significant change in Co (p<0.05) was due to the increase at 3 months of follow up compared with preoperative level (p<0.02); ‡Preoperative, n=35; 3 months, n=30; 1 year, n=20; 2 years, n=22

Study 2 showed a statistically significant elevation in Co ion levels during the 2 year follow-up period compared to preoperative levels.[18] However, there was no evidence in either study that an elevation in metal ion levels resulted in an immune response.

Circulating leukocyte profiles were stable and there was no observed increase in CD16+ monocyte levels, an important subpopulation of leukocytes that become elevated as part of the inflammatory response to antigens.[17,18]

Caution should be taken when using the data based on metal ion analysis of blood/serum. While it is believed that elevated levels of Co or Cr ions in the circulatory system are an indicator of liner wear from MDM hips,[1] confirmatory evidence from a corresponding retrieved implant is not always available. Well-designed studies are required to investigate the link between elevated serum metal ion levels and fretting corrosion as well as to determine the clinical significance of the results.

Are canted liners a risk factor for fretting corrosion at the modular interface?

Romero et al. reported an incidence of malseating of the CoCr liner within the MDM Stryker implant of 5.8% (32/551).[12] *In vitro* modelling, which used current as a measure of fretting/corrosion, found that significantly less fretting/corrosion occurred for well-seated liners compared to malseated liners when peak loads greater than 2200N were applied (p<0.05). The onset fretting load, defined as the load at which there was marked increase (inflection point) in the fretting/corrosion current, was lower for canted liners than well-seated liners (2400 vs 2800N, respectively).[12] These loads are within the range expected during activities of daily living. Their results suggest that malseated liners may be at risk for fretting corrosion.[12]

Of the three cases reported by Sonn et al., all had evidence of fretting corrosion of the CoCr liner, with the liners of two MDM (Stryker) implants found to be canted upon revision surgery.[8]

The clinical consequences of malseating are unknown and further research is warranted.[12,22]

Conclusions

- Implant retrieval has confirmed the occurrence of fretting corrosion of the CoCr liner of MDM implants[2–8]
- Elevated serum metal ions compared with reference levels from healthy volunteers have been reported in seven studies of patients with MDM implants, however, it is not always possible to determine the specific impact of the CoCr liner on this elevation due to other metal ion sources[1,7–9,11,16,19]
- Canted liners may be at risk of fretting corrosion at the acetabular liner interface[12]
- Further studies are warranted to determine the extent to which the CoCr liner/titanium shell presents a fretting corrosion risk in MDM implants

Additional information

Table 2. Characteristics of studies reporting on MDM implant retrieval and serum metal ions

Author	Study design (single centre unless specified)	Primary or revision THA	n	Mean length of implantation (LOI)	Implant type	Femoral head
Abdelaal et al. 2021[7]	Retrospective, case study	Primary	1	96 months	MDM (Stryker)	CoCr (n=1)
Barlow et al. 2017[16]	Prospective case series	Primary	80 (20 MDM)	15 months	MDM (Stryker)	CoCr (n=10) Ceramic (n=10)
Chalmers et al. 2019[19]	Prospective cohort, noncomparative	Both	24	48 months	MDM (Stryker)	CoCr (n=0) Ceramic (n=24)
Civinini et al. 2020[9]	Cross-sectional study	Revision	37	61 months	Delta TT (Lima Corp)	CoCr (n=37) Ceramic (n=0)
Diamond et al. 2018[10]	Retrospective cohort, noncomparative	Revision	60 (16 for serum analysis)	39 months	MDM (Stryker)	CoCr (n=59) Ceramic (n=1)
Kolz et al. 2020[6]	Implant retrieval case series	Both	12	26 months	MDM (Stryker)	CoCr (n=8) Ceramic (n=4)
Lombardo et al. 2019[5]	Implant retrieval analysis	-	18 (10 MDM [Stryker])	13 months	MDM (Stryker) vs other hip systems	CoCr (n=8) Ceramic (n=2)
Markel et al. 2019[17]	Prospective cohort, noncomparative	Primary	49	24 months	MDM (Stryker)	CoCr (n=0) Ceramic (n=49)
Markel et al. 2019[18]	Prospective cohort, noncomparative	Primary	39	24 months	MDM (Stryker)	CoCr (n=0) Ceramic (n=39)
Matsen Ko et al. 2016[1]	Retrospective cohort, noncomparative	Primary	100	28 months	MDM (Stryker)	CoCr (n=99) Ceramic (n=1)
Nam et al. 2019[11]	Prospective cohort, noncomparative	Primary	43	24 months	MDM (Stryker)	CoCr (n=14) Ceramic (n=29)
Sonn et al. 2020[8]	Retrospective, case series	Both (2 primary; 1 revision)	3	42 months 48 months 48 months	MDM	CoCr (n=1) Ceramic (n=2)
Spece et al. 2018[3]	Implant retrieval case series	Both	29 (28 liners)	16 months	MDM (Stryker)	CoCr (n=25) Ceramic (n=4)
Sutter et al. 2017[4]	Retrospective, cohort, multicentre	Revision	64	38 months	MDM (Stryker)	
Tarity et al. 2017[2]	Implant retrieval analysis	Both	18	15 months	MDM (Stryker) vs MoM	CoCr (n=15) Ceramic (n=3)

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